

personal computer with Internet access. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>.

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 (44 USC 3501–3520) (the PRA). 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. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 2004.

Beverly Cherniak Rothstein,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[HRSA–04–078]

Special Projects of National Significance: An Evaluation of Innovative Methods for Integrating Buprenorphine Opioid Abuse Treatment in HIV Primary Care Settings; CFDA 93.928

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of fiscal year (FY) 2004 funds to be awarded under

the Special Projects of National Significance (SPNS) Program for the development and evaluation of innovative methods for integrating buprenorphine opioid abuse treatment in HIV primary care settings.

Program Purpose: The purpose of this new grant initiative is to support and examine the effectiveness of the integration of advancements in substance abuse treatment (buprenorphine) in HIV primary care settings. Grantees are expected to participate in multi-site evaluation activities as well as accomplish a local evaluation of interventions. An Evaluation and Technical Assistance Center (ETAC) will be responsible for coordinating and conducting a multi-site analysis, providing clinical expertise, developing guidelines for integrated programs, conducting cost-effectiveness analysis, and dissemination of results.

Program Requirements: The demonstration projects will focus on the development and evaluation of interventions that examine a number of relevant issues including (a) barriers and facilitators for clients successfully engaging in integrated substance abuse treatment using buprenorphine while also being treated for HIV, (b) how delivery of care is impacted by an integrated approach, and (c) how continuity of both HIV primary care and substance abuse (buprenorphine) treatment will be affected. The Center will work with SPNS and demonstration sites to develop an overall multi-site evaluation of the initiative. Subsequently, the Center will assist grantees on program development and evaluation issues. The Center will be responsible for describing the methods, theoretical framework, and principles of the evaluation design. The Center must also develop a technical assistance plan for grantees. Throughout the initiative, the SPNS Program expects the Center to describe the roles and characteristics of the clients, providers, and practitioners who participate in the projects, and the interventions used by grantees. In addition, the Center will gather information that will describe the effect of integrating buprenorphine treatment into primary care structures and health care systems.

Eligible Applicants: The statute, Section 2691(a) of the Public Health Service Act specifies that grants may be awarded to public and non-profit private entities to fund special programs for the care and treatment of people with HIV disease. Eligible applicants may include, but are not limited to, State, local, or tribal public health, mental health, housing, or substance

abuse departments; public or non-profit hospitals and medical facilities; faith-based and community-based organizations, institutions of higher education, and national service provider and/or policy development associations and organizations. With regard to this initiative, all applicants must have significant experience evaluating substance abuse treatment programs, HIV primary care and treatment, and the integration of these endeavors.

Funding Priorities: This SPNS Initiative is designed to demonstrate and evaluate innovative and replicable models with regard to HIV treatment and care in various settings. The authorizing legislation specifies three SPNS program objectives: (1) To support the development of innovative models of HIV care; (2) to evaluate the effectiveness of innovative program designs; and (3) to promote replication of effective models.

Authorizing Legislation: The SPNS Program is authorized by section 2691 of the Public Health Service (PHS) Act, (42 U.S.C. 390ff–101).

Availability of Funds: The program has \$3.5 million dollars available for this initiative. The Health Resources and Services Administration (HRSA) expects to make up to ten (10) awards for demonstration projects (Category A) and one award for an Evaluation and Program Support Center (Category B). It is anticipated that each Category A project site will be awarded up to \$300,000 per year for 5 years. The Category B Evaluation and Support Center will be awarded up to \$500,000 per year for 5 years. The budget and project periods for approved and funded projects will begin on or about September 1, 2004. Funds must be requested for all 5 years of the initiative.

Cost Sharing/Matching: There are no cost sharing/matching requirements under this grant initiative.

Application Deadline: Applications must be received in the HRSA GAC by the close of business April 15, 2004, to be considered for competition. Applications will meet the deadline if they are either (1) received on or before the deadline date or (2) postmarked or E-marked on or before the deadline date, and received in time for submission to the objective review panel. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted instead of a postmark. Private metered postmarks shall not be accepted as proof of timely mailing.

Late Applications: Applications which do not meet the criteria above are considered late applications. 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 such circumstances 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. 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). If there are tables that are not supported as data entry forms from within the application, they should be downloaded to your hard drive, filled in, and then uploaded as attachments with your application. Applications submitted electronically will be time/date stamped electronically, which will serve as receipt of submission. To look for funding opportunities, go to <http://www.hrsa.gov/grants> and follow the links.

DUNS Number: Beginning October 1, 2003, applicants were required to have a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711. Please include DUNS number on application face page. 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 electronically applying for HRSA grants. Information about registering with the CCR can be found at <http://www.hrsa.gov/grants/ccr.htm>.

Where to Request and Send an Application: To prepare and submit an application, organizations must obtain: (1) The SPNS Buprenorphine Substance Abuse Treatment Guidance and (2) the

official Federal grant application kit. To obtain the official grant application kit (PHS 5161-1) and program guidance materials for this announcement call the HRSA Grant Application Center at 877-477-2123 and request the OMB Catalogue of Federal Domestic Assistance (CFDA) number 93.928, FY 2004 Integrating Buprenorphine/Substance Abuse Treatment in HIV Primary Care Settings. These forms may also be downloaded from the Health Resources and Services Administration's Web site at: <http://www.hrsa.gov/grants/forms.htm>. The Guidance can be found at <http://www.hrsa.gov/grants/>. 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.

Notification of Intent to Apply: To allow HRSA to plan for the Objective Review Process, letters of intent are requested from all applicants. Such letters should be sent to: Division of Independent Review, Director, Attention: FY 2004 Integrating Buprenorphine/Substance Abuse Treatment in HIV Primary Care Settings, HRSA Grants Application Center (GAC), The Legin Group, Inc., 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879, fax number: 877-477-2345. Letters should be received by March 30, 2004. Receipt of these notices of intent will not be acknowledged. An applicant is eligible to apply even if no letter of intent is submitted.

ADDRESSES: Please mail one (1) original (ink-signed) and two (2) unbound photocopies of completed applications to the HRSA Grant Application Center, c/o The Legin Group, Inc., 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879, Attention: FY 2004 Integrating Buprenorphine/Substance Abuse Treatment in HIV Primary Care Settings, HRSA-04-078. Grant applications sent to any other address will be returned. Applicants are strongly advised to obtain the Guidance before preparing applications.

FOR FURTHER INFORMATION CONTACT: Additional information regarding this funding announcement may be requested from Lois Eldred, Dr PH, Chief, Demonstration Project Development and Evaluation Branch, Office of Science and Epidemiology, HIV/AIDS Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 7C-07, Rockville,

MD 20857; telephone 301-443-3327; fax 301-443-4965; e-mail address LEldred@hrsa.gov. For assistance related to technical and program issues regarding the overall SPNS Program, please contact Pamela Belton, Program Analyst, Demonstration Project Development and Evaluation Branch, HIV/AIDS Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 7C-07, Rockville, MD 20857; telephone: 301-443-9976; fax 301-443-4965 or e-mail address PBelton@hrsa.gov. For information regarding business, administration, and fiscal issues related to the awarding of grants under this notice, contact Ms. Pamela Baker, Grants Management Specialist, Division of Grants Management Operations, Health Resources and Services Administration, 5600 Fishers Lane, Room 11A-16, Rockville, MD 20857; telephone 310-443-0197, fax 301-594-6096 or e-mail address pbaker@hrsa.gov.

SUPPLEMENTARY INFORMATION: All applications submitted to the SPNS Program will be reviewed and rated by an objective review panel. All applicants funded should recognize that this initiative is not designed to provide continuous support once the initiative is complete and evaluated. Applicants are strongly encouraged to secure non-SPNS funding support during their initiative if the evaluation suggests that the program/intervention is effective and merits continuation.

Healthy People 2010 Objectives: The PHS encourages applicants to address at least one of the Healthy People 2010 objectives related to HIV and AIDS in their work plans. Potential applicants may obtain a copy of Healthy People 2010 (Full Report) or Healthy People 2010 (Summary Report) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Web site: <http://www.access.gpo.gov>; telephone: 202-512-1800).

Reporting and Other Requirements: In addition to deliverables described in guidance materials, the successful applicant under this notice must submit two semi-annual activity summary reports, in accordance with provisions of the general regulations which apply under 45 CFR 74.51 "Monitoring and reporting of program performance" (with the exception of State and local governments to which 45 CFR part 92 reporting requirements apply), and comply with audit requirements of OMB Circular A-133. Further, the PHS also strongly encourages all award recipients to provide a smoke-free workplace and

to promote the non-use of all tobacco products. In particular, 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.

Public Health System Reporting Requirements: This program is also subject to the PHS Reporting Requirements which have been approved by the OMB under No. 0937-0195. Under these requirements, any community-based, non-governmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to keep State and local health officials apprised of proposed health services grant applications submitted from within their jurisdictions. Instructions on this matter are contained in the Guidance for this initiative, available from the GAC.

Paperwork Reduction Act: Should there be any data collection activities associated with this funding that fall under the purview of the Paperwork Reduction Act, OMB clearance will be sought.

Executive Order 12372: The SPNS Grant Program is subject to the provisions of Executive Order 12372, concerning intergovernmental review of Federal Programs, 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 Single Point of Contact (SPOC) for the review. Applicants (other than federally recognized Indian tribes) should contact their 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 under E.O. 12372 is 60 days after the application due date. HRSA does not guarantee that it will accommodate or explain its responses to State process recommendations received after that date. (See "Intergovernmental Review of Federal Programs," Executive Order 12372, and 45 CFR part 100, for a description of the review process and requirements. For additional information go to: <http://www.whitehouse.gov/omb/grants/spoc.html>.)

Review Process: Applications submitted in response to the NOAF will be reviewed for threshold criteria and merit by an Objective Review Committee. Applicants should carefully review the criteria, in relation to the Program Requirements, to ensure that their applications address each criterion. Reviewers will use only the information you include in your application. Therefore, it is important that you write clearly and be specific. You should assume that the reviewers know nothing about your organization or the work you do. The threshold criteria for Category A demonstration project sites and Category B Evaluation and Support Center are: (1) Need (15 points), (2) Response (25 points), (3) Evaluative Measures (20 points), (4) Impact (15 points), (5) Resources/Capabilities (15 points) and (6) Support Requested (10 points). These criteria are more completely defined in the Application Kit.

Dated: February 26, 2004.

Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

[CIS NO. 2313-04]

Information Regarding the H-2B Numerical Limitation for Fiscal Year 2004

AGENCY: Bureau of Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice advises the public that the Department of Homeland Security (DHS), Bureau of Citizenship and Immigration Services (CIS) will no longer accept H-2B petitions for temporary nonimmigrant workers for the remainder of Fiscal Year (FY) 2004 now that it is clear that the demand for H-2B workers will exceed the statutory numerical limit (the cap) for H-2B petitions for FY 2004. This notice is published so that the public will understand the procedures for processing of H-2B petitions now that CIS has received enough H-2B petitions to reach the cap. These procedures are intended to minimize confusion and burden to employers who use the H-2B program.

DATES: This notice is effective March 16, 2004.

FOR FURTHER INFORMATION CONTACT: Kevin J. Cummings, Business and Trade Services Branch/Program and Regulation Development, Bureau of Citizenship and Immigration Services, Department of Homeland Security, 425 I Street, NW., ULLB 3rd Floor, Washington, DC 20536, telephone (202) 305-3175.

SUPPLEMENTARY INFORMATION:

Who Is an H-2B Nonimmigrant?

Section 101(a)(15)(h)(ii)(b) of the Immigration and Nationality Act (Act) describes an H-2B alien as an alien coming temporarily to the United States to perform temporary nonagricultural labor or services. This definition is reflected at 8 CFR 214.2(h)(1)(ii)(D) and (h)(6)(i).

What Is the Cap or Numerical Limitation on the H-2B Nonimmigrant Classification?

Section 214(g)(1)(B) of the Act provides that the total number of aliens who may be issued H-2B visas or otherwise granted H-2B status during any fiscal year may not exceed 66,000.

What Is the Effect of This Notice?

This notice advises the public that as of March 10, 2004, CIS will no longer accept H-2B petitions for temporary nonimmigrant workers for the remainder of FY 2004. However, CIS will adjudicate petitions received on or before March 9, 2004 in the order in which they are received.

Does This Notice Apply to All H-2B Petitions Filed During FY 2004?

No. The procedures described in this notice relate only to H-2B petitions filed for beneficiaries subject to the numerical limitations and who will be engaged in temporary work to commence on or before September 30, 2004.

Amendments to previously approved petitions and petitions for extension of stay are not affected by this procedure. Likewise, petitions for aliens who already hold H-2B status, *i.e.* petitions filed on behalf of an H-2B alien by a new or additional employer are also not affected by this procedure. This procedure also does not relate to petitions filed before October 1, 2004, for employment to commence on or after October 1, 2004.

What Is the CIS Procedure for Processing H-2B Petitions During the Remainder of FY 2004?

This notice informs the public that CIS has received a sufficient number of