

Dated: March 6, 2003.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03050]

National Organization Strategies for Prevention, Early Detection or Survivorship of Cancer in Underserved Populations; Notice of Availability of Funds

Application Deadline: April 28, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) of the Public Health Service Act, (42 U.S.C. 241 (a)). The Catalog of Federal Domestic Assistance Number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year 2003 funds for cooperative agreements for National Organization Strategies for the Prevention, Early Detection or Survivorship of Cancer in Underserved Populations. This program addresses the "Healthy People 2010" focus area of Cancer.

This program will assist national organizations in the development of health programs and cancer prevention and control infrastructure enhancement to deliver cancer education and awareness activities for individuals who may be underserved, uninsured or underinsured, at risk, or of racial/ethnic minorities. In addition, CDC will assist established national programs in developing and disseminating current national, state, and community-based comprehensive information on cancer prevention, early detection, or survivorship. This project includes facilitating the exchange of expertise and coordination of program efforts related to cancer prevention and control among a variety of public and private not-for-profit agencies at the national level.

Programs must address the "Healthy People 2010" focus area of Cancer. Proposals will be accepted that address the following priorities: strategies for the prevention, early detection, or

survivorship of cancers among underserved populations. Measurable outcomes of the program will be in alignment with the following goal of the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP): To increase early detection, prevention, or survivorship of cancers of the breast, cervix, colon, prostate, skin, and ovary for underserved and priority populations. This includes, but is not limited to African Americans, American Indian/Alaska Natives, Asian Americans, Hispanics, older Americans, rural and urban Americans, etc.

C. Eligible Applicants

Applications may be submitted by national, public and private nonprofit and faith-based organizations, that have the capacity and ability to conduct nationwide programs and activities related to promoting health education, awareness, and information dissemination.

National organizations that serve as an umbrella organization for their constituents (regional or local chapters or memberships) provide a unique opportunity to address barriers to prevention and screening, improve quality of care, and improve the priority population's access to cancer prevention, early detection, or survivorship programs.

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.

D. Funding

Availability of Funds

Approximately \$2,000,000 is available in FY 2003, to fund approximately six to eight awards. It is expected that the average award will be \$250,000, ranging from \$100,000 to \$350,000. It is expected that the awards will begin on or about August 15, 2003 and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Funds may be used to support personnel, and to purchase supplies and services directly related to program activities and consistent with the scope of this announcement. 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 another source. Funds provided under this announcement 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 cancer.

Applicants are encouraged to maximize the public health benefit from use of CDC funding within the approved budget line items to enhance the grantee's ability to achieve stated goals and objectives. As part of increased flexibility efforts, recipients have the ability to redirect up to 25 percent of the total approved budget or \$250,000, whichever is less, to achieve stated goals and objectives within the scope of the award except from categories that require prior approval such as contracts, change in scope, and change in key personnel. A list of required prior approval actions will be included in the Notice of Grant Award.

Recipient Financial Participation

Recipient financial participation is not required for this program.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2, CDC activities.

1. Recipient Activities

a. Develop and disseminate programs or strategies designed to improve cancer prevention, early detection, or survivorship among the priority population. Performance will be measured by the extent to which the applicant identifies strategies to reach the priority population, either directly or through their constituency.

b. Develop and carry out strategies to improve knowledge, attitudes, and behaviors regarding cancer prevention, early detection, or survivorship practices among the priority populations. Performance will be measured by the methods identified to ultimately reach the priority population either directly or through their constituency.

c. Establish specific, measurable, and realistic short-term (one year) and long-term (five year) program objectives at national, state, and/or local levels consistent with the purpose of this

program announcement for the accomplishment of program activities. Performance will be measured based upon the submission of realistic, time-phased, and achievable goals and objectives.

d. Identify and select appropriate staff, describe organizational structure, staff experience and background, identify training needs or plan, job descriptions, and curricula vitae for both proposed and current staff. Performance will be measured by the extent the program has demonstrated or put in place program infrastructure including staff and other resources to accomplish the goals and objectives of the program.

e. Establish relationships with CDC-funded state health departments, American Indian/Alaska Native organizations, U.S. territories, the District of Columbia, and/or other organizations implementing cancer education and awareness activities or programs regarding cancer prevention, early detection or survivorship. Performance will be measured based on the extent the program uses coalitions and partnerships in developing and implementing cancer prevention, early detection, and survivorship activities.

f. Participate in a minimum of two constituency or CDC meetings per year to facilitate the accomplishment of program objectives. Performance will be measured by the extent to which the program participates in or facilitates at least two meetings per year (annual, regional, etc.) to either gain information or to educate constituents in achieving the accomplishment of program goals and objectives.

g. Evaluate achievement of each goal and objective through a well-designed evaluation plan. Effectiveness will be measured based on the development of objective, quantitative measures that will demonstrate the accomplishment of program goals, objectives, and intended outcome.

h. Disseminate intervention information at the national, state, and local levels regarding program achievements and activities. Performance will be measured by the extent the program develops a mechanism for reaching its constituency with intervention information or activities on reaching the priority population.

i. Participate in the dissemination and sharing of pertinent program information with other CDC funded grantees, appropriate agencies and partners. Performance will be measured by the activities undertaken to share information with partners.

2. CDC Activities

a. Collaborate with recipients in the development, implementation, evaluation, and dissemination of programs designed to improve knowledge, attitudes, prevention and screening behaviors, or survivorship of the priority populations.

b. Provide periodic updates about public knowledge, attitudes, and practices regarding prevention, early detection or survivorship of cancer, including up-to-date scientific information.

c. Collaborate with recipients to develop meeting agendas including identifying speakers/presenters.

d. Collaborate with recipients in the development of publications, manuals, modules, etc. that relate to the purpose of this program announcement.

e. Facilitate the exchange of program information, technical assistance, and the development of partnerships between recipients funded under this announcement and community organizations, health departments, and other partners.

F. Content

Letter of Intent (LOI)

A letter of intent (LOI) is requested for this announcement. The Program Announcement title and number must appear in the LOI. The narrative should be no more than two, double-spaced pages, printed on one side, with one-inch margins, and un-reduced font. The LOI should include the following information:

1. Selected cancer(s) and priority population(s).
2. Proposed constituency.
3. Proposed outcomes.

Your letter of intent will be used to enable CDC to determine the level of interest in this announcement and to assist in planning the objective review.

Applications

The application should consist of the elements outlined below. The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The application should be no more than 30 pages, double-spaced, printed on one side, with one-inch margins and 12-point font, including PHS forms and budget justification. Applicants should also submit appendices (including curriculum vitae,

job descriptions, organizational charts, and any other supporting documentation), which should not exceed an additional 20 pages.

Please provide the following information:

Executive Summary

The applicant should provide a clear, concise 1–2 page written summary to include:

1. Need for cancer prevention, early detection, or survivorship education and awareness activities among the selected priority area and population.

2. Identification of major activities proposed to develop or implement cancer education and awareness activities.

3. Requested amount of funding.

4. Statement of capability to conduct the proposed activities as identified for the priority population.

Background and Need

1. Describe the priority population as it relates to the purpose of this program announcement, the cancer disease burden of the selected cancer within the priority population, and barriers or gaps in cancer prevention, early detection and survivorship efforts.

2. Describe the applicant's history and experience with program activities or any services provided to the priority population, and the rationale for use of previously conducted or newly developed innovative strategies to enhance the delivery of health messages, services, or programs regarding the prevention, early detection, or survival of cancer—especially cancers of the breast, cervix, colon, prostate, ovary, or skin.

Goals and Objectives

1. **Objectives:** Identify specific, realistic, and time-phased, measurable, short-term (one year) and long-term (five year) objectives consistent with the intent of this program announcement.

2. **Activities:** Clearly identify the specific activities/strategies that will be undertaken to achieve each of the proposed short-term objectives during the budget period.

3. **Milestone Chart:** Submit a milestone-to-completion chart consistent with the time frame of the project period.

Project Management

1. Describe the organization's structure and function, size, national membership substructure, activities on a regional, state, or local level, and methods of routine communication with members.

2. Describe each current or proposed staff position for this program by job

title, function, general duties, and activities with which that position will be involved. Include the level of effort and allocation of time for each project activity by staff position.

Collaborative Activities

Describe past and proposed collaborative working partnerships with providers, community groups, or others who serve the priority population and have established linkages in the priority population.

Program Evaluation Plan

Identify methods for measuring progress toward attaining program goals and objectives and monitoring activities consistent with this program announcement. The evaluation plan should include quantitative assessment mechanisms; the outcome expected; the minimum information to be collected and the system(s) for reporting the information.

Budget and Justification

Provide a detailed line item budget and narrative justification of all operating expenses consistent with the proposed objectives and planned activities. Be precise about program purpose of each budget item and itemize calculations when appropriate.

Participation in CDC sponsored training, workshops, or meetings is essential to the effective implementation of cancer prevention, early detection, or survivorship programs. Travel funds should be budgeted for the following meetings:

Two persons to Atlanta, Georgia to attend the National Cancer Prevention and Control Conference (three days.)

Three to five persons to Atlanta, Georgia to report program implementation progress (reverse site visit) and for consultation and technical assistance. (two days, one trip per year.)

Up to two additional two-person trips to Atlanta, or other destinations to attend or assist with national workgroups, task forces, or committees (one to three days.)

G. Submission and Deadline

Letter of Intent (LOI) Submission

On or before April 11, 2003, submit the LOI to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Submit the signed original and two copies of PHS 5161-1 (OMB Number 0920-0428). Forms are available 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) at: (770) 488-2700. Application forms can be mailed to you.

Submission Date, Time, and Address

The application must be received by 4 p.m. Eastern Time April 28, 2003. Submit the application to: Technical Information Management-PA 03050, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd, Room 3000, Atlanta, GA 30341-4146.

CDC Acknowledgement of Application Receipt

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

Deadline

Letters of intent and applications shall be considered as meeting the deadline if they are received before 4 PM Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received 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, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various goals and objectives identified in response to this announcement. Measures of effectiveness must relate to the performance goal stated in section "B. Purpose" of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and shall be an element of evaluation.

An independent review group appointed by CDC will evaluate each application against the following criteria:

Evaluation Criteria (100 Points Total)

1. Goals and Objectives (30 Points)

The extent to which applicant's plan for achieving the proposed activities appears realistic and feasible and relates to the programmatic requirements and purposes of this program announcement including, the degree to which short-term (one year) and long-term (five year) objectives are specific, time-phased, measurable, realistic, and related to identified needs.

2. Project Management (25 Points)

The degree to which proposed staffing, organizational structure, staff experience and background, training needs or plan, job descriptions and curricula vitae for both proposed and current staff indicate past experience in carrying out similar programs, and the ability to carry out the purposes of the current program.

3. Evaluation Plan (20 Points)

The extent to which the proposed evaluation plan addresses progress toward meeting goals and objectives, assesses impact, and appears to be reasonable and feasible.

4. Collaborative Activities (15 Points)

The extent to which applicant describes clear and complete plans to develop relationships or conduct activities between the program and other organizations, agencies, or other partners that will relate to the program and provide for complementary or supplementary interactions.

5. Background and Need (10 Points)

The extent to which the applicant describes the cancer burden and specific needs related to the purpose of this program announcement.

6. Budget and Justification (Not Scored)

The extent to which the budget is reasonable and consistent with the purpose and activities of the program.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of: 1. 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:

- a. Current Budget Period Activities Objectives.
- b. Current Budget Period Financial Progress.
- c. New Budget Period Program Proposed Activity Objectives.

- d. Detailed Line-Item Budget and Justification.
 - e. Additional Requested Information.
 - 2. Financial status report, no more than 90 days after the end of the budget period.
 - 3. Final financial and performance reports, no more than 90 days after the end of the project period.
- Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 of the program announcement as posted on the CDC Web site.

- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status

Executive Order 12372 does not apply to this program.

J. Where to Obtain Additional Information

For this and other CDC announcements, the necessary applications, and associated forms can be found at the CDC Internet address: <http://www.cdc.gov>.

Click on "Funding" then "Grants and Cooperative Agreements".

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd, Atlanta, GA 30341-4146, Telephone: (770)488-2700.

For business management and budget assistance, contact: Glynnis Taylor, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: (770)488-2752, e-mail address: GLD1@CDC.GOV.

For program technical assistance, contact: Amy Harris, MPA, Office of Program and Policy Information, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., Atlanta, Georgia 30341-3717, Telephone: (770)488-4226, e-mail: ABHarris@CDC.GOV.

Dated: March 5, 2003.

Sandra R. Manning,

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

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DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Food and Drug Administration

[Docket No. 03N-0079]

Agency Information Collection Activities; Proposed Collection; Comment Request; Consumer and Producer Surveys on Economic Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on proposed voluntary surveys of consumers and producers in order to help FDA comply with Executive Order 12866, the Regulatory Flexibility Act (RFA), and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

DATES: Submit written or electronic comments on the collection of information by May 12, 2003.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal

agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity, of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Consumer and Producer Surveys on Economic Issues (OMB Control Number 0910-0478)—Extension

Under section 903(d)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research relating to regulated articles and to collect information relating to responsibilities of the agency. Executive Order 12866, RFA, and SBREFA direct Federal agencies to conduct regulatory impact analysis, and to consider flexible regulatory approaches. In order to perform the mandatory analysis it is often necessary to survey regulated producers to determine existing practices and the changes in those practices likely under various policy options, both consumers and manufacturers to explore attitudes towards policy proposals, and industry experts to solicit expert opinion. FDA is seeking OMB clearance to conduct future surveys to implement Executive Order 12866, RFA, and SBREFA. Participation in the surveys will be voluntary. This request covers regulated