

development, and offers a variety of suggested approaches that may be considered for improving the reliability, robustness, and clinical relevance of such trials. FDA is sponsoring a public workshop to provide an opportunity for experts in rheumatology clinical trials and interested representatives of industry, academia, and the public to discuss the working draft of the guidance document and to exchange ideas on developing and assessing new treatment modalities for RA as well as the types of claims that might be reasonably pursued and the data necessary to support such claims.

After consideration of all data, information, or views submitted on the draft guidance and at the workshop, FDA will issue a final guidance document and announce its availability with a notice published in the Federal Register.

Dated: February 29, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96-5211 Filed 3-5-96; 8:45 am]

BILLING CODE 4160-01-F

Health Resources and Services Administration

Ryan White Title IV Grants for Coordinated HIV Services and Access to Research for Children, Youth, Women, and Families

AGENCY: Health Resources and Services Administration (HRSA), PHS.

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that applications will be accepted for fiscal year (FY) 1996 funds for grants for projects that enhance access to clinical research trials and other research, and develop and support the provision of coordinated comprehensive services and activities for children, youth, women and families infected/affected by the Human Immunodeficiency Virus (HIV). Projects will be funded to implement programs of family-centered, community-based coordinated care and research for children, youth, women, and families infected/affected by HIV, or those at risk for developing infection. These projects are authorized under, and expected to meet provisions contained within, Section 2671 of the Public Health Service Act [as enacted by Title IV, of the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act of 1990, Public Law 101-381 (42 U.S.C. 300ff-11 *et seq.*)]. Within the HRSA, Ryan White Title IV projects are administered by the

Maternal and Child Health Bureau (MCHB).

This program announcement is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for the EMSC program, the amount of available funding for this specific grant program cannot be estimated. In addition, reauthorization of the Ryan White CARE Act, currently pending in Congress, could add new Title IV grant requirements in addition to those included in this notice.

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS national activity for setting priority areas. Title IV directly addresses the Healthy People 2000 objectives related to the priority area of HIV infection. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock Number 017-001-0474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202 783-3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to 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 routine education, library, day care, child care or early development services are provided to children.

ADDRESSES: Grant applications for the Ryan White Title IV Program (PHS form #5161-1, approved under OMB #0937-0189) must be obtained from and submitted to: Mona D. Thompson, Grants Management Branch, Office of Program Support, Maternal and Child Health Bureau, HRSA, Room 18-12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-3429. You must obtain application materials in the mail.

Federal Register notices and application guidance for MCHB programs are available on the World Wide Web via the Internet at address: <http://www.os.dhhs.gov/hrsa/mchb>. Click on the file name you want to

download to your computer. It will be saved as a self-extracting (Macintosh or Wordperfect 5.1 file). To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a Wordperfect 5.1 file. If you have difficulty accessing the MCHB Home Page via the Internet and need technical assistance, please contact Linda L. Schneider at 301-443-0767 or "lschneider@hrsa.ssw.dhhs.gov".

DATES: The application deadline date is April 19, 1996. Competing applications will be considered to be on time if they are:

(1) Received on or before the deadline date, or

(2) Postmarked on or before deadline date and received in time for orderly processing.

As proof of timely mailing, applicants should obtain a legibly dated receipt from the commercial carrier or the U.S. Postal Service; private metered postmarks will not be accepted as proof of timely mailing.

Late applications not accepted for processing or those sent to an address other than specified in the **ADDRESSES** section will be returned to the applicant.

FOR FURTHER INFORMATION CONTACT: Additional information regarding technical and program issues may be obtained from: the Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-9051. Requests for information concerning business management issues should be directed to: Sandra Perry, Acting Grants Management Officer (GMO), Maternal and Child Health Bureau, at the address specified in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

The Pediatric AIDS Program was initiated in 1988. The program grew from 13 projects funded at \$4.4 million to a total of 59 projects funded at \$25.4 million in FY 1995. Since 1988, the program has evolved from a primary focus on the coordination of services for the management and care of infected children and their families to also address the broader prevention and care needs of youth and women infected/affected by HIV. In FY 1994, Congress funded the Pediatric AIDS Program under section 2671, Title IV of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act 1990, Public Law 101-381 (Title IV). As a result of

authorization under Title IV, the focus of the program was expanded to include the development of innovative models linking clinical trials offered by the National Institutes of Health (NIH) and other research entities, with systems of comprehensive primary/community-based medical and social services.

In 1994 published results from a NIH clinical trial (ACTG 076) demonstrated the potential for reducing perinatal HIV transmission by two-thirds when pregnant women and their newborns were given zidovudine (ZDV). The ZDV therapy regimen has been published in the Centers for Disease Control's Morbidity and Mortality Weekly Report (MMWR 1994:43 (RR-11)).

Over the past year, the CDC has issued recommendations for enhanced voluntary HIV counseling and testing for women of child bearing age, and the HRSA issued an *Advisory: The Use of Zidovudine (ZDV) to reduce Perinatal HIV Transmission in HRSA-Funded Programs*. This advisory contains practical, specific steps for implementing U.S. Public Health Services recommendations for offering zidovudine (ZDV) to pregnant women. A copy of this advisory will be mailed to all Title IV applicants with the application guidance. Applicants are expected to review this advisory and describe how they will implement these recommendations in their application.

Reauthorization of the Ryan White CARE Act is pending in Congress. The final version of the Act, which will include Title IV, is expected to contain new requirements concerning arrangements between Title IV programs and research entities and enhancement of opportunities for Title IV Clients to participate in clinical research. Reauthorization of the Ryan White CARE Act could result in incorporation of additional requirements for Title IV grants in the applications guidance for these projects.

Purpose

The purpose of Title IV funding is to link clinical research and other research activities with comprehensive care systems, and to improve and expand the coordination of a system of comprehensive care for children, youth, women, and families who are infected/affected by HIV. Funds will be used to support programs that: (1) cross established systems of care to coordinate service delivery, HIV prevention efforts, and clinical research and other research activities; and (2) address the barriers to comprehensive care and research experienced by children, youth, women, and families infected/affected by HIV.

While children, youth, and women represent the most recently impacted and rapidly growing population groups affected by HIV, they also represent the groups facing the greatest barriers in accessing care and research. These groups are disproportionately members of communities of color with limited economic resources. Given these realities, children, youth, and women affected by HIV are confronted with a complex array of economic and social issues that increase their need for comprehensive services and increase the cost and intensity of care. Existing systems of care are often not prepared to respond to these needs and require targeted resources and interventions in order to develop infrastructures and provider capacities that would allow them to provide quality care to these populations.

Given these unmet needs, activities under these grants should address the following goals:

- Link HIV/AIDS clinical research trials and other research activities with comprehensive systems of care, resulting in increased access for children, youth, women, and their families.
- Foster the development and support of comprehensive care infrastructures, including primary care, that increase access to culturally-competent, family-centered, community-based, coordinated care.
- Emphasize prevention within the comprehensive care system in order to reduce the spread of the HIV infection to vulnerable populations.

Funding Category

Applications which do not fall within this program category will not be considered for funding.

The Ryan White Title IV Program for Children, Youth, Women, and Families develops and supports innovative projects that foster collaboration between clinical research institutions and family-centered, primary/community-based medical and social service programs, and that coordinate systems of comprehensive HIV care for children, youth, women and their families. Projects will focus on local capacity-building, making maximum use of all available public and private resources for reaching and providing health care and supportive services to the target population. Projects should strengthen existing comprehensive care infrastructures by: (1) broadening the coalition of agencies, providers, community organizations and consumers that participate in the identification of needs, services planning, the coordination and delivery

of services, and the financing of services for HIV affected populations; and (2) identifying and addressing systemic issues that affect provider collaboration and impact the provision of coordinated high quality comprehensive care.

Preference for funding in this category will be given to projects that have: (1) established and currently support a comprehensive, coordinated, system of HIV care serving either children, youth, women, or families; and (2) linked with, or initiated activities to link with clinical trials or other research. This means that these projects will be funded ahead of new groups of applications in this category.

Special Concerns

Grantees supported by Title IV of the Ryan White CARE Act should coordinate their projects with other Federal, State, and local programs concerned with HIV and/or serving the target population of children, youth, women and families affected by or at risk for HIV, particularly: Title V Maternal and Child Health programs; Ryan White Titles I, II and III(b) programs; providers funded by the Substance Abuse and Mental Health Services Administration; the Health Resources and Services Administration; the Centers for Disease Control prevention efforts; and clinical trials funded by NIH or other sources.

HRSA's Maternal and Child Health Bureau places special emphasis on improving service delivery to women, children and youth from communities with limited access to comprehensive care. In order to assure access and cultural competence, it is expected that projects will involve individuals from the populations to be served in the planning and implementation of the project. The Bureau's intent is to ensure that project interventions are responsive to the cultural and linguistic needs of special populations, that services are accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by the MCHB.

In keeping with the goals of advancing the development of human potential, strengthening the Nation's capacity to provide high quality education by broadening participation in MCHB programs of institutions that may have perspectives uniquely reflecting the Nation's cultural and linguistic diversity, and increasing opportunities for all Americans to participate in and benefit from Federal public health programs, HRSA will place a funding priority on projects from

Historically Black Colleges and Universities (HBCU) or Hispanic Serving Institutions (HSI) in all categories and subcategories in this notice for which applications from academic institutions are encouraged. This is in conformity with the Federal Government's policies in support of White House Initiatives on Historically Black Colleges and Universities (Executive Order 12876) and Educational Excellence for Hispanic Americans (Executive Order 12900). An approved proposal from a HBCU or HSI will receive a 0.5 point favorable adjustment of the priority score in a 4 point range before funding decisions are made.

Applications will be reviewed with particular attention to inclusion of women and persons from culturally distinct populations. Funding will be provided to those which, in the Department's view, best meet the statutory purposes of the Ryan White Title IV Program and address achievement of the Health People 2000 objectives related to HIV infection.

Review Criteria

Applications for grant categories will be reviewed and rated by objective review panels according to the following weighted criteria:

1. Documentation of the HIV medical and social support service needs of children, youth, women and families. Weight: 15 percent.

2. Demonstration of capacity to coordinate and support a comprehensive system of HIV care for children, youth, women and families. Weight: 25 percent.

3. Demonstrated capacity to provide clinical trials or to establish linkages with providers offering clinical trials, or other research. Weight: 15 percent.

4. The degree to which the Title IV's program priority of consumer involvement has been implemented. Weight: 10 percent.

5. The degree to which the proposed plan:

- Addresses the issues identified in response to Review Criteria I;
- Reflects the legislative and programmatic priorities of the Title IV program (access to clinical trials, reduction of perinatal HIV transmission, and consumer involvement);
- Contains goals and objectives that are clear, measurable, and time framed; and
- Presents an evaluation strategy capable of documenting the achievement of project goals. Weight: 25 percent.

6. The degree to which the proposed budget clearly supports administrative and programmatic activities necessary to manage the program and accomplish proposed goals and activities. Weight: 10 percent.

Eligible Applicants

Grants may be awarded to public or nonprofit private entities that provide or arrange for primary health care. Eligible entities may include, but are not limited to, State or local health departments, university medical centers, public or nonprofit private hospitals, community health centers (as defined in section 330(a) of the Act), hemophilia treatment centers, drug abuse treatment agencies, tribal health programs, school based clinics and institutions of higher education.

If any additional eligibility requirements are established in a reauthorized Ryan White CARE Act, they will be clearly identified in the application guidance.

Allowable Costs

The HRSA may support reasonable and necessary costs of HIV Project grants within the scope of approved projects. Allowable costs may include salaries, equipment and supplies, travel, contractual arrangements, consultants, and others, as well as indirect costs. The HRSA adheres to administrative standards reflected in the *Code of Federal Regulations* (45 CFR Part 92 and 45 CFR Part 74). All other sources of funding to support this project must be accurately reflected in the applicant's budget.

Reporting Requirements

A successful applicant under this notice will submit reports in accordance with the provisions of the general regulations which apply under 45 CFR Part 74, Subpart J, Monitoring and Reporting of Program Performance, with the exception of State and local governments to which 45 CFR Part 92.40 will apply. Financial reporting will be required in accordance with 45 CFR Part 74, Subpart I, with the exception of State and local governments, to which 45 CFR Subpart C will apply.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937-0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to

provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

(a) A copy of the face page of the application (SF 5161).

(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 and local health agencies.

The project abstract may be used in lieu of the one-page PHSIS, if the applicant is required to submit a PHSIS.

Executive Order 12372

The Title IV Program has been determined to be subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, 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. The application packages to be made available under this notice (Form PHS 5161-1 with revised face sheet HHS Form 424 and with Program Narrative and Checklist approved under OMB 0937-0189) 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) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their State SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to "accommodate or explain" State process recommendations it receives after that date. (See Part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR part

100 for a description of the review process and requirements.)

(The OMB Catalog of Federal Domestic Assistance number for the HIV Program for Children, Youth, Women, and Families is 93.153)

Dated: February 29, 1996.

Ciro V. Sumaya,
Administrator.

[FR Doc. 96-5209 Filed 3-5-96; 8:45 am]

BILLING CODE 4160-15-M

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of a Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Environmental Health Sciences Special Emphasis Panel (SEP) meeting:

Name of SEP: Development of Deuterated Nitroso Spin Traps for Identifying Xenobiotic Free Radical Metabolites (SBIR Phase I Topic 45) & Synthesis of New Nitrones in Spin Traps (Phase II Topic 38) (Telephone Conference Call).

Date: March 11, 1996.

Time: 10:30 A.M.

Place: National Institute of Environmental Health Sciences North Campus, Building 17, Conference Room 1713 Research Triangle Park, NC.

Contact Person: Dr. John Braun, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541-1446.

Purpose/Agenda: To review and evaluate contract proposals.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to this meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle. (Catalog of Federal Domestic Assistance Programs Nos. 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health.)

Dated: March 1, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-5314 Filed 3-1-96; 4:33 pm]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Policy Development and Research

[Docket No. FR-3917-N-49]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: May 6, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB Control Number and should be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW., Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: John Carson, Research Analyst, Office of Policy Development and Research—telephone (202) 708-3700 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and, (4) minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated collection techniques or other forms of information technology (e.g. permitting electronic submission of responses).

This notice also lists the following information:

Title of Proposal: Survey of Vouchered-out Households.

Description of the need for the information and proposed use: Currently, HUD's Office of Property Disposition is in the process of disposing, through demolition, several privately-owned multifamily assisted properties which have been acquired by the Department as a result of foreclosure or deteriorating safety and social conditions. Prior to disposing of these properties, eligible resident households are provided with Section 8 housing vouchers to obtain alternative housing. In order to gain insight into the transformation of project-based programs to tenant-based assistance, the Department proposes to study several of these vouchered-out projects. Specifically, the Department is interested in learning more about housing and neighborhood outcomes for renter households who receive a voucher to leave multifamily assisted housing for residence in unassisted housing. The results of this study will have a direct bearing on the Department's policies for re-locating households from distressed assisted housing.

Members of affected public: 200 households who received a voucher to leave assisted housing will be interviewed concerning their experiences in obtaining alternative housing with a voucher.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: Information will be collected through one-time telephone interviews with 200 members of households who moved from assisted housing to private housing with a voucher. These interviews will last an average of .417 hours (25 minutes) for a total respondent burden of 83.4 hours (200 X .417).

Status of the proposed information collection: Pending OMB approval.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: February 27, 1996.

Michael A. Stegman,

Assistant Secretary, Office of Policy Development and Research.

[FR Doc. 96-5194 Filed 3-5-96; 8:45 am]

BILLING CODE 4210-62-M