

President from among the members of the Committee. The 17 members were appointed as follows:

(A) Presidential Appointees—Nine members were selected by the President and include three members who are officers or employees of the United States and six members with experience in the field of aging, including providers and consumers of aging services.

(B) House Appointees—Two members were selected by the Speaker of the House of Representatives, after consultation with the Committee on Education and the Workforce and the Committee on Ways and Means of the House of Representatives; and two members were selected by the Minority Leader of the House of Representatives, after consultation with such committees.

(C) Senate Appointees—Two members were selected by the Majority Leader of the Senate, after consultation with members of the Committee on Health, Education, Labor and Pensions and the Special Committee on Aging of the Senate; and two members were selected by the Minority Leader of the Senate, after consultation with members of such committees.

Support services will be provided by the Office of the Executive Director of the White House Conference on Aging. The Secretary may establish such other committees, including technical committees, as may be necessary to assist in the planning, conducting, and reviewing of the Conference. The Committee will notify the Department Committee Management Officer upon establishing any subcommittees and provide all required information, including name, membership, and functions of any such subcommittee(s) and estimated frequency of meetings. Any subcommittee will be composed exclusively of Committee members. The Committee chairperson will appoint the chairperson of any subcommittee. Any subcommittee will comply with the applicable requirements of the Federal Advisory Committee Act.

III. Compensation

Appointed members of any such committee (other than any officers or employees of the Federal Government), while attending conferences or meetings of the committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at a rate to be fixed by the Secretary, but not to exceed the daily equivalent of the maximum rate of pay payable under section 5376 of title 5, United States Code (including travel time). While away from their homes or regular places of business, such members may be

allowed travel expenses, including per diem in lieu of subsistence, as authorized under section 5703 of such title for persons employed intermittently in Federal Government service.

Dated: June 15, 2004.

Ann Y. McGee,

Executive Director, White House Conference on Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Developing and Implementing the Institute for Quality in Laboratory Medicine

Announcement Type: New.

Funding Opportunity Number: 04151.

Catalog of Federal Domestic

Assistance Number: The Catalog of Federal Domestic Assistance number is 93.064.

Key Dates:

Letter of Intent Deadline: July 7, 2004.

Application Deadline: July 22, 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 and implement a series of activities associated with the development of an Institute of Quality in Laboratory Medicine. These activities aim to improve the effectiveness of laboratory testing services while, at the same time, enhancing the quality of laboratory testing services in the United States. These enhancements in testing practices and the quality of laboratory testing services will be related to areas of public health significance such as, for example, detection and prevention of cancer, more timely assessment of human health, testing for genetic conditions, and other diseases of importance to the public's health, and the regulations, *i.e.*, Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) governing laboratory testing.

Measurable outcomes of the program will be in alignment with the following performance goal for the Public Health Practice Program Office (PHPO):

"Assure the public health infrastructure at the Federal, state, and local levels has the capacity to provide essential public health services to the citizens of the nation to respond to bioterrorism, other

infectious disease outbreaks, other public health threats, emergencies and prepare frontline state and local health departments and laboratories to respond to current and emerging public health threats."

This program addresses the "Healthy People 2010" focus area(s): "Access to Quality Health Services" and "Public Health Infrastructure".

Activities

Awardee activities, in collaboration with the CDC and its partners in the Quality Institute Conference, are as follows:

a. Develop plans to establish and evaluate a core set of measures for the quality of laboratory services and assess the feasibility of using this core set of indicators in a variety of laboratory settings.

b. Develop plans for implementing sentinel networks to enhance the value of laboratory practices and evaluate changes in practice over time; including alternative approaches to identified barriers (eg: regulatory barriers)

c. Provide a plan for creating a national report on the quality of laboratory services including strategies that can be used to improve quality assurance activities, recognition of where most testing errors may be occurring, and issues related to near patient testing. The report may include such items as information on the electronic health record, the expanded role of the electronic health record, database interoperability, evidenced based practice, the changing laboratory quality assurance paradigm (pre-analytic, analytic, and post-analytic), models to integrate evidence, optimizing time from research evaluation of a diagnostic test to its clinical utility, current challenges, and long-term challenges. The plan would include suggested partners to provide data for the report, mechanisms to maintain the report as a virtual document, and an outline of the proposed report's content.

d. Manage a process to incorporate and implement an Institute for Quality in Laboratory Medicine, including the logistics of the formation, legal documents, and structure of institute.

e. Lead efforts to improve laboratory quality systems in resource limited laboratories through:

i. Developing, promoting, and distributing laboratory health systems consensus standards, guidelines, and reports that target the needs of resource limited laboratories.

ii. Providing education, training, and mentoring opportunities in quality systems for leaders and quality

assurance managers from resource-limited countries that have responsibilities for laboratory quality systems activities.

Phase 2, Year 2

f. Develop a plan to evaluate the cost effectiveness of interventions and practices to enhance the quality of laboratory services and health care.

g. Assist with integration of information systems, including the implementation of new electronic systems to improve communication between laboratories and care providers, and others in the health care system.

h. Develop a program to assist laboratories in developing, implementing, and evaluating best practices in provision of laboratory services.

Phase III, Year 3

i. Provide leadership in assessing the impact of IQLM on laboratory services and patient safety.

j. Assist with planning a program of health services research for laboratory medicine and workforce training in health services research methods.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. CDC, in collaboration with its partners from the Quality Institute Conference, will provide for this program the following:

a. Provide consultation and technical assistance in the planning, implementation, and evaluation of program activities including an outline of a proposed business plan for IQLM.

b. Serve in an advisory capacity to the awardee in the development of data collection instruments and not otherwise be involved in the collection, use, or ownership of the data.

c. Provide a written summary of up to date scientific information related to the nation's laboratory capacity at the request of the awardee.

d. Provide consultation and technical assistance related to testing and any published reports or other scientific information that would assist recipient in understanding the possible impact of laboratory service quality and patient safety on testing in the US.

e. Provide a written summary of up to date testing information on the use of quality assurance materials, or other information recipient would find useful in developing programs related to testing.

f. Provide current CLIA information and access to experienced senior CLIA staff to assist recipient concerning CLIA regulations and their impact on laboratory testing.

g. Provide information from the CDC sponsored Quality Institute Conference and assist recipient in working with Quality Institute partners and in establishing any expert focus groups from whom strategies and recommendations could be developed, e.g., assistance might be related to helping establish collaborations with world expert scientists who may participate on focus group panels.

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 Fundings: \$200,000.

Approximate Number of Awards: One.

Approximate Average Award: \$200,000 (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: \$200,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Three 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 nonprofit organizations.
- Private nonprofit 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).

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

CDC will accept and review applications with budgets greater than the ceiling of the award range.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Applications from the above referenced entities are being solicited because they represent organizations that have sufficient background, experience, and current knowledge of testing in the nation's clinical laboratories. The organizations already have in place established assessment programs for evaluating laboratory services and practices that can reach laboratories globally; have experience working with one or more of the following groups: medical specialty organizations, laboratory accreditation and standard setting bodies, laboratory professional organizations, who aim to enhance the laboratory infrastructure with regard to testing, practices, guidelines and standards. These organizations are being solicited because they have a variety of established methods for evaluating laboratory practices and services.

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: Five;
- Font size: 12-point unrounded;
- Double 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:

- Purpose;
- Goals and Objectives;
- Methods and Technical Approach;
- Project Management and Staffing;
- Budget;

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

- Maximum number of pages: 25
- If your narrative exceeds the page limit, only the first pages, which are within the page limit, will be reviewed.
- Font size: 12 point unrounded
- 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

- Double spaced

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

- Purpose
- Table of Contents
- Goals and Objectives
- Measures of effectiveness to demonstrate accomplishment of program activities
- Methods and Technical Approach
- Project Management and Staffing
- Evaluation Plan
- Required Resources/ Budget/ timeline

The budget justification will not be considered to be part of the page limit. 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, 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 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/pubcommnt.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: July 7, 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: July 22, 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

Executive Order 12372 does apply to this program. http://12.46.245.173/pls/portal30/SYSTEM.EXE_12372_RPT.show.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

None.

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:

Tracy L. Carter, M.P.H., Laboratory Program Specialist, Centers for Disease Control and Prevention, PHPPD/DLS, MS-G25, 4770 Buford Highway NE., Atlanta, Georgia 30341, Telephone Number: 770-488-2523, Fax: 770-488-8282, E-mail address: tsc1@cdc.gov.

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-PA# 04151, 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. Methods and Technical Approach (30 points)

a. Does the applicant clearly and succinctly describe the steps to be taken in the planning and implementation of the proposed cooperative agreement?

b. Are the methods to be used to carry out the responsibilities of the proposed cooperative agreement feasible and explained in sufficient detail?

2. Project Management and Staffing (30 points)

a. Does the applicant describe a project management and staffing plan, and demonstrate sufficient knowledge, expertise, and other resources required to perform the responsibilities in this project?

b. Does the applicant describe the staff qualifications and time allocations of key personnel to be assigned to this project, facilities and equipment, and other resources available for performance of this project?

3. Goals and Objectives (20 points)

a. Does the applicant clearly describe an understanding of the objectives of this project, the relevance of the proposal to the stated objectives, and any unique characteristics of the populations to be studied?

b. Are the goals and objectives measurable, specific, and achievable?

4. Evaluation Plan (20 points)

Does the applicant describe the schedule for accomplishing the activities to be carried out in this project and methods for evaluating the accomplishments?

5. Budget (reviewed, but not scored)

Is the proposed budget reasonable, clearly justified, and consistent with the intended use of funds?

6. Performance Measures (reviewed, but not scored)

Is the application consistent with the Government Performance and Results Act of 1993 (<http://www.whitehouse.gov/omb/mgmt-gpra/gplaw2m.html>)?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by PHPPPO. 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 "V.1. Criteria" section above.

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.

VI.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-10 Smoke Free Workplace Requirements;
- AR-11 Healthy People 2010;
- AR-12 Lobbying Restrictions,;
- 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 hard copies of the following reports:

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. Budget.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.
2. Financial status report and annual progress 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.

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: Joe Boone, Ph.D., Associate Director for Science, Division of Laboratory Systems, Public Health Practice Program Office, 4770 Buford Hwy., NE., Atlanta, GA 30341-3717, Telephone: (770) 488-8080, fax: (770) 488-8282, e-mail: dboone@cdc.gov.

For financial, grants management, or budget assistance, contact: Sharon Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2748, e-mail: sqr2@cdc.gov.

VIII. Other Information

Web site for information about 2003 Quality Institute and related activities: <http://www.phppo.cdc.gov/mlp/qiconference/>.

Dated: June 16, 2004.

William P. Nichols,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 69 FR 17166-17167, dated April 1, 2004) is amended to reorganize the Division of Health Interview Statistics, National Center for Health Statistics.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functional statement for the *Division of Health Interview Statistics (CS7)* insert the following:

Division of Health Interview Statistics (CS7). The Division of Health Interview Statistics plans and administers