

NICEATM can be found at the following Web site: <http://iccvam.niehs.nih.gov>.

## References

EPA 1998. Health Effects Test Guidelines, OPPTS 870.2500, Acute Eye Irritation, EPA 712-C-98-195. Available: [http://www.epa.gov.opptsfrs/OPPTS\\_Harmonized/870\\_Health\\_Effects\\_Test\\_Guidelines/Drafts/870-2400.pdf](http://www.epa.gov.opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Drafts/870-2400.pdf).

UN. 2003. Globally Harmonized System of Classification and Labelling of Chemicals (GHS). (ST/SG/AC.10/30). United Nations, New York and Geneva. Available: <http://www.unecce.org/trans/danger/publi/ghs/officialtext.html>.

Dated: March 15, 2004.

## Kenneth Olden,

Director, National Institute of Environmental Health Sciences.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Funding Opportunity Title: Notice of Funding Availability (NOFA) for the Drug-Addiction-Treatment-Act-of-2000 (DATA) (Title XXXV of the Children's Health Act of 2000) Physician Clinical Support System (Short Title: DATA Physician Clinical Support System)

Announcement Type: Initial.

Funding Opportunity Number: TI 04-005.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Due Date for Applications: June 2, 2004.

(Note: Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due August 1, 2004.)

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), announces the availability of FY 2004 funds for the Drug-Addiction-Treatment-Act-of-2000 (DATA) (Title XXXV of the Children's Health Act of 2000) Physician Clinical Support System (Short Title: DATA Physician Clinical Support System). A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: <http://www.grants.gov>.

For complete instructions, potential applicants must obtain a copy of SAMHSA's standard Infrastructure Grants Program Announcement (INF-04 PA (MOD)), and the PHS 5161-1 (Rev.

7/00) application form before preparing and submitting an application. The INF-04 PA (MOD) describes the general program design and provides instructions for applying for all SAMHSA Infrastructure Grants, including the DATA Physician Clinical Support System. SAMHSA's Infrastructure Grants provide funds to increase the capacity of mental health and/or substance abuse service systems to support effective programs and services. Additional instructions and specific requirements for this funding opportunity are described below.

#### I. Funding Opportunity Description

*Authority:* Section 509 of the Public Health Service Act, as amended and subject to the availability of funds.

The purpose of the DATA Physician Clinical Support System cooperative agreement is to develop a coordinated, clinical support program for physicians who are treating addicted patients with buprenorphine products. The target participants for the clinical support system are primary care physicians, pain specialists, psychiatrists and other non-addiction medical practitioners, who are often reluctant to treat addicted patients and are not as familiar with opioid addiction treatment as addictions specialists are. However, addictions specialists will also be encouraged to participate in the DATA Physician Clinical Support System or to serve as mentors.

Applicants are expected to develop a coherent, well-designed program to assist physicians in developing the skills and confidence to treat addicted patients, thereby reducing resistance and barriers to the availability of treatment. By enlisting the assistance of professional medical groups and other organizations, the grantee will offer physicians the information and consultation they need to provide safe and effective buprenorphine treatment.

Applicants must select activities from the following list of infrastructure development activities, as appropriate to their proposed project:

- Provider/network development (*i.e.*, physician clinical support network/system development to inform physicians of established standards of care);
- Organizational/structural change (*e.g.*, to increase access to and efficiency of services);
- Development of the physician workforce;
- Development of interagency coordination mechanisms (between national professional medical organizations or related organizations); and

- Quality improvement efforts.

Applicants must demonstrate the ability to provide consultative services, telephone consultation, on-site training, observation of practice, and peer mentoring to physicians treating patients for opioid addiction. Applicants may propose other activities, such as conducting a limited number of regional meetings or online Web conferences to improve physician workforce performance.

Physician support activities must focus on the following content areas:

- Assessment and diagnosis using the *Diagnostic and Statistical Manual, Fourth Edition, Text Revision (DSM-IV-TR)*;
- Induction, maintenance, and detoxification protocols;
- Strategies to avoid complications and treat them;
- Ancillary medications;
- Recommended visit and monitoring schedules;
- Special psychosocial strategies on motivating patients, setting limits, or implementing contingency plans;
- Medically supervised withdrawal and opioid withdrawal scales;
- Referrals to counseling, other ancillary services, or self-help groups;
- Diagnosis and treatment of psychiatric co-morbidities or co-occurring disorders, including, but not limited to, chronic pain, poly-substance abuse, hepatitis C and HIV disease;
- HIV screening, counseling, testing, and referrals;
- Referrals to higher levels of care;
- Special needs patients, including pregnant, adolescent, and elderly patients; and
- Important patient recovery indicators.

*Background:* The need for medication-assisted treatment for opioid addiction greatly exceeds the Nation's treatment capacity. To address this long-standing problem, the Drug Addiction Treatment Act of 2000 (DATA) was enacted to allow trained, qualified physicians to prescribe specifically approved narcotic medications for the treatment of opioid addiction in their offices or settings outside traditional opioid treatment programs.

The Food and Drug Administration approved two brand-name medications containing buprenorphine for this treatment in 2002. SAMHSA was assigned responsibility to assist with training physicians under DATA. Approximately 4,000 physicians have been trained and 2,500 are approved to prescribe these medications. Yet, the stigma of addiction tends to discourage primary care physicians from obtaining training and treating this population.

Also, the lack of physician experience, concerns over practical issues, and limited understanding of the appropriate role of medication in opioid treatment all appear to be factors in the slow adoption of this form of treatment intervention by the medical profession.

## II. Award Information

1. *Estimated Funding Available/ Number of Awards:* It is expected that up to \$500,000 will be available to fund one award in FY 2004. The maximum allowable award for this Category I—Small Infrastructure Grant Award is \$500,000 in total costs (direct and indirect) per year for up to 3 years. Proposed budgets cannot exceed the allowable amount in any year of the proposed project. The actual amount available for the award may vary, depending on unanticipated program requirements and the number and quality of the applications received. Annual continuations will depend on the availability of funds, grantee progress in meeting program goals and objectives, and timely submission of required data and reports.

2. *Funding Instrument:* Cooperative Agreement.

*Roles and Responsibilities of Federal Staff:* Federal staff members will:

- Participate in the selection of physician and non-physician members of a steering committee that will plan, implement, and coordinate the support system;
- Assist the grantee to plan for health care infrastructure development;
- Help to establish measures of cost-effectiveness;
- Assist the grantee to meet quality improvement goals;
- Ensure that consultation services are provided to the regions of the country with the greatest need;
- Provide advice and assistance in developing the evaluation;
- Foster learning and collaboration and coordinate with other SAMHSA-funded activities, such as the DATA waiver program, the DATA evaluation, and Addiction Technology Transfer Centers (ATTCs); and
- Provide some of the on-site training, observation of practice, consultative services, peer mentoring, and other services envisioned under this program.

The Government Project Officer (GPO) will serve as a voting member of the steering committee, but will not chair the committee.

*Roles and Responsibilities of Grantee:* The grantee will be required to establish a steering committee to oversee the development of the Physician Clinical Support System and determine the direction of the project. Steering

committee membership will be comprised of representatives from participating national professional medical organizations authorized by law to conduct DATA training, other stakeholders, and the GPO. The steering committee will be required to meet, at a minimum, yearly and confer by conference call quarterly to develop strategies to bring the project to fruition. The grantee is also expected to implement and evaluate the program in full cooperation with SAMSHA staff members and contractors. The grantee also will be required to:

- Comply with all aspects of the terms and conditions of the cooperative agreement (to be issued with the award);
- Participate in selecting a chairperson for the steering committee;
- Provide required reports, including those related to the Government Performance and Results Act (GPRA); and
- Respond to requests for information or data related to the program.

## III. Eligibility Information

1. *Eligible Applicants:* Eligibility is limited to the national professional medical organizations authorized by DATA to carry out training. These are the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, and the American Psychiatric Association. While any of these entities may apply individually, SAMHSA encourages a consortium comprised of all or several eligible organizations to apply. If a consortium is formed for this purpose, a single organization in the consortium must be the legal applicant, the recipient of the award, and the entity legally responsible for satisfying the grant requirements. If a consortium submits an application, the application must include a written agreement outlining the roles and responsibilities of each participating national professional medical organization. This agreement must be signed by an authorized official of each member of the consortium and attached to the application as a new Appendix 4, "Roles and Responsibilities of Participating National Professional Medical Organizations." These eligibility criteria supersede the criteria specified in Section III-1 of the INF-04 PA (MOD).

2. *Cost Sharing or Matching* is not required.

3. *Other:* Applicants must also meet certain application formatting and submission requirements or the application will be screened out and

will not be reviewed. These requirements are described in Section IV-2 below, as well as in the INF-04 PA (MOD).

## IV. Application and Submission Information

1. *Address to Request Application Package:* Complete application kits may be obtained from the National Clearinghouse for Alcohol and Drug Information (NCADI) at 1-800-729-6686. When requesting an application kit for this program, the applicant must specify the funding opportunity title (DATA Physician Clinical Support System) and the funding opportunity number (TI 04-005). All information necessary to apply, including where to submit applications and application deadline instructions, is included in the application kit. The PHS 5161-1 application form is also available electronically via SAMHSA's World Wide Web Home Page: <http://www.samhsa.gov/> (Click on 'Grant Opportunities') and the INF-04 PA (MOD) is available electronically at <http://www.samhsa.gov/grants/2004/standard/Infrastructure/index.asp>.

When submitting an application, be sure to type "TI 04-005, DATA Physician Clinical Support System" in Item Number 10 on the face page of the application form. Also, SAMHSA applicants are required to provide a DUNS Number on the face page of the application. To obtain a DUNS Number, access the Dun and Bradstreet Web site at <http://www.dunandbradstreet.com> or call 1-866-705-5711.

2. *Content and Form of Application Submission:* Information including required documents, required application components, and application formatting requirements is available in the INF-04 PA (MOD) in Section IV-2.

### *Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications*

SAMHSA's goal is to review all applications submitted for grant funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. If you do not adhere to these requirements, your application will be screened out and returned to you without review.

- Use the PHS 5161-1 application.
- Applications must be received by the application deadline. Applications received after this date must have a proof of mailing date from the carrier dated at least 1 week prior to the due

date. Private metered postmarks are not acceptable as proof of timely mailing. Applications not received by the application deadline or not postmarked at least 1 week prior to the application deadline will not be reviewed.

Information provided must be sufficient for review.

Text must be legible.

- Type size in the Project Narrative cannot exceed an average of 15 characters per inch, as measured on the physical page. (Type size in charts, tables, graphs, and footnotes will not be considered in determining compliance.)

- Text in the Project Narrative cannot exceed 6 lines per vertical inch.

Paper must be white paper and 8.5 inches by 11.0 inches in size.

To ensure equity among applications, the amount of space allowed for the Project Narrative cannot be exceeded.

- Applications would meet this requirement by using all margins (left, right, top, bottom) of at least one inch each, and adhering to the page limit for the Project Narrative stated in the INF-04 PA (MOD).

- Should an application not conform to these margin or page limits, SAMHSA will use the following method to determine compliance: The total area of the Project Narrative (excluding margins, but including charts, tables, graphs and footnotes) cannot exceed 58.5 square inches multiplied by the page limit. This number represents the full page less margins, multiplied by the total number of allowed pages.

- Space will be measured on the physical page. Space left blank within the Project Narrative (excluding margins) is considered part of the Project Narrative, in determining compliance.

The page limit for Appendices stated in the INF-04 PA (MOD) cannot be exceeded.

To facilitate review of your application, follow these additional guidelines. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, the information provided in your application must be sufficient for review. Following these guidelines will help ensure your application is complete, and will help reviewers to consider your application.

The 10 application components required for SAMHSA applications should be included. These are:

- Face Page (Standard Form 424, which is in PHS 5161-1)
- Abstract
- Table of Contents
- Budget Form (Standard Form 424A, which is in PHS 5161-1)

- Project Narrative and Supporting Documentation

- Appendices

- Assurances (Standard Form 424B, which is in PHS 5161-1)

- Certifications (a form in PHS 5161-1)

- Disclosure of Lobbying Activities (Standard Form LLL, which is in PHS 5161-1)

- Checklist (a form in PHS 5161-1)

Applications should comply with the following requirements:

- Provisions relating to confidentiality, participant protection and the protection of human subjects, as indicated in the INF-04 PA (MOD).

- Budgetary limitations as indicated in Sections I, II, and IV-5 of the INF-04 PA (MOD).

- Documentation of nonprofit status as required in the PHS 5161-1.

Pages should be typed single-spaced with one column per page.

Pages should not have printing on both sides.

Please use black ink, and number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

Send the original application and two copies to the mailing address in the funding announcement. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use heavy or lightweight paper, or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD-ROMs.

### 3. *Submission Dates and Times:*

Applications must be received by June 2, 2004. You will be notified by postal mail that your application has been received. Additional submission information is available in the INF-04 PA (MOD) in Section IV-3.

4. *Intergovernmental Review:* Because the DATA Physician Clinical Support System program is national in scope, applicants are not required to comply with the requirements of Executive Order 12372 or the Public Health System Impact Statement (PHSIS) as detailed in Section IV-4 of the INF-04 PA (MOD).

5. *Funding Restrictions:* Information concerning funding restrictions is available in the INF-04 PA (MOD) in

Section IV-5. Funds for the DATA Physician Clinical Support System program may not be used for the following activities allowed in the INF-04-PA (MOD) in Section I-2:

- Needs assessment;
- Strategic planning;
- Financing/coordination of funding streams;
- Policy development to support needed service improvements (e.g., rate-setting activities, establishment of standards of care, development/revision of credentialing, licensure, or accreditation requirements);
- Performance measurement development; or
- Data infrastructure/MIS development.

In addition, the grantee may not use funds for training physicians to qualify for the DATA waiver. SAMHSA already has adequate mechanisms in place to subsidize the 8-hour training that is required for some candidates to meet DATA qualification requirements.

## V. Application Review Information

1. *Evaluation Criteria:* Applications will be reviewed against the Evaluation Criteria and requirements for the Project Narrative specified in the INF-04 PA (MOD). The following information describes the exceptions or limitations to the INF-04 PA (MOD) and provides special requirements that pertain only to the DATA Physician Clinical Support System program. Applicants for the DATA Physician Clinical Support System program are required to discuss the following requirements in their applications, in addition to the requirements specified in the INF-04 PA (MOD):

1.1 In "Section A: Statement of Need":

a. Applicants must address the issues/needs of the target population. The target population for this program is the population of persons with opioid addiction disorders. The catchment area is the Nation as a whole.

b. Applicants do not have to respond to the fourth bullet, which requires applicants to " \* \* \* show that identified needs are consistent with priorities of the State or county that has primary responsibility for the service delivery system."

1.2 In "Section B: Proposed Approach":

Applicants must describe how stakeholders and other organizations that choose to participate in the proposed project will collaborate with each other in implementing the DATA Physician Clinical Support System.

1.3 Applicants must provide "Roles and Responsibilities of Participating

National Professional Medical Organizations,” as a new Appendix 4 of the application rather than the Letter to the SSA as described in Section IV–2.2 in the INF–04 PA (MOD).

1.4 Applicants do not have to include Appendix 5, Copy of State or County Strategic Plan, as specified in the INF–04 PA (MOD) in their applications.

1.5 Performance Measurement: All SAMHSA grantees are required to collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results Act (GPRA). The DATA Physician Clinical Support System grantee will be required to report on the following:

- Number of consultation events, training events, technical assistance events or contacts;
- Number of physicians participating in each event;
- Percentage of physicians satisfied with educational and support services offered; and
- Percentage of physicians who report that consultation or training events resulted in appropriate practice change(s).

Applicants must document their ability to collect and report on these measures in “Section D: Evaluation and Data.” The grantee will be required to use the relevant data collection instruments approved by OMB for collecting customer satisfaction data, e.g., the CSAT Baseline Meeting Satisfaction Survey, the CSAT Follow-up Meeting Satisfaction Survey, the CSAT Baseline Training Satisfaction Survey, or the CSAT Follow-up Training Satisfaction Survey. These instruments are available at <http://www.csat-gpra.samhsa.gov/knowledge.cfm>. Hard copies of the instruments are available in the application kits distributed by SAMHSA’s National Clearinghouse for Alcohol and Drug Information (NCADI). Training and technical assistance on data collection and entry will be provided by CSAT.

2. *Review and Selection Process:* Information about the review and selection process is available in the INF–04 PA (MOD) in Section V–2.

#### VI. Award Administration Information

Award administration information, including award notices, administrative and national policy requirements, and reporting requirements are available in the INF–04 PA (MOD) in Section VI. SAMHSA’s standard terms and conditions are available at [http://www.samhsa.gov/grants/2004/useful\\_info.asp](http://www.samhsa.gov/grants/2004/useful_info.asp).

#### VII. Agency Contact for Additional Information

For questions concerning program issues, contact: Raymond Hylton, RN, MSN, SAMHSA/Center for Substance Abuse Treatment, DPT, 5600 Fishers Lane, Rockwall II, Suite 618, Rockville, MD 20857; 301–443–6502; e-mail: [rhylton@samhsa.gov](mailto:rhylton@samhsa.gov).

For questions on grants management issues, contact: Kathleen Sample, SAMHSA/Division of Grants Management, 5600 Fishers Lane, Rockwall II, Suite 630, Rockville, MD 20857; (301) 443–9667; e-mail: [ksample@samhsa.gov](mailto:ksample@samhsa.gov).

#### Daryl Kade,

*Director, Office of Policy, Planning and Budget, Substance Abuse and Mental Health Services Administration.*

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#### DEPARTMENT OF HOMELAND SECURITY

##### Bureau of Citizenship and Immigration Services

##### Agency Information Collection Activities: Proposed Collection; Comment Request

*Action:* Notice of information collection under review: application for issuance or replacement of Northern Mariana Card.

The Department of Homeland Security, Bureau of Citizenship and Immigration Services (CIS), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on January 13, 2004, at 69 FR 1990, allowing for a 60-day public comment period. No comments were received by the CIS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until April 23, 2004. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Homeland Security Desk Officer, 725

17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(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, including the validity of the methodology and assumptions used;

(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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of currently approved collection.

(2) *Title of the Form/Collection:* Application for Issuance or Replacement of Northern Mariana Card.

(3) *Agency Form Number, if any, and the Applicable Component of the Department of Homeland Security Sponsoring the Collection:* Form I–777, Program and Regulation Development, Citizenship and Immigration Services.

(4) *Affected Public who will be Asked or Required to Respond, as well as a Brief Abstract: Primary:* Individuals or households. This information collection is used by applicants to apply for a Northern Mariana identification card if they received United States citizenship pursuant to Public Law 94–241 (Covenant to Establish a Commonwealth of the Northern Mariana Island).

(5) *An Estimate of the Total Number of Respondents and the Amount of Time Estimated for an Average Respondent to Respond:* 100 responses at 30 minutes (.50 hours) per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 50 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Regulations and Forms