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Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh> "Implementation of Third Party Programs Under the FDA Modernization

Act of 1997; Final Guidance for Staff, Industry and Third Parties" is available at <http://www.fda.gov/cdrh/thirdparty>.

#### IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the guidance at any time. Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 2001.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Fiscal Year (FY) 2001 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 Mental Health Services (CMHS) announces the availability of FY 2001 funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Guidance for Applicants (GFA), including Part I, Circles of Care, and Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity	Application deadline	Est. funds FY 2001	Est. No. of awards	Project period
Circles of Care .....	May 10, 2001 .....	\$2.4 million .....	7-9	3 years.

The actual amount available for the award may vary, depending on unanticipated program requirements and the number and quality of application received. FY 2001 funds for the activity discussed in this announcement were appropriated by Congress under Public Law No. 106-310. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement application were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

**General Instructions:** Applicants must use application form PHS 5161-1 (Rev. 7/00). 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: National Mental Health Services Knowledge Exchange, Network (KEN), PO Box 42490, Washington, DC 20015, Telephone: 1-800-789-2647.

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

When requesting an application kit, the applicant must specify the particular activity for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

**Purpose:** Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) announces the availability of FY 2001 funds for grants to federally recognized tribal governments and urban Indian organizations to plan, design, and assess the feasibility of implementing a culturally appropriate system of care for American Indian and Alaska Native (AI/AN) children and their families who are experiencing or are at risk of serious emotional/behavioral disturbance. This is the second issuance of the grant program which seeks to provide tribal communities with tools and resources to design systems of care for their children that reflect the unique needs of their communities. This grant program will not fund actual services. An important focus will be to integrate traditional healing methods indigenous to the communities with conventional treatment methodologies.

**Eligibility:** Tribal governments and urban Indian organizations as defined by the Indian Self Determination Act, Pub. L. 93-638, and the Indian Health Care Improvement Act, Pub. L. 94-437 can apply. The terms "Indian," "tribal," "AI/AN," and "Native American" include Alaska Native organizations. Collaboration with tribal colleges or universities is strongly encouraged. Previous Circle of Care grantees are not eligible to apply.

**Availability of Funds:** Approximately \$2.4 million will be available for 7-9 awards. The average award will be approximately \$275,000 per year in total costs (direct and indirect), with awards ranging from \$250,000-\$350,000. Actual funding levels will depend on the availability of funds, state population, problems identified in the National Household Survey on Drug Abuse, and other factors.

**Period of Support:** Support may be requested for up to 3 years. Annual non-competitive awards depend on the availability of funds and progress achieved.

**Criteria for Review and Funding—General Review Criteria:** Competing applications requesting funding under this activity 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.

**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.

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

**Program Contact:** For questions concerning program issues contact: Jill Shepard Erikson, M.S.W. and Gary De Carolis, M.Ed., Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 11C-16, Rockville, MD 20857, Telephone: 301-443-1333, Email: [jerickso@samhsa.gov](mailto:jerickso@samhsa.gov), [gdec Carol@samhsa.gov](mailto:gdec Carol@samhsa.gov).

For questions regarding grants management issues, contact: Gwen Simpson, Division of Grants Management, OPS, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rm 13-103, Rockville, MD 20857, (301) 443-4456, E-mail: [gsimpson@samhsa.gov](mailto:gsimpson@samhsa.gov).

**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 copy of the face page of the application (Standard form 424).
- 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 2001 activity is subject to the Public Health System Reporting Requirements.

**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.

**Executive Order 12372:** Applications submitted in response to the FY 2001 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 2, 2001.

**Richard Kopanda,**

*Executive Officer, SAMHSA*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Fiscal Year (FY) 2001 Funding Opportunities

**AGENCY:** Substance Abuse and Mental Health Services Administration (SAMHSA) HHS.

**ACTION:** Notice of funding availability, revision of program announcement and notice of special racial and ethnic minority initiative.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration's Center for Mental Health Services in partnership with the Center for Substance Abuse Treatment and the Center for Substance Abuse Prevention announces the availability of FY 2001 funds for the following activity. This activity has two parts. The first action is to announce a technical revision of the standing program announcement for the Community Action Grants Program. The second activity is to announce a Notification of Funding Availability for a Special Racial and Ethnic Priority Initiative under the Community Action Program.

This notice is not a complete description of the activity; potential applicants must obtain a copy of the Program Announcement, including Part I, Community Action Grants for Service Systems Change and a copy of the Special Racial and Ethnic Minority Initiative; and Part II, General Policies and Procedures Applicable to all SAMHSA Guidance for Applicants for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity	Application deadline	Est. funds FY 2001	Est. no. of awards	Project period
Re-issuance of Community Action Grant & Special Racial and Ethnic Minority Initiative.	May 10, 2001 & Sept. 10, 2001.	\$5.1 million .....	34-51 .....	1 year.