

Evaluation and Research (HFD-310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2073.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Nycomed, Inc., 1250 South Collegeville Rd., P.O. Box 5000, Collegeville, PA 19426-0900, has filed an application requesting approval for the export of the human drug Visipaque™ (iodixanol) Injection 270 mg I/mL and 320 mg I/mL supplied in 50 mL vial, 100 mL, 150 mL, and 200 mL bottle to Canada. The

product is used in angiocardiology (left ventriculography, aortic root injections, and selective coronary arteriography) and can be used in the diagnosis of coronary artery disease as well as evaluation of the function of the chambers of the heart and heart valves. The application was received and filed in the Center for Drug Evaluation and Research on December 28, 1994, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by February 21, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under

authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: January 31, 1995.

Kathy P. Mirracco,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 1995 Funding Opportunities for Grants From the Center for Mental Health Services

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

ACTION: Notice of funding availability.

SUMMARY: The Center for Mental Health Services (CMHS), SAMHSA, announces that FY 1995 funds are available for grants for the following activities. These activities are discussed in more detail under Section 4 of this notice.

Activity	Application deadline	Estimated funds available	Estimated number of awards	Project period (years)
AIDS Provider Educ	05/10/95	\$980,000	5-6	3
Innovative Child Services	05/10/95	\$2.6 million	6-8	3
Consumer/Family Networks	05/10/95	\$750,000-1.2 million	5-8	3
Consumer TA Center(s)	05/10/95	\$350,000-700,000	1-2	3

The actual amount available for awards and their allocation may vary, depending on unanticipated program requirements and the volume and quality of applications. Awards are made for grant periods which generally run from 1 up to 3 years in duration. FY 1995 funds for mental health services and demonstration programs are appropriated by the Congress under Public Law 103-333. 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 Center's mental health services and demonstration activities address issues related to

Healthy People 2000 objectives: to promote the physical, social, psychological and economic well-being of adults with mental disorders and children and adolescents with or at risk for a serious emotional, behavioral, or mental disorder.

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) 783-3238).

GENERAL INSTRUCTIONS: Applicants for grants must use application form PHS 5161-1 (Rev. 7/92; OMB No. 0937-0189). The Application Kit contains the PHS 5161-1, Standard Form 424 (Face Page) and *complete instructions* for preparing and submitting applications. The Kit may be obtained from the contact person identified for each

activity covered by this notice (see Section 4).

When requesting an Application Kit, the applicant must specify the particular activity(ies) 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.

APPLICATION SUBMISSION: Applications must be submitted to: Center for Mental Health Services Programs, Division of Research Grants, NIH, Westwood Building, Room 240, 5333 Westbard Avenue, Bethesda, Maryland 20892.*

APPLICATION DEADLINES: The deadlines for receipt of applications are listed in the table above.

Competing applications must be received by the indicated receipt dates to be accepted for review. An

* If an overnight carrier or express mail is used, the Zip Code is 20816.

application received after the deadline may be acceptable 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. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a national holiday, it will be extended to the following work day.

Applications received after the receipt date(s) or those sent to an address other than the address specified above *will be returned to the applicant without review.*

FOR FURTHER INFORMATION CONTACT:

Requests for activity-specific technical information should be directed to the contact person identified for each activity covered by this notice (see Section 4). Requests for information concerning business management issues should be directed to: Grants Management Office, Center for Mental Health Services, 5600 Fishers Lane, Room 15C-05, Rockville, Maryland 20857, (301) 443-4456.

SUPPLEMENTARY INFORMATION: To facilitate the use of this Notice of Funding Availability, information in this section has been organized, as outlined in the Table of Contents below. In addition, the discussion of the specific FY 1995 funding activities is presented under the following headings:

- Application Deadline.
- Purpose.
- Priorities.
- Eligible Applicants.
- Grants/Amounts.
- Catalog of Federal Domestic Assistance Number.
- Program Contact.

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1. Program Background and Objectives

The Center for Mental Health Services (CMHS) has been given a statutory

mandate to take a national leadership role in the development and demonstration of improved mental health services. Toward that end, Center activities involve facilitating the application of scientifically established findings and practice-based knowledge to prevent and treat mental disorders, improving access, reducing barriers and promoting high quality, effective programs and services for people with, or at risk for, these disorders.

2. Special Concerns

The CMHS will address a number of special concerns in 1995. Particular emphasis will be placed on helping localities design and implement comprehensive approaches to service delivery, networking, and coordination with other Federal and non-Federal programs. Special emphasis will be given to providing assistance for individuals in varied racial and ethnic groups; adolescents; early intervention programs; rural populations; adolescents involved in the juvenile justice system; and individuals with, or at risk for, HIV/AIDS.

3. Criteria for Review and Funding

Competing applications requesting funding under the specific project activities in Section 4 will be reviewed for technical merit in accordance with established PHS/SAMHSA peer review procedures.

Applications that are accepted for review will be assigned to an Initial Review Group (IRG) composed primarily of non-Federal experts. Applications will be recommended for approval or disapproval on the basis of technical merit. Applications recommended for approval will be assigned scores according to level of merit.

Notification of the IRG's recommendation will be sent to the applicant upon completion of the initial review. In addition, the IRG recommendations on technical merit of applications over \$50,000 will undergo a second level of review by the CMHS National Advisory Council, whose review may be based on policy considerations, as well as technical merit. Only applications recommended for approval by the Council may be considered for funding by CMHS.

3.1 General Review Criteria

As published in the **Federal Register** on July 2, 1993 (Vol. 58, No. 126), SAMHSA's "Peer Review and Advisory Council Review of Grant and Cooperative Agreement Applications and Contract Proposals," peer review groups will take into account, among

other factors as may be specified in the application guidance materials, the following general criteria:

- Potential significance of the proposed project;
- Appropriateness of the applicant's proposed objectives to the goals of the specific program;
- Adequacy and appropriateness of the proposed approach and activities;
- Adequacy of available resources, such as facilities and equipment;
- Qualifications and experience of the applicant organization, the project director, and other key personnel; and
- Reasonableness of the proposed budget.

3.2 Funding Criteria for Approved Applications

Applications recommended for approval by the peer review group and the CMHS National Advisory Council (if applicable) will be considered for funding on the basis of their overall technical merit as determined through the review process.

Other funding criteria will include;

- Availability of funds.
- Additional funding criteria specific to the programmatic activity may be included in the application guidance materials.

4. Special FY 1995 Mental Health Service Activities

Project activities are grouped in this notice under one section: Grants.

4.1 Grants

Four major activities for CMHS grant programs are discussed below.

4.1.1 Mental Health Care Provider Education In HIV/AIDS

- Application Deadline May 10, 1995.
- Purpose: The goal of the program is to enhance the Nation's ability to have an impact upon the HIV/AIDS epidemic by training the traditional mental health care providers and other health care workers who often are front-line providers of mental health services, such as medical students, primary care physicians, and the clergy and other spiritual providers.

Applicants will be expected to propose a comprehensive training program that addresses the mental health needs of people with HIV/AIDS. The program is to train traditional mental health providers (psychiatrists, psychologists, nurses, social workers, counselors, and marriage and family counselors), other first line providers of mental health services (e.g., medical students, primary care physicians), and nontraditional providers (e.g., the clergy and other spiritual providers, alternative

health care workers). Training programs proposed must target at least 5 provider groups. The program must address the neuropsychiatric and the psychosocial aspects of HIV/AIDS; coping with HIV/AIDS; and approaches to prevent the spread of HIV infection. Applicants shall make appropriate use of existing curricula.

- Priorities: None.
- Eligible Applicants: Applications may be submitted by any public or private nonprofit organization.
- Grants/Amounts: 5 to 6 awards, with individual awards varying from \$125,000 to \$200,000 for the first year.
- Catalog of Federal Domestic Assistance Number: 93.244.
- Program Contact: For programmatic or technical information contact: Barbara J. Silver, Ph.D., Director, HIV/AIDS Provider Education Program, Center for Mental Health Services, 5600 Fishers Lane, Room 15-81, Rockville, Maryland 20857, (301) 443-7817.
- Application kits and complete instructions for submitting an application may be obtained from: Global Exchange, Inc., 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3015, (301) 656-3100.

4.1.2 Evaluating Innovative Children's Mental Health Services

- Application Deadline: May 10, 1995.
- Purpose: The purpose of this announcement is to encourage demonstrations which focus on evaluating the effectiveness of innovative models of organizing, delivering, and financing mental health service systems of care for children and adolescents with or at risk for serious emotional, behavioral or mental disturbances and their families, especially those systems that include community-based services and interagency coordination.
- Priorities: None.
- Eligible Applicants: Centralized state assistance is often helpful in obtaining continued support for successful intervention projects. Therefore, State mental health authorities may choose to be direct applicants. Direct application for funding may also be made by political subdivisions of a State, and private nonprofit organizations such as community-based organizations, universities, colleges, and hospitals. In the case where an applicant is not the State mental health authority, the applicant will be required to obtain a letter of support from the State mental health authority.

- Grants/Amounts: 6 to 8 awards, with individual awards varying from \$300,000 to \$400,000 for the first year.

- Catalog of Federal Domestic Assistance Number: 93.125.
- Program Contact: For application kit and/or programmatic or technical information contact: Ms. Diane L. Sondheimer, Child, Adolescent and Family Branch, Center for Mental Health Services, 5600 Fishers Lane, Room 11C-17, Rockville, Maryland 20857, (301) 443-1333.

4.1.3 Demonstration Grants for Consumer and Family Networks

- Application Deadline: May 10, 1995.
- Purpose: The goals for these demonstration grants are to implement and evaluate strategies to: (1) Empower consumer and family networks and strengthen their ability to participate in State and local mental health service planning and health care reform policy activities related to improving community-based services for the target population; and (2) foster the financial self-sufficiency of consumer and family organizations.
- Priorities: None.
- Eligible Applicants: CMHS is limiting potential applicants for projects under this announcement to State mental health authorities. Multiple organizations are generally involved in implementing these initiatives; and the State mental health authorities are uniquely qualified to undertake the coordination function, since they work directly with the major consumer and family groups and oversee a wide range of mental health service providers.

Due to funding limitations, only States and territories that do not have a current, active Community Support Programs (CSP) Service Systems Improvement Demonstration (SSID) grant, or those that have an active CSP SSID grant with a project period that ends on or before August 31, 1995, excluding no-cost extensions, are eligible to apply.

- Grants/Amounts: 5 to 8 awards, with individual awards varying from \$125,000 to \$150,000 for the first year.
- Catalog of Federal Domestic Assistance Number: 93.125.
- Program Contact: For application kit and/or programmatic or technical information contact: Mr. Neal Brown, Chief, Community Support Programs Branch, Center for Mental Health Services, 5600 Fishers Lane, Room 11C-22, Rockville, Maryland 20857, (301) 443-3653.

4.1.4 National Consumer Technical Assistance Centers

- Application Deadline: May 10, 1995.
- Purpose: The goals of these Centers are to: (1) Serve as a resource center for consumers involved in the Community Support Programs (CSP) Service System Improvement Demonstration (SSID) grants, with a special emphasis on assisting the groups to achieve financial self-sufficiency; (2) operate a national resource center for consumers involved in developing consumer-operated services by reaching out to racial and ethnic minorities, assisting in planning, providing, and evaluating mental health services, and in planning for health care reform activities; and (3) facilitate the development of a coalition of national or multi-state consumer organizations involved in self-help and system improvement efforts.
- Priorities: It is CMHS's expectation that the TA Center(s) will be planned, directed, and operated by primary mental health consumers.
- Eligible Applicants: Applications may be submitted by States, political subdivisions of States, and private nonprofit agencies, as well as current CMHS/CSP TA Center grantees.
- Grants/Amounts: 1 to 2 awards, with individual amounts varying from \$300,000 to \$350,000 for the first year.
- Catalog of Federal Domestic Assistance Number: 93.125.
- Program Contact: For application kit and/or programmatic or technical information contact: Mr. Neal Brown, Chief, Community Support Programs Branch, Center for Mental Health Services, 5600 Fishers Lane, Room 11C-22, Rockville, Maryland 20857, (301) 443-3653.

5. 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 1995 activity described above is not subject to the Public Health System Reporting Requirements.

6. PHS Non-use of Tobacco Policy Statement

The PHS strongly encourages all grant and cooperative agreement recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Specific application guidance materials may include more detailed guidance as to how the Center will implement SAMHSA's policy on promoting the non-use of tobacco.

7. Executive Order 12372

Applications submitted in response to most, if not all, of the FY 1995 activities listed above are subject to the intergovernmental review requirements of Executive Order (E.O.) 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: Office of Extramural Activities Review, Substance Abuse and Mental Health Services Administration (SAMHSA), 5600 Fishers Lane, Room 13C-06, Rockville, Maryland 20857, ATTN: SPOC.

The due date for State review process recommendations is no later than 60 days after the specified deadline date for

the receipt of applications. The CMHS does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cut-off.

Application guidance materials will specify if a particular FY 1995 activity described above is not subject to the provisions of Executive Order 12372.

Dated: February 3, 1995.

Richard Kopanda,

Acting Executive Officer, SAMHSA.

[FR Doc. 95-3342 Filed 2-9-95; 8:45 am]

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Fiscal Year (FY) 1995 Funding Opportunities for Grants and Cooperative Agreements From the Center for Substance Abuse Prevention

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

ACTION: Notice of funding availability.

SUMMARY: The Center for Substance Abuse Prevention (CSAP), SAMHSA, announces that FY 1995 funds are available for grants and cooperative agreements for the following activities. These activities are discussed in more detail under Section 4 of this notice.

Activity	Application deadline	Estimated funds available (000's)	Estimated No. of awards	Project period (years)
Knowledge Dissemination Conference Grants	05/10/95 09/10/95	\$1,000	20	1
High-Risk Youth Demonstration Grants:				
High Risk Youth	05/10/95	11,478	36	3
Adolescent Females	05/10/95	4,079	13	3
Replications	05/10/95	4,000	12	3
Community Prevention Coalition Demonstration Grants	05/10/95	33,000	100-125	3
Faculty Development Grants	05/10/95	2,000	8	3
Communications Cooperative Agreements	05/10/95	2,300	11	3

The actual amount available for awards and their allocation may vary, depending on unanticipated program requirements and the volume and quality of applications. Awards are made for grant periods which generally run from 1 up to 3 years in duration. FY 1995 funds for services demonstration activities are appropriated by the Congress under Public Law 103-333. 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, page 35962) 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 Center's services demonstration activities address issues related to Healthy People 2000 objectives for reducing the risk for using and abusing alcohol, tobacco and other drugs.

Additional themes include community empowerment; changes in the services delivery system to effect closer collaboration among substance abuse prevention activities, mental health services and the health care system; prevention and reduction of violent actions; cultural competence of prevention strategies; and

encouragement to reach out to female adolescents at risk for substance abuse and not generally served by traditional programs.

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: 202-783-3238).

GENERAL INSTRUCTIONS: Applicants for grants and cooperative agreements must use application form PHS 5161-1 (Rev. 7/92; OMB No. 0937-0189). The Application Kit contains the PHS 5161-1, Standard Form 424 (Face Page) and