

Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

VI.3. Reporting

You must provide CDC with an original, plus two copies of the following reports:

1. Interim progress report, (PHS 2590, OMB Number 0925-0001, rev. 5/2001 as posted on the CDC Web site) 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 sent to the Grants Management 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 scientific/research issues, contact: Elsa Villarino, Extramural Project Officer, CDC, National Center for HIV, STD and TB Prevention, Division of Tuberculosis Elimination, 1600 Clifton Road, Mail stop E10, Telephone: 404-639-5340, E-mail: evillarino@cdc.gov.

For questions about peer review, contact: Andrew Vernon, Scientific Review Administrator, CDC, National Center for HIV, STD and TB Prevention, Office of the Director, Associate Director for Science Office, Telephone: 404-639-8000, E-mail: avernon@cdc.gov.

For financial, grants management, or budget assistance, contact: Jesse Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2747, E-mail: jtr4@cdc.gov.

Dated: May 7, 2004.

William P. Nichols,

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

[FR Doc. 04-10856 Filed 5-12-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Accessing and Improving Medical Examiner/Coroner Data

Announcement Type: New.

Funding Opportunity Number: 04123.

Catalog of Federal Domestic

Assistance Number: 93.136.

Key Dates:

Application Deadline: June 17, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under section 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act and section 391 (a) [42 U.S.C. 280b (a)] of the Public Service Health Act, as amended.

Purpose: The purpose of the program is to collaborate with a national organization that represents medical examiners (ME) and/or coroners to develop strategies for improving data collection from ME/coroners. This program addresses the "Healthy People 2010" focus area of Injury and Violence Prevention.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Injury Prevention and Control (NCIPC):

1. Increase the capacity of injury prevention and control programs to address the prevention of injuries and violence.

Activities

Awardee activities for this program are as follows:

- a. Provide expert advice in regard to working with state ME to access ME data.
- b. Serve as a liaison with medical examiners in the National Violent Death Reporting System (NVDRS) funded states. This could include gaining feedback from ME/Coroners regarding the impact of NVDRS on operational activities and costs.
- c. Develop a set of recommendations for gaining input from coroners regarding violent death reporting data. The recommendations would address a process for getting coroners more involved in the organization.

d. Send one medical examiner to the NVDRS implementation training to provide consultation on working with medical examiner offices.

e. Explore the possibility of an additional ME/Coroner set of variables that can be added to the electronic death certificate.

f. Provide at least one educational update per year regarding NVDRS in the potential grantees' organizational newsletter.

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:

a. Provide technical assistance for planning and conducting program activities.

b. Provide educational materials for use with the organization's membership as needed.

c. Provide technical assistance regarding the development of strategies to increase involvement of coroners and medical examiners.

d. Identify and facilitate training opportunities for ME representative for improvement of data collection accuracy.

e. Facilitate discussion with the National Center for Health Statistics (NCHS) for inclusion of additional ME variables into the electronic death certificate for enhanced data collection through NVDRS.

f. Attend relevant organizational functions to provide NVDRS updates.

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: \$55,000.

Approximate Number of Awards: One.

Approximate Average Award: \$55,000.

Floor of Award Range: None.

Ceiling of Award Range: \$55,000.

Your application will not be eligible for review if you request a funding amount greater than the upper threshold. You will be notified that you did not meet the submission requirements.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Two 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 such as:

- Public nonprofit organizations
- Private nonprofit organizations

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other Eligibility Requirements

If your application is incomplete or non-responsive to the requirements listed below, it will not be entered into the review process. You will be notified that your application did not meet the submission requirements. Eligible applicants should be a national professional organization of physician medical examiners, medical death investigators and death investigation system administrators who perform the official duties of the medicolegal investigation of deaths of public interest in the United States. Applicant should provide a brief description of organizational membership.

Data from medical examiners/coroners is one of the major data sources that is vital for the development and implementation of the National Violent Death Reporting System (NVDRS).

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

Application: You must include a project narrative with your application

forms. Your narrative must be submitted in the following format:

- Maximum number of pages: 20
- If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unredacted
- Double spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Held together only by rubber bands or metal clips; not bound in any other way.

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

The narrative should consist of, at a minimum, Background, Goal and Objectives, Methods, Evaluation, Management and Collaboration.

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, etc.

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

For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgo/funding/pubcomm.htm>. If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

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

IV.3. Submission Dates and Times

Application Deadline Date: June 17, 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 carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This program announcement is the definitive guide on submission 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 you did not meet the submission requirements.

CDC will 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 not 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 must be less than 12 months of age.

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

Submit the original and two hard copies of your application by mail, or express delivery service to: Technical Information Management-PA# 04123, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

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 (30 points)
 - a. Is a plan for educating organizational members regarding the NVDRS included?
 - b. Does the applicant describe methods for developing standards for representing concepts and data elements among its members?
2. Goal(s) and Objectives (20 points)
 - a. Are objectives that are measurable, specific, time phased and achievable provided?
3. Background and Need (15 points)
 - a. Does the applicant describe its role regarding access to ME/coroners and the need for a NVDRS?
4. Collaboration (15 points)
 - a. Does the applicant document a process for developing a working relationship between medical examiners and coroners?
5. Management (10 points)
 - a. Does the applicant provide details regarding staff responsible for activities related to the objectives?
 - b. Does the applicant provide an organizational chart of the organization?
6. Evaluation (10 points)
 - a. Is a plan for evaluating and reporting results of proposed activities included?
7. Budget (not scored)
8. Performance Measures (not scored)
 - a. Are measures of effectiveness included and do they address those areas identified under the "Purpose" section above?

V.2. Review and Selection Process

An objective review panel will evaluate your application according to the criteria listed above.

V.3. Anticipated Announcement and Award Dates

September 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applications 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 or 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-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-20 Conference Support
- AR-21 Small, Minority, and Women-Owned Business

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. Detailed Line-Item Budget and Justification.
 - 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.
- This report 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: Leroy Frazier, Jr., Project Officer, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Hwy, NE., MS K60, Atlanta, GA 30341, Telephone: 770-488-1507, E-mail: Lfrazier1@cdc.gov.

For budget assistance, contact: Nancy Pillar, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2721, E-mail: nfp6@cdc.gov.

Dated: May 7, 2004.

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

[FR Doc. 04-10857 Filed 5-12-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N-1852]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug