

Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:**

Peter Rickman, Center for Drug Evaluation and Research (HFD-615), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-0315.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Content and Format of an Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products." PET is a medical imaging modality used to assess the body's biochemical processes. Radionuclides are manufactured into PET radiopharmaceutical drug products that are administered to patients for medical imaging. The images of the body's biochemical processes are then evaluated, generally for diagnostic purposes.

Under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), ANDA's may be submitted for drug products that are the same as a listed drug, i.e., identical in active ingredient(s), dosage form, strength, route of administration and conditions of use, except for those uses for which approval cannot be granted because of exclusivity, or for which an existing patent may be omitted (21 CFR 314.92). Because a new drug application (NDA) for Fludeoxyglucose F18 Injection (NDA 20-306) was approved on August 19, 1994, for the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures, ANDA's may be submitted for drug products that are the same as this reference listed drug product and for the same use. The purpose of the draft guidance document is to assist applicants who wish to submit an ANDA for Fludeoxyglucose F18 Injection. The draft guidance is one of several issues to be discussed at an April 28, 1997, FDA workshop on PET radiopharmaceutical drug products. The workshop, which will be held in Rockville, MD, was announced in the **Federal Register** on March 14, 1997 (62 FR 12218). Other issues to be discussed at the workshop include: Registration and listing requirements, chemistry and manufacturing controls, sterility assurance, bioequivalence requirements, and labeling.

This guidance document represents the agency's current thinking on the content and format of an ANDA for PET radiopharmaceutical drug products. It does not create or confer any rights for, or on, any person and does not operate to bind FDA or the public. An alternative approach may be used if

such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance document to the Dockets Management Branch (address above). 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 draft guidance document and received comments also may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this draft guidance is available on the Internet using the World Wide Web (<http://www.fda.gov/cder/guidance.htm>).

Dated: April 18, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Availability of Funds for Planning Grants To Establish Comprehensive HIV Primary Health Care Services; The Ryan White Comprehensive AIDS Resources Emergency Act of 1990, as Amended by the Ryan White CARE Act Amendments of 1996

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Availability of Grants to Support Planning Activities To Establish Comprehensive Primary Health Care Services with Respect to Human Immunodeficiency Virus (HIV) Disease.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1997 discretionary grants to support communities and health care service entities in their preparations to provide a high quality and broad, comprehensive scope of primary health care services for people in underserved areas who are living with HIV or at risk of infection. The Ryan White Title III HIV Planning Grants are intended to assist health care service entities to qualify for grant support under the Ryan White Title III Early Intervention Services Program.

These grants are awarded under the provisions of Part C of Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White CARE Act Amendments of 1996, Public Law 104-146 (42 U.S.C. 300ff-51-300ff-67).

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting health priorities. This grant program is related to the objectives cited for special populations, particularly people with low income, minorities, and the disabled, which constitute a significant portion of the homeless population. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock No. 017-001-00474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

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.

**DUE DATE:** Applications are due on May 23, 1997. Applications will be considered to have met the deadline if they are: (1) received on or before the deadline date; or (2) postmarked on or before the established deadline date and received in time for orderly processing. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailing. Applications postmarked after the announced closing date will not be considered for funding.

**ADDRESSES:** Application kits (Form PHS 5161-1) with revised face sheet DHHS Form 424, as approved by the Office of Management and Budget under control number 0937-0189 may be obtained from, and completed applications should be mailed to HRSA Grants Application Center, 40 West Gude Drive, Suite 100, Rockville, MD 20850 (telephone: 1-888-300-4772). The Bureau of Primary Health Care's Office of Grants Management can also provide assistance on business management issues, and can be reached at 4350 East-

West Highway, Bethesda, MD 20814 (telephone: 301-594-4235).

**FOR FURTHER INFORMATION CONTACT:**

For general information and technical assistance, contact Dr. Deborah Parham of the HIV Primary Care Programs Branch, Division of Programs for Special Populations, Bureau of Primary Health Care, 4350 East-West Highway, Bethesda, MD 20814 (telephone: 301-594-4444).

**SUPPLEMENTARY INFORMATION:**

**Number of Awards**

It is anticipated that approximately 13 grants will be awarded, ranging from approximately \$25,000 up to \$50,000 each year for a two-year project period. The awarding of Ryan White Title III HIV Planning Grants will not obligate the HRSA to support applicants for additional Planning Grants or for future operational funding. Continuation awards for the second year will be made subject to the availability of funds and the satisfactory progress in the previous year toward meeting the goals and objectives of the proposed planning process.

**Eligible Applicants**

Eligible applicants are public or nonprofit private entities who are not currently grant recipients of the Ryan White Title III Early Intervention Services Program. In awarding the grants, preference will be given to entities that provide primary care services in rural or underserved communities.

The HIV Planning Grant is intended to assist health care service entities to qualify for grant support under the Ryan White Title III Early Intervention Services Program. Eligible applicants for that grant program are public or private, nonprofit entities that are: current primary care service providers to populations at risk for HIV disease; community health centers under Section 330 of the PHS Act; migrant health centers under Section 330(g) of the PHS Act; health care for the homeless grantees under Section 330(h) of the PHS Act; family planning grantees under Section 1001 of the PHS Act, other than states; comprehensive hemophilia diagnostic and treatment centers; or federally qualified health centers under section 1905(1)(2)(B) of the Social Security Act.

**Project Requirements**

Funds are to be used to mobilize and organize community resources, and to strengthen organizational capacity so that HIV comprehensive primary health care services can be established or

strengthened. Proposed planning activities should address the requirements for the Ryan White Title III Early Intervention Services Program, as specified in the statute (sections 2651, 2661 and 2662 of the PHS Act).

Grant recipients are expected to: engage and coordinate suitable community organizations to plan for HIV primary care services; conduct an initial HIV/AIDS primary care needs assessment for the proposed service area; develop a plan of action to address priority needs; and undertake the necessary preparations to become operational. Related to these endeavors, Ryan White Title III Planning Grant recipients may also strengthen their organizational capability in clinical, administrative, managerial, fiscal and MIS structures.

The expected outcome of this grant program is either that (1) grant recipients become prepared, through the planning process, to offer comprehensive HIV primary care services to their communities; or (2) grant recipients lead a process of community development, at the conclusion of which other health care entities emerge as the most appropriate and capable service providers of comprehensive HIV primary care, and become prepared to offer such services to their communities.

**Criteria for Evaluating Applications**

Competitive applications for HIV Planning Grant support will be evaluated in accordance with the following criteria:

- The need in the community for assistance, based on the 2-year period preceding the proposed grant period. In awarding the grants, preference will be given to applicants who provide primary care services in rural or underserved areas where emerging or ongoing HIV issues have not been adequately addressed. Applicants must present a compelling case for grant support by drawing the connection between the services that they hope to establish and the significant disease burden and need for HIV primary care services among underserved populations in their communities.
- The adequacy, scope and completeness of the proposed planning activities.
- The applicant's role in the community and the extent to which proposed actions can reasonably assure effective collaboration with potential partners, including other Federal Ryan White programs.
- The degree to which the proposed budget is appropriate to the program

plan and the degree to which coordination with other funding sources is well documented.

- The extent to which the applicant demonstrates the active inclusion of people living with HIV/AIDS, or the organizations that represent them, in the planning and evaluation process.
- The adequacy and completeness of proposed evaluation activities, which are designed to ensure that goals and objectives are achieved in a timely manner and that the planning process is effective.

**Other Award Information**

Public Health System Reporting Requirements: Under these requirements (approved by the Office of Management and Budget 0937-0195), 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:

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

The Program to Provide Outpatient Early Intervention Services with Respect to HIV Disease, of which the Ryan White Title III HIV Planning Grant is a subpart, has been determined to be a program which is 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 will contain a listing of States which have chosen to set up a review system and will provide a State point of contact (SPOC) in the

State for the review. Applicants (other than federally-recognized Indian tribal governments) should contact their SPOC 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 appropriate deadline dates. The BPHC does not guarantee that it will accommodate or explain its responses to State process recommendations received after the date. (See "Intergovernmental Review of Federal Programs", 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 this program is 93.918.)

Dated: April 17, 1997.

**Claude Earl Fox,**

*Acting Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Rural Telemedicine Grant Program

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

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

**SUMMARY:** The Office of Rural Health Policy, HRSA, announces that applications are being accepted for Rural Telemedicine Grants to facilitate development of rural health care networks through the use of telemedicine and develop a baseline of information for the systematic evaluation of telemedicine systems serving rural areas.

**DATES:** Applications for the program must be received by the close of business on June 20, 1997. Applications shall be considered as meeting the deadline if they are either (1) received on or before the deadline date at the address noted below; or (2) postmarked on or before the deadline date and received by the granting agency in time for the independent review. Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service in lieu of a postmark. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications are

considered late if they do not meet the above criteria; late applications will be returned to the sender.

**ADDRESSES:** Completed applications must be sent to HRSA GRANTS APPLICATION CENTER, 40 West Gude Drive, Suite 100, Rockville, MD 20850.

**FOR FURTHER INFORMATION CONTACT:** Requests for technical or programmatic information on this announcement should be directed to Cathy Wasem or Amy Barkin, Office of Rural Health Policy, HRSA, 5600 Fishers Lane, Room 9-05, Rockville, MD 20857, (301) 443-0835, cwasem@hrsa.dhhs.gov or abarkin@hrsa.dhhs.gov. Requests for information regarding business or fiscal issues should be directed to Martha Teague, Office of Grants Management, Bureau of Primary Health Care, HRSA, West Tower, 11th Floor, 4350 East West Highway, Bethesda, MD 20814, (301) 594-4258.

#### SUPPLEMENTARY INFORMATION:

##### Application Packet

The standard application form and general instructions for completing applications (Form PHS-5161-1 [Revised 5/96], OMB #0937-0189) have been approved by the Office of Management and Budget. To receive an application kit call toll-free: HRSA GRANTS APPLICATION CENTER at 1-888-300-HRSA. Individuals in rural areas where the 1-888 number cannot be dialed should call the operator and ask that the operator connect them to 1-888-300-4772.

##### Authority

Grants for these projects are authorized under section 330A of the Public Health Service (PHS) Act as amended by the Health Centers Consolidation Act of 1996, Public Law 104-299. Awards will be made from funds appropriated under Public Law 104-208 (HHS Appropriation Act for FY 1997).

##### Legislative and Program Background

Section 330A of the PHS Act, as amended by Pub. L. 104-299, authorizes the Rural Health Outreach, Network Development and Telemedicine Grant Program. Grants supported under this program are to "expand access to, coordinate, restrain the cost of, and improve the quality of essential health care services, including preventive and emergency services, through the development of integrated health care delivery systems or networks in rural areas and regions." Two approaches to achieve these goals are through projects funded under the Rural Health Outreach and the Rural Network Development

Program. A third approach is through projects funded under the Rural Telemedicine Grant Program. This program announcement pertains only to the Rural Telemedicine Grant Program. (The **Federal Register** Notice for the Rural Health Outreach and Rural Network Development Program was published December 13, 1996. Applications were due March 31, 1997).

Rural residents in the United States often lack access to a range of health services—from basic preventive services to highly specialized services—that would enable them to prevent, recover from, or cope with disease and disability. Consistent with the legislation, the Office of Rural Health Policy (ORHP) views integrated health care delivery systems or networks as a means to stabilize and integrate fragile rural health care systems with more sustainable, comprehensive delivery networks. ORHP believes that telemedicine has the potential to facilitate the development of integrated health care networks, thereby fostering improved access to quality health care services and reducing the isolation of rural practitioners.

The goal of ORHP's Rural Telemedicine Grant Program is to improve access to quality health services for rural residents and reduce the isolation of rural practitioners through the use of telemedicine technologies.

The two objectives of the Rural Telemedicine Grant Program are: (1) To demonstrate how telemedicine can be used as a tool in developing integrated systems of health care, thereby improving access to health services for rural individuals across the lifespan and reducing the isolation of rural health care practitioners; and (2) to evaluate the feasibility, costs, appropriateness, and acceptability of rural telemedicine services and technologies. Such evaluation is needed to determine how best to organize and provide telemedicine services in a sustainable manner.

Under its Rural Telemedicine Grant Program, ORHP funded eleven telemedicine projects in fiscal year 1994 for a period of three years. Building on the lessons learned from these first telemedicine grantees, new grantees will be expected to further the development of integrated health care networks by using telemedicine to increase access to a wide range of clinical services based on community need.

##### Funds Available

Approximately \$4 million is available for the Rural Telemedicine Grant program in FY 1997. The Office of Rural