

800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1206 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by 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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

#### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB Control Number 0910-0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB Control Number 0910-0485.

#### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Two copies of mailed 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 and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 8, 2003.

**Linda S. Kahan,**

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

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

[CFDA 93-145, HRSA 04-076]

#### Cooperative Agreement for a Twinning Center (CATC)

**AGENCIES:** Health Resources and Services Administration, Centers for Disease Control and Prevention, and National Institutes of Health, Department of Health and Human Services; United States Agency for International Development.

**ACTION:** Notice of availability of funds.

**SUMMARY:** This notice announces the availability of funds for a Cooperative Agreement for the establishment of a Twinning Center (TC) to support twinning and volunteer activities as part of the implementation of the President's International Mother and Child HIV Prevention Initiative (Initiative). The Cooperative Agreement will be awarded for a 5-year project period.

**Program Purpose:** The purpose of this funding is to support the President's Initiative, focusing on the reduction/prevention of mother-to-child transmission (PMTCT) of HIV/AIDS. This 5-year Initiative, through a combination of improving care, prophylaxis of HIV-positive mothers, and building healthcare delivery capacity is expected to reach up to one million women annually and reduce mother-to-child HIV transmission by 40 percent within those 5 years in 14 targeted countries in Africa and the Caribbean. This is a unified government initiative, coordinated and implemented by a PMTCT Interagency Steering Committee, led by the Office of the Global AIDS Coordinator in the Department of State, that include as members the Offices of National AIDS Policy (ONAP) and Management and Budget in the White House, the United States Agency for International Development (USAID), the Department of State, and the Department of Health and Human Services (HHS) and its component agencies, the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH).

Fourteen countries and one regional office in the Caribbean were initially selected to be part of the Initiative, based on high HIV burden, limited country resources, and host government and civil society commitment to fighting the HIV epidemic and scaling up PMTCT programs. The President's Initiative is intended to complement other bilateral and international support efforts, including support through the Global Fund to Fight AIDS, Tuberculosis, and Malaria. In addition, the Initiative represents specific U.S. Government assistance to help the Initiative countries reach the United Nations General Assembly Special Session on AIDS' goals for reducing mother-to-child HIV transmission.

A long term goal of the President's Initiative is capacity building in clinics and communities to deliver PMTCT. Two of the strategies outlined by the President for human and institutional capacity building are twinning and volunteer activities, which will be implemented through a TC and a Volunteer Health-Care Corps (VHC), although other strategies, including other forms of training, will be employed. The volunteer activities under this program will exist within the twinning partnerships, although the TC will also coordinate with the activities of target country volunteers outside of the twinning activities. The goal of the TC is to strengthen human and organizational capacity through twinning and healthcare volunteers to rapidly expand the pool of trained providers, managers, and allied health staff delivering quality HIV/AIDS services to HIV-infected pregnant women and HIV-exposed infants in 14 target countries in Africa and the Caribbean. The TC will work collaboratively with HRSA's HIV/AIDS Bureau, CDC, USAID, and ONAP to assist in the implementation of the President's Initiative at the country level. The guiding principle for the TC and VHC is that the implementation of this program will be based on the needs of the targeted country as identified by the USAID/CDC field offices' human resources plan.

The definition of "twinning" for the purposes of this Notice of Availability of Funds (NOAF) for a Cooperative Agreement for a Twinning Center (CATC) is the definition developed by the Canadian Interagency Coalition on AIDS and Development in its publication *Beyond Our Borders: A Guide to Twinning for HIV/AIDS Organizations*: A formal, substantive collaboration between two similar organizations. "Formal" means there is an agreement or contract, verbal or

written. "Substantive" means the interaction between the twinning partners is significant and lasts for a period of time. "Collaboration" means that the partner organizations work together on a specific project or exchange information and skills.

A centrally-funded TC will broker and facilitate relationships between twinning partners, plan and fund logistics for the VHC, and fund in-country twinning partners. The twinning plan will build upon existing relationships between U.S. and target country institutions as well as initiate new twinning partnerships.

**Eligible Applicants:** Public or nonprofit private entities, including schools and academic health sciences centers, community-based organizations, and faith-based organizations are eligible to apply for the CATC. Eligible organizations for twinning funding assistance at the in-country level will depend on the specific twinning activity, but may include hospitals, health clinics, training/educational institutions, and non-government organizations, including community- and faith-based organizations. Applicants for the TC must have domestic and international experience providing technical assistance to HIV/AIDS service organizations.

**Authorizing Legislation:** Department of Health and Human Services: Section 307 of the Public Health Service (PHS) Act, 42 U.S.C. 242l. United States Agency for International Development: Foreign Assistance Act of 1961, as amended, and Executive Order 11223.

**Availability of Funds:** Funds are available under the appropriation included in Pub. L. 107-116 for International HIV/AIDS activities. It is estimated that up to \$150,000,000 for up to 5 years may be available to support the TC and twinning activities in the 14 target countries, with \$2,000,000 for the TC and up to \$2,000,000 for twinning activities in the 14 countries during the first year. There will be 2 separate awards to the same recipient for these activities: funding for target country twinning activities will be awarded by USAID, and funding for the provision of technical assistance activities by the TC will be awarded by HRSA/DHHS. Funding awards will be made during the first or early second quarter of the Federal fiscal year 2004 (calendar year October 1, 2003 to March 31, 2004). The TC will be funded for a 12-month budget period, with a project period of up to 5 years. Continuation awards for the TC after the first year will be made based upon satisfactory performance and the availability of Federal funds.

Funding for in-country twinning activities funded by USAID will be made on a specific project basis, with funding for 1 year and a project period of up to 5 years. Continuation funding for specific twinning activities will be based upon satisfactory performance of existing twinning partnerships, initiation of new twinning partnerships, and availability of Federal funds.

**Application Deadline:** Applications for this cooperative agreement must be received in the HRSA Grants Application Center (GAC) by close of business December 29, 2003. Applications shall be considered as meeting the deadline if they are either (1) received on or before the deadline date or (2) postmarked on or before the deadline date, and received in time for submission to the objective review panel. One original and two copies of an application will be required. A legible dated receipt from a commercial carrier or the U.S. Postal Service will be accepted instead of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Grant applications postmarked after the deadline will be returned.

**Late applications:** Applications which do not meet the criteria above are considered late applications. Health Resources and Services Administration (HRSA) shall notify each late applicant that its application will not be considered in the current competition.

The Chief Grants Management Officer (CGMO) or a higher level designee may authorize an extension of published deadlines when justified by circumstances such as acts of God (e.g., floods or hurricanes), widespread disruptions of mail service, or other disruptions of services, such as a prolonged blackout. The authorizing official will determine the affected geographical area(s).

**Electronic Submission:** HRSA encourages applicants to submit applications on-line. To register and/or log-in to prepare your application, go to <https://grants.hrsa.gov/webexternal/login.asp>. For assistance in using the on-line application system, call 877-GO4-HRSA (877-464-4772) between 8:30 am to 5:30 pm ET or e-mail [callcenter@hrsa.gov](mailto:callcenter@hrsa.gov).

Application narratives and spreadsheets will need to be created separately and submitted as attachments to the application. You will be prompted to "upload" your attachments at strategic points within the application interface. The following document types will be accepted as attachments: WordPerfect (.wpd), Microsoft Word (.doc), Microsoft Excel (.xls), Rich Text

Format (.rtf), Portable Document Format (.pdf).

To look for funding opportunities, go to <http://www.hrsa.gov/grants> and follow the links.

**DUNS Number:** Beginning October 1, 2003, applicants will be required to have a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. If applicants are submitting an application on or after October 1, 2003 a DUNS number is required. To obtain a DUNS number, access [www.dunandbradstreet.com](http://www.dunandbradstreet.com) or call 1-866-705-5711. Please include DUNS number next to OMB Approval Number on the application face page. Applications will not be reviewed without a DUNS number.

Additionally, the applicant organization will be required to register with the Federal Government's Central Contractor Registry (CCR) in order to do business with the Federal Government, including electronic. Information about registering with the CCR can be found at <http://www.hrsa.gov/grants.htm>.

**Where to Request and Send an Application:** To prepare and submit an application, organizations must obtain: (1) the CATC Program Guidance and (2) the official Federal grant application kit required for these cooperative agreements, PHS Form 5161-1, along with 2 separate budgets (one budget for the HRSA-funded activities and one budget for the USAID-funded activities) using Standard Form (SF) 424. The Program Guidance is available on the HIV/AIDS Bureau Web site at the following Internet address: <http://www.hab.hrsa.gov/grant.htm>. The PHS Form 5161-1 is available at the following Internet address: <http://forms.psc.gov/forms/PHS/phs.html>. The SF 424 is available at the following Internet addresses: [http://forms99.psc.gov/Forms/sf-424\\_2.htm](http://forms99.psc.gov/Forms/sf-424_2.htm) (instructions for HRSA budget) and [http://www.usaid.gov/procurement\\_bus\\_opp/procurement/forms/SF-424/](http://www.usaid.gov/procurement_bus_opp/procurement/forms/SF-424/) (instructions for USAID budget). For those organizations who do not have access to the Internet, hard copies of the Program Guidance, PHS Form 5161-1 and SF 424 may be obtained from the HRSA GAC. You can reach the HRSA GAC toll-free at (877) 477-2123, fax (877) 477-2345, or e-mail: [hrsagac@hrsa.gov](mailto:hrsagac@hrsa.gov). Please request the Office of Management and Budget Catalogue of Federal Domestic Assistance Number 93-145, HRSA 04-076 and Program Code CATC.

**Notification of Letter of Intent:** Letters of intent will be used by the Funding Agencies to estimate the number of applications which will be submitted.

This will help determine the number and types of reviewers which will be required for the objective review. Therefore applicants must submit a one-page letter of intent. This letter must identify the applicant organization, its intent to apply, and briefly describe the proposal to be submitted.

**ADDRESSES:** All Cooperative Agreement applications should be mailed or delivered to: HRSA Grant Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland 20879. Applications sent to any other address will be returned.

**FOR FURTHER INFORMATION CONTACT:**

Additional information on the TC and the HRSA/DHHS technical assistance portion of the Cooperative Agreement may be obtained from Thurma Goldman, MD, MPH, HIV/AIDS Bureau, at (301) 443-1993; fax (301) 443-9645; e-mail: [tgoldman@hrsa.gov](mailto:tgoldman@hrsa.gov); mail HIV/AIDS Bureau, HRSA 5600 Fishers Lane, Parklawn Building, Room 7-13, Rockville, Maryland 20857.

Additional information on the twinning activity funding portion of the Cooperative Agreement may be obtained from Mr. Eduardo G. Elia, USAID, Contracts Specialist, M/OP/GH/POP, at (202) 712-0901; fax (202) 216-3132; e-mail [eelia@usaid.gov](mailto:eelia@usaid.gov); mail USAID, M/OP/GH/POP, Ronald Reagan Building, 1300 Pennsylvania Avenue, NW, RRB 7.09-133, Washington, DC 20523-7100.

**Pre-Application Technical Assistance Conference Call:** There will be a pre-application technical assistance conference call with potential applicants approximately 3 weeks after publication of the Notice of Availability of Funds (NOAF) for the CATC. The conference call will be with HRSA and USAID officials familiar with the NOAF requirements. The purpose of the call will be to answer questions which potential applicants may have about the application guidance or questions about completing the application. All questions to be discussed at the conference call must be submitted in advance of the call to HRSA, by fax, e-mail, or regular mail. Questions should be submitted to: Thurma Goldman, M.D., M.P.H., Program Director, Global HIV/AIDS, HIV/AIDS Bureau, HRSA, 5600 Fishers Lane, Room 7-13, Rockville, MD 20857, at (301)-443-1993; fax: 301/443-9645; e-mail: [TGoldman@hrsa.gov](mailto:TGoldman@hrsa.gov). To find out the exact date and time of the technical assistance conference call, and timeframe for submission of questions, please call the HRSA's HIV/AIDS Bureau main office on (301) 443-1993.

**Technical Oversight of the Cooperative Agreements:** The TC

Cooperative Agreement will be managed by two Project Officers. The USAID Project Officer will provide oversight and technical management of the Cooperative Agreement activities associated with the award and monitoring of funds for the actual expenses of the in-country twinning partners and volunteer activities. The HRSA Project Officer will provide oversight and technical management of the activities associated with the operation and management of the TC and VHC and the provision of technical assistance to the twinning partners (including the identification of organizations and partnerships and proposed activities) and VHC.

Guidance for the CATC will be provided by a Technical Assistance Group, which will be subordinate to the PMTCT Interagency Steering Committee, comprised of members of the Presidential Initiative Human Resources Workstream. Guidance will be provided to the TC via the USAID and HRSA Project Officers. The Guidance will provide overall direction for the TC's goals and objectives in the development and implementation of partnerships.

**SUPPLEMENTARY INFORMATION:**

Cooperative Agreements are a type of Federal assistance that involves a substantial level of government participation in funded activities. Under the cooperative agreement, HRSA and USAID require that certain activities be planned jointly and include approval from HRSA, USAID, and the TC Technical Assistance Group. HRSA and USAID responsibilities will be in the following areas:

(a) Provide consultation and technical assistance in planning, operation, and evaluation activities, including the identification and selection of in-country partners;

(b) facilitate the coordination and collaboration among program partners, such as USAID, CDC and their field offices or missions, and the TAG and TC;

(c) facilitate efforts in the provision of technical assistance and training in twinning to specified individuals and organizations;

(d) participate, as appropriate, in the planning and implementation of any meetings, training activities, or workgroups conducted during the period of the cooperative agreement;

(e) provide technical assistance to the TC to increase its capacity to succeed in this international collaboration;

(f) maintain an ongoing dialogue with the TC concerning program plans, policies, and other issues which have

major implications for any activities undertaken by the applicants under the cooperative agreement;

(g) review, provide comments, recommendations, and approvals for documents, curricula, program plans, budgets, work to be contracted out, key personnel (including consultants and contractors), workplan revisions, etc. prior to printing, dissemination or implementation;

(h) provide feedback to the TC on quarterly and other reports; and

(i) serve as the official interface between the TAG and the TC.

Detailed information on grantee responsibilities is provided in the application guidance.

The applicant receiving the award will be required to submit quarterly reports, a mid-term report during the 30th month of the project, and a final report at the end of the project.

The applicant receiving the award will not be required to match or share in project costs. Any matching or cost sharing will not be considered as part of the selection decision.

This program is subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Application packages made available under this Guidance will contain a listing of States which have chosen to set up such a review system and will provide a Single Point of Contact (SPOC) for the state's review. Information on states affected by this program and State Points of Contact may also be obtained from the Grants Management Specialist cited in the application guidance, as well as at <http://www.whitehouse.gov/omb/grants/spoc.html>. All applicants other than federally recognized American Indian tribes should contact their SPOCs as early as possible to alert them to prospective applications and receive any necessary instruction on the State process used under this Executive Order.

The activities proposed to be implemented through this award are not considered to be research activities.

Non-Federal reviewers will participate in the review of submitted applications. Applicants have the option of omitting from the application copies (but not from the original) specific salary rates or amounts for individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information.

*Review Process:* Applications submitted in response to this NOAF will be reviewed for threshold criteria and technical merit by an Objective Review Committee. Each application must address and apply for both aspects of the TC: (A) Brokering, facilitation, and management of twinning partners; and (B) funding of in-country twinning and volunteer activity. The threshold criteria are: (1) Program Approach and Implementation Plan for Building Human and Organizational Capacity (30 points), (2) Institutional Capability and Past Performance (20 points), (3) Personnel Capability and Experience (20 points), (4) Program Evaluation and Quality Improvement (15 points), and (5) Clarity and Justification of the Budget (15 points). Technical Merit criteria are more completely defined in the Application Kit.

Dated: October 20, 2003.

**Elizabeth M. Duke,**

*Administrator, Health Resources and Services Administration.*

[FR Doc. 03-27335 Filed 10-29-03; 8:45 am]

**BILLING CODE 4165-15-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 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 (301) 443-7978.

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.

*Proposed Project: Obligated Service for Mental Health Traineeships: Regulations (42 CFR Part 62a) and Forms—(Extension, no change; OMB No. 0930-0074)—SAMHSA's Center for Mental Health Services (CMHS) awards grants to institutions for training instruction and traineeships in mental health and related disciplines. Prior to statutory change in 2000, graduate student recipients of these clinical traineeships were required to perform service, as determined by the Secretary to be appropriate in terms of the individual's training and experience, for a length of time equal to the period of support. The clinical trainees funded prior to implementation of the statutory change are required to submit SAMHSA Form 111, which ensures agency receipt of a termination notice prior to the end of support, and the SAMHSA Form SMA 111-2, which is an annual report on employment status and any changes in name and/or address, to SAMHSA. The annual burden estimate is provided below.*

42 CFR citation and associated forms	Number of respondents	Responses/respondent	Average burden/response (hrs.)	Annual burden (hrs.)
64a.104(a,b), (c)(1), Termination Notice and Exit Interview—SMA 111 .....	39	1	.10	4
64a.105(b)(2), Annual Payback Activities Certification—SMA 111-2 .....	95	1	.18	17
Total .....	134	.....	.....	21

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 24, 2003.

**Anna Marsh,**

*Acting Executive Officer, SAMHSA.*

[FR Doc. 03-27324 Filed 10-29-03; 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 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 (301) 443-7978.

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.

*Proposed Project: Substance Abuse Prevention and Treatment Block Grant—45 CFR part 96 (OMB No. 0930-0163; Extension, no change)—This rule provides guidance to States regarding the Substance Abuse Prevention and Treatment Block Grant legislation, including requirements regarding the sale or distribution of tobacco products to individuals under age eighteen. The rule implements the reporting and recordkeeping requirements of 42 U.S.C. 300x21-35 and 51-64 by specifying the content of the States' annual report on and application for block grant funds, including the annual conduct of random, unannounced inspections to ensure compliance with 42 U.S.C. 300x-26, related to sale or distribution of tobacco to individuals under age eighteen. The reporting burden hours will be counted towards the total burden for the Substance Abuse*