

Dated: April 7, 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

Assessment of Best Practices for Standardized Quality Assurance Activities in Pathology and Laboratory Medicine

Announcement Type: New.

Funding Opportunity Number: 04140.

Catalog of Federal Domestic

Assistance Number: 93.064.

Key Dates:

Letter of Intent Deadline: May 13,
2004.

Application Deadline: June 14, 2004.

Executive Summary: This program will evaluate the effectiveness of standardized approaches to quality assurance in pathology and laboratory medicine, in order to determine approaches that produce measurable and sustainable improvements against established benchmarks. Areas of primary interest are: pre-analytic process, including the test requisition; post-analytic processes, including the test report; implementation of CLIA-waived tests in point of service environments; error identification and reduction; and quality assurance activities in anatomic pathology (autopsies, surgical pathology, cytopathology and/or genetic testing).

I. Funding Opportunity Description

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

Purpose: The purpose of the program is to determine standardized approaches to quality assurance in pathology and laboratory medicine that can be applied in multiple, diverse settings (e.g. community hospitals, academic medical centers, and independent laboratories) that demonstrate measurable and sustainable improvements over time. The program focuses on specific opportunities for error reduction, or process improvement in: pre-analytic processes, including test requisitions; post-analytic processes, including test reports; implementation of CLIA-waived tests in point of service environments, and; anatomic pathology (autopsies, surgical pathology, and cytology and/or

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

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

Activities

Awardee activities for this program are as follows:

- Evaluate quality assurance methods that have been standardized and implemented in multiple, diverse laboratory settings for common laboratory practices.
 - Determine best practices in quality assurance methods for addressing pre-analytic components of laboratory testing, including the test requisition.
 - Determine best practices in quality assurance methods for addressing post-analytic components of laboratory testing, including the test report.
 - Determine best practices in quality assurance methods for addressing implementation of CLIA-waived tests in the point of service test environment.
 - Determine best practices in quality assurance methods in anatomic pathology (autopsy, surgical pathology and/or cytopathology).
 - Provide leadership in assessing the impact of reporting surgical pathology results in a template format.
 - Provide leadership in developing strategies that lead to wider use of proven methods of quality assurance and error reduction.
 - Provide leadership in developing strategies that lead to improved use of CLIA-waived tests.
 - Provide leadership in developing programs that evaluate and improve laboratory practice over a specified time period.
- 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:
- Provide consultation and technical assistance in the planning, implementation, and evaluation of program activities.

- Provide information on numbers and types of laboratories and numbers and types of waived tests.

- Provide consultation and technical assistance related to scientific information on errors in laboratory medicine.

- Provide information on CLIA regulations and their impact on laboratory testing.

- Provide information from the CDC-sponsored Institute for Quality in Laboratory Medicine.

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:
\$100,000.

Approximate Number of Awards:
One.

Approximate Average Award:
\$100,000.

Floor of Award Range: None.

Ceiling of Award Range: \$100,000 (This ceiling is for the first 12-month budget period.).

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: 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.
- Universities.
- Research institutions.
- Community-based organizations.
- Faith-based 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.

Applicants must have experience in the administration and evaluation of standardized quality assurance programs in multiple, diverse laboratory sites (including community hospitals and academic medical centers). This experience is required for an applicant to be able to assess the effectiveness of these quality assurance programs and to determine best practices.

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:
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:

- Description of organization.
- Goals and objectives.
- Methods and Technical Approach.
- Project Management and Staffing (Expertise in standardized processes for quality assurance in laboratory medicine and pathology).

- Budget—total 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: 30. 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.
- 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:

- Applicant's knowledge of and experience with standardized approaches to quality assurance in laboratory medicine and pathology.
- Applicant's knowledge of and experience with quality assurance activities addressing pre-analytic processes (including test requisition), post-analytic processes (including test report), implementation of CLIA-waived tests in point of service environments, error identification and reduction; anatomic pathology and/or genetic testing.

- Applicant's proposal (including plan, methods, objectives, timeline, and staff) to evaluate the effectiveness of standardized approaches to quality assurance activities in pre-analytic processes (including test requisition), post-analytic processes (including test report), implementation of CLIA-waived tests in point of service environments, error identification and reduction; anatomic pathology and/or genetic testing.
- Applicant's proposed performance measures.
- Applicant's proposed budget and budget justification (which will not be counted toward the page limit for the narrative).

Additional information may be included in the application appendices. The appendices will not be counted

toward the narrative page limit. This additional information includes:

- Examples of past work on standardized quality assurance measures in pathology and laboratory medicine.
- Publications in standardized approaches to quality assurance in pathology and laboratory medicine.
- 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/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: May 13, 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: June 14, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4:00 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 carriers 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.

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/pgofunding/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., Centers for Disease Control and Prevention, Division of Laboratory Systems, Public Health Practice Program Office, 4770 Buford Highway NE, MS-G25, Atlanta, GA 30341, Telephone: 770 488-2523, Fax: 770-488-8282, E-mail: 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# 04140, 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. Are the proposed methods feasible?
- b. Will the proposed methods achieve the program goals and objectives?
- c. Do the proposed methods address pre-analytic processes?
- d. Do the proposed methods address post-analytic processes?
- e. Do the proposed methods address implementation of waived tests in the point of service environment?
- f. Do the proposed methods address anatomic pathology?

2. Project Management and Staffing (30 Points)

- a. Does the applicant have the staff, knowledge, and expertise required to perform the responsibilities associated with the project?
- b. Are adequate qualified personnel committed to the project?

3. Program Goals and Objectives (20 Points)

Does the proposal address the program goals and objectives?

4. Evaluation Plan (20 Points)

Does the applicant describe a feasible schedule for accomplishing the activities related to this project and a plan for evaluating their progress?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by PHPPO. 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/pgofunding/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, 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: Toby L. Merlin, MD, Project Officer, Centers for Disease Control and Prevention, Division of Laboratory Systems, Public Health Practice Program Office, 4770 Buford Highway NE, MS-G25, Telephone: 770-488-8256, E-mail: tmerlin@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.

Dated: April 7, 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

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: Reporting and Recordkeeping.

Title: Case Plan Requirement, Section 422, 471(a)(16) and 475(5)(A)(B) of the Social Security Act.

OMB No. 0980-0140.

Description: Under section 471(a) of Title IV-E of the Social Security Act

(the Act), to be eligible to receive Title IV-E Federal financial assistance payments, states must develop a case plan (as defined in section 475(1)) for each child receiving foster care maintenance payments. Section 471(a)(16) states that in order for a state to be eligible for payments under this part, there must be a state plan, approved by the Secretary of the U.S. Department of Health and Human Services, which provides for the development of a case plan for each child receiving foster care assistance under the state plan and provides for a case review system which meets the requirements described in section 475(5)(B) with respect to each child. Through these requirements, states also comply, in part, with Title IV-B, section 422(b)(10) of the Act, which assures certain protections for children in foster care.

Respondents: State Title IV-B and Title IV-E Agencies

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Case Plan	701,461	1	2.60	1,823,799

Estimated Total Annual Burden Hours: 1,823,799.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: grjohnson@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 7, 2004.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegations of Authority

Notice is hereby given that I delegate to the Commissioner, Administration on Developmental Disabilities, with authority to further redelegate, the following authority vested in the Assistant Secretary for Children and Families by the Secretary under Title II, Subtitle D, Parts 2 and 5 of the Help America Vote Act of 2002, Pub. L. 107-252, 116 Stat 1666, 1698-1699, 1702-1703 (2002), 42 U.S.C. 15421-15425, 15461-15462.

(A) Authority to administer the Title II, Subtitle D, Parts 2 and 5 of the Help America Vote Act of 2002, Pub. L. 107-252, 116 Stat 1666, 1698-1699, 1702-

1703 (2002), 42 U.S.C. 15421-15425, 15461-15462, and as amended, hereafter.

(B) Effect on Existing Delegations.

None

(A) Limitations.

1. This delegation shall be exercised under the Department's existing delegation and policy on regulations.

2. This delegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

3. I hereby affirm and ratify any actions taken by the Commissioner, Administration on Developmental Disabilities, or any other Administration on Developmental Disabilities officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation.

4. Any redelegation shall be in writing and prompt notifications must be provided to all affected managers, supervisors, and other personnel.

(D) Effective Date.

This delegation is effective immediately.

Dated: April 2, 2004.

Wade F. Horn,

Assistant Secretary for Children and Families.

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