

The extent to which the applicant builds in the capacity for mid-course correction(s) based on those evaluations.

#### 5. Budget (Not scored)

The extent to which the budget is reasonable in the amount(s) requested, justified by the application content, and consistent with the intentions of this announcement.

#### H. Other Requirements

Technical Reporting Requirements  
Provide CDC with original plus two copies of:

1. An annual progress report
2. A financial status report, no more than 90 days after the end of the budget period; and
3. A final financial status and performance report, no more than 90 days after the end of the project period.

Send all reports to: Sharron Orum, Grants Management Specialist, Procurement and Grants Office, Grants Management Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application package.

- AR-7 .... Executive Order 12372 Review.
- AR-8 .... Public Health System Reporting Requirements.
- AR-9 .... Paperwork Reduction Act Requirements.
- AR-10 .. Smoke-Free Workplace Requirements.
- AR-11 .. Healthy People 2000.
- AR-12 .. Lobbying Restrictions.
- AR-15 .. Proof of Non-Profit Status.
- AR-20 .. Conference Activities within Grants/Cooperative Agreement.

#### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act (42 U.S.C. 301 and 317(k)(2)), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

#### J. Where to Obtain Additional Information

Please refer to Program Announcement Number 99029 when requesting information. To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sharron Orum, Grants

Management Specialist, Procurement and Grants Office, Grants Management Branch Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341, Telephone: (770) 488-2716, Email address: spo2@cdc.gov.

See also the CDC home page on the Internet: <http://www.cdc.gov>

For program technical assistance, contact: Deborah Rogers Mercy, Centers for Disease Control and Prevention (CDC), Office of Managed Care/OPPE, Room 2035, 1600 Clifton Road, M/S D33, Atlanta, GA 30333, Telephone: (404) 639-4943, Email address: dem2@cdc.gov.

Dated: April 5, 1999.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 99-8882 Filed 4-8-99; 8:45 am]

BILLING CODE 4163-18-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Disease Control and Prevention

[Program Announcement 99108]

#### Cooperative Agreement for Promoting Investigator-Initiated Prevention Research in Managed Care; Notice of Availability of Funds

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) Epidemiology Program Office, Division of Prevention Research and Analytic Methods in cooperation with the Office of Prevention Research, announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for investigator-initiated prevention research in managed care settings. Despite spending significantly more money per capita on health than any other country in the world, recommended and effective preventive services are not routinely delivered in the United States.

The primary purpose of this program is to fund research designed to increase the utilization of priority preventive services in the United States. Desirable secondary outcomes include: (1) Improvements in surveillance and information systems, (2) furthering the science of performance measurement, (3) novel public-private partnerships for health, and (4) interventions which reduce racial and ethnic disparities in the receipt of priority preventive services.

This program relates to the following priority areas of "Healthy People 2000": Immunization and infectious disease, sexually transmitted diseases, tobacco, heart disease and stroke, cancer, and clinical preventive services.

##### B. Eligible Applicants

Applications are invited from non-profit and for-profit managed care plans and their affiliated research entities and membership organizations.

Applicant Requirements:

1. A principal investigator (PI) who has conducted research in managed care settings, published findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.

2. Demonstrated experience (on the applicant's project team) in conducting, evaluating, and publishing prevention or health services research in peer reviewed journals.

3. Effective and well-defined working relationships within the performing organization and with outside entities to ensure successful implementation of proposed activities.

4. A match between the applicant's proposed theme and research objectives and the program interests described in this notice.

**Note:** Pub. L. 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

##### C. Availability of Funds

Approximately \$750,000 will be available in FY 1999 to award 3-5 projects. Funding will range from approximately \$150,000 to \$250,000 per award. Awards are expected to begin on or about September 1, 1999, for 12-month budget period within a project period of up to two years. Proposals for one year projects are encouraged. Funding estimates may change.

Continuation awards for projects with approved two year project periods will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

##### D. Program Requirements

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

##### Recipient Activities

1. Design and conduct a prevention research project addressing one or more of the following questions:

- a. Evaluating the ability of health plans to monitor the delivery of one or more priority preventive services;
- b. Estimating the delivery of one or more priority preventive services, particularly those not measurable via available administrative data, and assessing the validity of such estimates;
- c. Evaluating health plan structural, environmental, and organizational factors associated with the delivery of one or more priority preventive services;
- d. Evaluating interventions designed to increase the use of one or more priority preventive services.

2. Collect, analyze, interpret, present and publish research project results.

#### **CDC Activities**

- 1. Provide technical assistance, advice and coordination; and assure that CDC guidelines regarding conflict of interest, Institutional Review Boards (IRBs), etc., are followed.
- 2. Assist in the monitoring of field data collection, helping to ensure standardization in methods; and assist in the interpretation and reporting of the collected information.
- 3. Assist by providing advice in the management and technical performance of the investigation.
- 4. Assist in promoting project findings to the scientific community at large.

#### **E. Application Content**

Your application should include:

- 1. A narrative description of the project's focus that justifies the need and presents the scientific basis for the proposed research. This focus should be grounded in the information provided in this program announcement and in applicable sections of "Healthy People 2000."
- 2. A description of the expected outcome(s) and their relevance to reducing morbidity, mortality, disability and economic loss.
- 3. Specific, measurable, time-phased objectives.
- 4. A detailed plan describing the methods by which the objectives will be achieved, including their sequence.
- 5. A comprehensive evaluation plan.
- 6. A description of the principal investigator's role and responsibilities.
- 7. A description of the proposed project staff regardless of funding source. It should include: Title, qualifications, experience, percentage of time which will be devoted to the project, project responsibilities, and the portion of salary which will be paid for under this proposal.
- 8. A description of other activities which are related to, but will not be supported by the grant.
- 9. When applicable, a description of the involvement of other participating

organizations/groups and their relationship to the proposed project. Include a clear statement of roles and commitments including letters of support.

10. A detailed one year budget and, when applicable, a projected second year budget.

An applicant organization has the option of having specific employee salary and fringe benefit figures omitted from copies of the application which will be made available to outside review groups. To exercise this option, the applicant must use asterisks, on the original and five copies of the application, to indicate those individuals for whom salaries and fringe benefits are not shown. Subtotals must still be shown. In addition, the applicant must submit an additional copy of page four of Form PHS-398, completed in full, with salary and fringe amounts shown. This budget page will be reserved for internal staff use only.

#### **F. Submission and Deadline**

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. On or before June 7, 1999 submit the application to: Sharron Orum, Grants Management Specialist, Procurement and Grants Office, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 2920 Brandywine, Room 3000, Atlanta, Georgia 30341, Announcement 99108.

Deadline: Applications shall be considered as meeting the deadline if they are either:

- (a) Received on or before the deadline date; or
- (b) Sent on or before the deadline date and received in time for objective review. (Applicants must request a legibly dated U.S. Postal Service postmark or a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of date and time of mailing.)

*Late Applications:* Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

#### **G. Evaluation Criteria**

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under Eligible Applicants, subtitle, Applicant Requirements (Items 1-4). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration.

Applications that are complete and responsive may be subjected to a preliminary evaluation by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant further review (triage); the CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process. Awards will be made based on priority score ranking by the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP) appointed by CDC, programmatic priorities and needs as determined by a secondary review committee, and the availability of funds.

The first review in the dual review process will be the peer review of all competitive applications by the SEP. Reviewers will comment on the following aspects of the application (significance, approach, innovation, investigators, and environment) in their written critiques in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of program goals. Each of these criteria will be addressed and considered by the reviewers in assigning the overall score, weighing them as appropriate for each application. Note that the application does not have to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

The SEP will also evaluate the appropriateness of the proposed project budget; the adequacy of plans to include racial and ethnic minorities and their subgroups, children and both genders as appropriate to the scientific goals of the research; the provisions for the protection of human subjects; and the safety of the research environment.

1. *Significance:* Does the study address a significant issue or problem affecting the monitoring, delivery, and/or evaluation of priority preventive services? If the aims of this application are achieved how will scientific knowledge be advanced? How will the public's health be advanced?

2. *Approach:* Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Are

there plans to regularly evaluate progress toward the stated objective(s)? Is an appropriate work plan included?

Has the applicant met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

3. *Innovation*: Does the project employ novel concepts, approaches, or methods? Are its aims innovative? Does it challenge existing paradigms? Will it test the efficacy of new methodologies or technologies?

4. *Investigator(s)*: Is the principal investigator an experienced researcher? Have any of the investigators conducted research in the area of proposed study?

5. *Environment*: Will the proposed research setting contribute to the probability of success? Does the proposed study take advantage of any unique features of research setting? Are there any collaborative agreements? Is there evidence of institutional/organizational support? Is there evidence of appropriate interest, commitment, and cooperation among the investigators and other interested parties as evidenced by letters detailing the nature and extent of involvement?

6. *Human Subjects*: Does the application adequately address the requirements of 45 CFR Part 46 for the protection of human subjects?

7. *Biohazards*: Are any hazards procedures proposed which would affect the safety and well-being of the research subjects and/or investigators?

8. *Budget*: Does the proposed budget seem appropriate? Does the proposed study length seem reasonable? Would you propose any modifications?

The secondary review committee, in the course of its review, will consider the following factors:

a. The results of the peer review (SEP).

b. The significance of the proposed activities in relation to the priorities and objectives stated in Healthy People 2000 and this program announcement.

c. National needs.

d. Program balance including currently funded research and organizational considerations.

e. Budgetary considerations.

## H. Other Requirements

Technical Reporting Requirements  
Provide CDC with original plus two copies of:

1. An annual progress report;  
2. A financial status report, no more than 90 days after the end of the budget period; and

3. A final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to: Sharron Orum, Grants Management Specialist, Procurement and Grants Office, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 2920 Brandywine, Room 3000, Atlanta, GA 30341.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application package.

- AR-1 ..... Human Subjects Requirements.
- AR-2 ..... Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR-8 ..... Public Health System Reporting Requirements.
- AR-9 ..... Paperwork Reduction Act Requirements.
- AR-10 .... Smoke-Free Workplace Requirements.
- AR-11 .... Healthy People 2000.
- AR-12 .... Lobbying Restrictions.

## I. Authority and Catalog of Federal Domestic Assistance Number

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## J. Where to Obtain Additional Information

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See also the CDC home page on the Internet: <http://www.cdc.gov>.

For program technical assistance, contact: Betsy L. Thompson, Centers for Disease Control and Prevention (CDC), Epidemiology Program Office, Div. of Prevention Research and Analytic Methods, Rm 1050B, 1600 Clifton Road, M/S D01, Atlanta, GA 30333, Telephone: (404) 639-3806, Email address: bst0@cdc.gov.

Dated: April 5, 1999.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 99-8848 Filed 4-8-99; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-0391]

### International Standard-Setting Activities; Codex Alimentarius Commission; Committee on Nutrition and Foods for Special Dietary Uses; Background Paper to Identify Perspectives and Issues Pertaining to International Guidelines on Vitamin and Mineral Supplements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is asking interested persons to submit comments that will be used by the U.S. delegate to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to prepare a background paper to be considered by the CCNFSDU prior to its considering the appropriateness of establishing guidelines for vitamin and mineral supplements for the purposes of international trade. The background paper will discuss the range of concerns and the differences in rationales on this topic. The United States, which has indicated its opposition to the development of such guidelines, has been asked to participate in the development of this background paper along with other governments. FDA is accepting this request in its role as the agency representing the United States in the CCNFSDU.

**DATES:** Submit written comments by June 8, 1999.

**ADDRESSES:** Submit written comments and recommendations to the Dockets Management Branch (HFA-305), Food