

Dated: March 15, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Infrastructure Development Initiatives Related to Oral Disease Prevention and Oral Health Promotion

Announcement Type: New.

Funding Opportunity Number: PA 04135.

Catalog of Federal Domestic Assistance Number: 93.283.

Key Dates:

Letter of Intent Deadline: April 12, 2004.

Application Deadline: May 6, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under section 317(k)(2) of the Public Health Service Act, [42 U.S.C. section 247b(k)(2)], as amended.

Purpose: The purpose of the program is to develop initiatives related to oral disease prevention and related chronic disease and health promotion capacity; and, to coordinate the dissemination of comprehensive oral disease prevention information and health promotion programmatic expertise among state and local agencies, and public and private sector organizations in the United States. The purpose of this program includes conducting projects that promote the development of leadership and infrastructure to establish sustainable oral health programs at the state level, promote progress on the action steps identified in "A National Call to Action to Promote Oral Health" (See section "VIII. Other Information" of this announcement for Internet links to all cited publications), advance underutilized, evidence-based oral disease and oral injury prevention efforts, develop and promote policies to address oral disease prevention for high-risk adults. This program addresses the "Healthy People 2010" focus area(s) of Oral Health and seeks to enhance the effectiveness of state health department programs to prevent and control oral diseases in accordance with "Oral Health in America: A Report of the Surgeon General" and "A National Call to Action to Promote Oral Health".

Measurable outcomes of the program will be in alignment with one (or more)

of the following performance goal(s) for the Centers for Disease Control and Prevention (CDC): Improve the lives of racial and ethnic populations who suffer disproportionately from the burden of disease and disability, and develop tools and strategies that will enable the nation to eliminate these health disparities by 2010.

Activities:

Awardee activities for this program are as follows:

- Collaborate with and provide technical assistance to state health agencies and state coalitions to develop and expand activities to improve and strengthen state oral health infrastructure. Performance will be measured by documentation of an annual summary of requests for collaboration and technical assistance and responses to such requests; provision of technical assistance for at least five states or all states requesting assistance if fewer than five requests are received during a project year; for each request receiving assistance; the nature of assistance provided and results (products, skills, etc.).

- Develop and implement a plan to promote progress on the action steps identified in "A National Call to Action to Promote Oral Health," in particular to change perceptions of oral health and its relation to general health, to overcome barriers by replicating effective preventive programs and proven efforts, and to increase collaborations on the national and state levels related to population-based preventive measures. Performance will be measured by documentation including adherence to the proposed timeline for plan development; identification of participants in the plan development and review process; progress on implementation of the plan; rationale for and descriptions of deviations from plan; and measurable outputs of promotional efforts.

- Initiate and conduct projects to increase utilization of evidence-based, population-based, oral disease and oral injury prevention measures (e.g., water fluoridation and school-based or school-linked dental sealant programs). Performance will be measured by documentation of adherence to the proposed timeline; measurable outputs; and methods of dissemination that demonstrate the extent the intended audience has been reached.

- Coordinate activities with other relevant state or national agencies and organizations to facilitate the development, implementation, and evaluation of oral disease prevention and health promotion programs, either as stand-alone programs or integrated

within broader chronic disease prevention and health promotion programs. Performance will be measured by documentation of adherence to the proposed timeline; identification of participants in the collaborative activities; progress on implementation of the planned activities; rationale for and descriptions of deviations from timeline; and measurable outputs of collaborative associations.

- Develop and promote policies to address oral disease prevention for high-risk adults, such as those with diabetes, users of tobacco products, or those with xerostomia. Performance will be measured by documentation of identification of sample policies or policy approaches and dissemination efforts.

- Monitor and evaluate program performance under this agreement and share program performance information through appropriate channels (conferences, reports, publications, etc.), including an annual meeting with CDC staff. Performance will be measured by documentation that evaluation has been completed; evaluation capacity and activities have become institutionalized; program accomplishments have been collected and shared with stakeholders; and evaluation results are used to improve program performance.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Participate in planning, implementing, and evaluating strategies and programs.

- Assist in the analysis and interpretation of the evaluation phase of projects or programs.

- Provide programmatic consultation and guidance in support of the program.

- Provide continuing updates on scientific and operational developments in the areas of oral disease prevention and control, related risk factors, and impacts on other chronic health conditions.

- Assist in the planning and implementation of linkages with State agencies.

- Assist in the technological and methodological dissemination of successful prevention and intervention models among targeted groups such as State health agencies and national health professional organizations.

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this

program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: \$150,000.

Approximate Number of Awards: One.

Approximate Average Award: \$150,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: \$170,000 (This ceiling is for the first 12-month budget period.)

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: 5 years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible applicants: Applications may be submitted by public and private nonprofit organizations and by governments and their agencies, such as:

- Public and private nonprofit organizations with a national reach.
- Faith-based organizations with a national reach.
- Federally recognized Indian tribal governments.
- Indian tribes.
- Indian tribal organizations.
- State and local governments or their

Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

- Political subdivisions of States (in consultation with States).

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching: Matching funds are not required for this program.

III.3. Other: If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

Because the program is planned to be national in scope, with outcomes useful to all state health agencies, applicants should have the capability to provide assistance to all states. Document your capability by providing evidence of past nationwide programs and activities designed to promote development of leadership and infrastructure to establish or enhance sustainable oral health programs at the state and local levels.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address to Request Application Package: To apply for this funding opportunity use application form PHS 5161. Application forms and instructions are available on the CDC web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>. If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at: 770-488-2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission:

Letter of Intent (LOI): Your LOI must be written in the following format:

- Maximum number of pages: Two.
- Font size: 12-point un-reduced.
- Single spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Written in plain language, avoid jargon. Your LOI must contain the following information:

- Announcement number, statement of the intent to apply, and the amount of funds to be requested.

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 35. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point un-reduced.

- Double spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

1. Executive Summary

Provide a clear and concise summary of the need for a national oral health program, proposed goals, major objectives and activities required for achievement of program goals and amount of federal funding requested for budget year one of this cooperative agreement. Include proof of non-profit status.

2. Needs Assessment and Capacity

Describe the documented need for the proposed activities, current activities that provide relevant experience and expertise to perform the proposed activities, and collaborative relationships with other agencies and organizations that will be involved in the proposed activities.

3. Five-Year Plan

Describe realistic five-year goals and measurable, time-phased objectives for each proposed project; the major activities to achieve each objective; plans for collaboration with partners, including the CDC; and the evaluation process that will be used to determine effectiveness and initiate modifications as needed.

4. Year One Operational and Evaluation Plan

Provide specific, measurable, and time-phased year one objectives for each proposed project, the specific activities proposed to achieve the year one objectives, and a projected timetable for completion that displays dates for the accomplishment of tasks and identifies responsible parties. For each year one objective, specify how achievement will be measured and documented.

5. Management and Staffing Plan

Describe how the program will be effectively managed. Include the following:

- a. Management structure including the lines of authority and plans for fiscal control.
- b. The staff positions responsible for implementation of the program.
- c. Qualifications and experience of the designated staff.

6. Budget and Justification

Provide a detailed budget request and line item justification that is consistent with the purpose of the program and the proposed objectives and activities.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes: Curriculum Vitae, Resumes, Organizational Charts, and Letters of Support.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711.

For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgo/funding/pubcomm.htm>.

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

IV.3. Submission Dates and Times: LOI Deadline Date: April 12, 2004.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: May 6, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be

given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770-488-2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications: Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: <http://www.whitehouse.gov/omb/grants/spoc.html>.

IV.5. Funding restrictions: Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds may be used to support personnel and to purchase supplies and services directly related to program activities and consistent with the scope of the cooperative agreement.
- While the purchase of equipment is discouraged, it will be considered for approval if justified on the basis of being essential to the program and not available from any other source.
- Funds provided under this cooperative agreement are not to be used to conduct research.
- Funds may not be used for the purchase or lease of land or buildings, construction of facilities, renovation of existing space, or the delivery of clinical and therapeutic services, personal health services, medications, rehabilitation or other costs associated with screening or treatment for oral diseases.

- If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

- Awards will not allow reimbursement of pre-award costs.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

IV.6. Other Submission Requirements:

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to: Scott M. Presson, Project Officer, NCCDPHP/Division of Oral Health, Centers for Disease Control and Prevention, 4770 Buford Hwy, MS F-10, Atlanta, GA 30341, Telephone Number: 770-488-6056, Fax: 770-488-6080, E-mail address: skp4@cdc.gov.

Application Submission Address: Submit the original and two copies of your application by mail or express delivery service to: Technical Information Management—PA# 04135, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria: You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Five-Year Plan (35 points)

- The applicant clearly identifies realistic five-year goals, measurable, time-phased objectives for each proposed project, and the major activities to achieve the objectives; provides a realistic plan for collaboration with partners including CDC in the projects; and describes an evaluation process that is likely to provide meaningful information about measures of progress and the achievement of objectives.

2. Year One Plan (30 points)

- The year one objectives are specific, measurable and time-phased; tasks and

activities are logical; the projected timetable is reasonable and realistic; and measures of progress and achievement are described.

3. Needs Assessment and Capacity (20 points)

- The applicant demonstrates experience and expertise to perform the proposed activities and provides evidence of collaborative relationships with other agencies and organizations relevant to the achievement of proposed goals and objectives.

4. Management and Staffing Plan (15 points)

- The applicant demonstrates management structure and staff positions with clear lines of authority and plans for fiscal control, and that designated staff have appropriate qualification and experience.

5. Budget and Justification (Not Scored)

- The applicant provides a detailed budget and justification consistent with the proposed program objectives and activities.

V.2. Review and Selection Process: Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center for Chronic Disease Prevention and Health Promotion. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "Review Criteria" section above.

V.3. Anticipated Announcement and Award Dates: Announcement of the award is anticipated on or around September 1, 2004.

VI. Award Administration Information

VI.1. Award Notices: Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

V.2. Administrative and National Policy Requirements: 45 CFR Part 74

and Part 92. For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-7 Executive Order 12372.
- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-14 Accounting System Requirements.
- AR-15 Proof of Non-Profit Status.

Additional information on these requirements can be found on the CDC web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

VI.3. Reporting Requirements: You must provide CDC with an original, plus two copies of the following reports:

- Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
 - Current Budget Period Activities Objectives.
 - Current Budget Period Financial Progress.
 - New Budget Period Program Proposed Activity Objectives.
 - Budget.
 - Additional Requested Information.
 - Measures of Effectiveness.
- Financial status report and annual progress report, no more than 90 days after the end of the budget period.
- Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Scott M. Presson, Project Officer, NCCDPHP/Division of Oral Health, Centers for Disease Control and Prevention, 4770 Buford Hwy, MS F-10, Atlanta, GA 30341, Telephone: 770-488-6056, E-mail: skp4@cdc.gov.

For financial, grants management, or budget assistance, contact: Lakasa Wyatt, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA

30341, Telephone: 770-488-2728, E-mail: lgw5@cdc.gov.

VIII. Other Information

For additional information see: A National Call to Action to Promote Oral Health: <http://www.nidcr.nih.gov/sgr/CallToAction.asp>.

Oral Health in America: A Report of the Surgeon General: <http://www.nidcr.nih.gov/sgr/oralhealth.asp>. Healthy People 2010: <http://www.healthypeople.gov/document/>.

Dated: March 15, 2004.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0328]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of January 8, 2004 (69 FR 1299), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0453. The approval expires on February 28, 2007.