

Dated: July 9, 2003.
Thomas A. Bartenfeld,
Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.
[FR Doc. 03–17811 Filed 7–14–03; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–94]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404)498–1210. Comments are invited 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)

ways to enhance 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. Send comments to Anne O’Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.
Proposed Project: National Nursing Home Survey (NNHS) 2004–2007 (OMB No. 0920–0353)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).
Section 306 of the Public Health Service Act states that the National Center for Health Statistics “shall collect statistics on health resources * * * [and] utilization of health care, including utilization of * * * services of hospitals, extended care facilities, home health agencies, and other institutions.” The data system responsible for collecting this data is the National Health Care Survey (NHCS). The National Nursing Home Survey (NNHS) is part of the Long-term Care Component of the NHCS. The NNHS was conducted in 1973–74, 1977, 1985, 1995, 1997, and 1999. NNHS data describe a major segment of the long-term care system and are used extensively for health care research, health planning and public policy. NNHS provides data on the

characteristics of nursing homes (e.g. Medicare and Medicaid certification, ownership, membership in chains/HMO/hospital systems), residents (e.g. demographics, functional status, services received, diagnoses, sources of payment), and staff (e.g. staffing mix, turnover, benefits, training, education). The survey provides detailed information on utilization and staffing patterns, and quality of care variables that is needed in order to make accurate assessments of the need for and effects of changes in the provision and financing of long-term care for the elderly. The availability and use of long-term care services are becoming an increasingly important issue as the number of elderly increases and persons with disabilities live longer. Equally as important is ensuring the adequacy and availability of the long-term care workforce. Data from the NNHS have been used by federal agencies, professional organizations, private industry, and the media.
NCHS plans to conduct the next NNHS in March-June 2004 with a repeat of the survey in 2006. This national survey follows a pretest of forms and procedures conducted in June-July 2003. The data collection forms and procedures have been extensively revised from the previous NNHS. The 2004 NNHS will be based on computer-assisted personal interview (CAPI) and computer-assisted telephone interview (CATI) methodologies. The total cost to respondents is their time to complete the survey.

Respondents	No. of respondents	No. of responses per respondent	Average burden per responses (in hrs.)	Total burden (in hrs.)
Facility Questionnaire	3,000	1	20/60	1,000
Nursing Home Staff Questionnaire	3,000	1	2.5	7,500
Current/Discharge Resident Sampling List	3,000	1	20/60	1,000
Current Resident Questionnaire	3,000	8	25/60	10,000
Discharged Resident Questionnaire	3,000	8	25/60	10,000
Direct Care Worker Sampling List	3,000	1	10/60	500
Direct Care Worker Questionnaire	1,800	4	30/60	3,600
Total				33,600

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[FR Doc. 03–17812 Filed 7–14–03; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03188]

Emerging Infections Program—FY03 Competitive Supplement; Notice of Availability of Funds

Application Deadline: August 14, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number
This program is authorized under the Public Health Service Act sections 301(a) [42 U.S.C. 241(a)], 317(k)(1) [42 U.S.C. 247b(k)(1)], and 317(k)(2) [42 U.S.C. 247b(k)(2)], as amended. 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 (FY) 2003 funds for competitive supplemental awards to current grantees of the Emerging Infections Programs (EIPs) cooperative agreements. This program addresses the "Healthy People 2010" priority areas of Immunization and Infectious Diseases.

These supplemental funds are available to assist grantees in developing and conducting projects in the following two areas:

Project A—Surveillance for Severe Acute Respiratory Syndrome (SARS) and Severe Pneumonia Syndrome
Project B—Enhanced surveillance for Viral Hepatitis

The purpose of these supplemental awards is to complement activities associated with the established EIP. EIPs are population-based centers designed to assess the public health impact of emerging infections and to evaluate methods for their prevention and control. This program will assist local, state, and national efforts to conduct surveillance and applied epidemiologic and laboratory research in emerging infectious diseases, and it will enhance bioterrorism preparedness.

Project A—Surveillance for SARS and Severe Pneumonia Syndrome Activities (See Appendix 1 as posted with this announcement on the CDC Web site):

The purposes of Project A are to:

1. Establish flexible, multi-state, long-term population-based surveillance for severe pneumonia syndrome.

2. Facilitate diagnostics for respiratory syndromes posing immediate threats/concerns (e.g., SARS, pandemic influenza, a bioterrorism agent), developing more effective approaches to respiratory disease outbreak investigation.

3. Characterize pneumonia etiologies at selected institutions.

Project B—Viral Hepatitis Activities (See Appendix 2):

The purpose of Project B is to develop model demonstration projects for enhanced surveillance for viral hepatitis. The specific objectives are to:

1. Provide stable estimates of the incidence of and risk factors for viral hepatitis.

2. Improve the completeness of case report data and ascertainment of cases.

3. Standardize the application of the case definition for viral hepatitis.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Infectious Diseases: Protect Americans from infectious diseases.

C. Eligible Applicants

Eligibility for these competitive supplemental awards is limited to the

ten current Emerging Infections Program grantees: California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee.

Eligibility is limited to existing EIP grantees because EIPs are population-based centers designed to work as a network to assess the public health impact of emerging infections and to evaluate methods for their prevention and control. The EIPs are well established with an infrastructure in place to provide the necessary foundation for the development of novel or innovative surveillance activities such as those proposed in this program announcement. EIPs are based in state health departments, each having a variety of established collaborators—local health departments, laboratorians, infection control professionals, healthcare providers, academic institutions, and other EIPs in the network.

Grantees interested in the enhanced surveillance for viral hepatitis must have laws or regulations requiring laboratory reporting of anti-HAV IgM, anti-HBc IgM, HBsAg, and antibody to HCV or HCV RNA (PCR) (HCV reporting preferable, but not required). Eligible health departments should have at least 50 reported cases of acute hepatitis A and 50 reported cases of acute hepatitis B in 2002. ("HAV"—Hepatitis A virus; "HB"—Hepatitis B; "HCV"—Hepatitis C virus; "RNA"—ribonucleic acid; "PCR"—polymerase chain reaction).

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

Project A—Surveillance for SARS and Severe Pneumonia Syndrome

Approximately \$500,000–600,000 is available in FY 2003 for four to five awards. Funding will begin on or about September 1, 2003 and be made for the remainder of the current EIP budget period that expires December 29, 2003. It is expected that individual awards will range from \$100,000–200,000. Information about subsequent funding, for the 12-month period beginning with the next EIP cycle on December 30, 2003, will be provided with EIP continuation funding guidance and will depend on availability of funds.

Project B—Enhanced Surveillance for Viral Hepatitis

Approximately \$300,000–400,000 is available in FY 2003 to fund two to three awards. Funding will begin on or about September 1, 2003 and be made for the remainder of the current EIP budget period that expires December 29, 2003. It is expected that individual awards will range from \$100,000–200,000. Information about subsequent funding, for the 12-month period beginning with the next EIP cycle on December 30, 2003, will be provided with EIP continuation funding guidance and will depend on availability of funds.

Recipient Financial Participation

Matching funds are 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 listed in 1. Recipient Activities, and CDC will be responsible for the activities listed in 2. CDC Activities.

1. Recipient Activities

Project A: Surveillance for SARS and Severe Pneumonia Syndrome

This multi-state surveillance activity will consist of three tiered activities, which should be integrated closely with related projects currently being conducted by the EIPs:

- a. Establish a flexible, multi-state, long-term population-based surveillance for severe pneumonia syndrome. As a first phase of this activity, surveillance for health care workers with hospitalized pneumonia should be established before the 2003 influenza season.

- (1) Characterize the rate of severe pneumonia and seasonal trends.

- (2) Describe demographic and epidemiologic characteristics of patients with severe pneumonia.

- (3) Characterize clinical features of severe pneumonia hospitalizations.

- b. Facilitate diagnostics for respiratory syndromes posing immediate threats/concerns (e.g., SARS, pandemic influenza, a bioterrorism agent).

- (1) When SARS-associated coronavirus (SARS-CoV) diagnostics become available to state laboratories: Detect SARS-CoV positive patients (including those who don't have a known epidemiologic link).

- (2) Characterize the rate of SARS-CoV positivity among severe pneumonia cases.

- (3) Expand facilitated diagnostic testing to other agents of concern as they arise and diagnostics become available.

c. Characterize pneumonia etiologies at selected institutions

(1) Identify causes of unexplained pneumonia.

(2) Refine and simplify pneumonia diagnostics to develop a "toolkit" appropriate for state health departments.

(3) Store a well-characterized set of specimens from people with severe respiratory illness for diagnostic testing/retrospective discovery of new pathogens.

Project B: Viral Hepatitis

a. Acute Hepatitis A and B.

(1) Establish laboratory-based surveillance for acute hepatitis A and B.

(2) Follow-up reports of laboratory markers of acute hepatitis A and B infection (anti-HAV IgM, anti-HBc IgM and/or HBsAg) to determine case status.

(3) Investigate cases of acute hepatitis A and B, and collect data on clinical manifestations, laboratory findings, and risk factors. Investigations may include provider and patient interview, and medical record review.

(4) Explore the feasibility of collecting serologic specimens on acute hepatitis A and B cases.

b. Acute Hepatitis C.

(1) Increase the sensitivity and specificity of case reporting (activities depend on local mechanism for reporting).

(2) Explore the feasibility of laboratory-based reporting for acute hepatitis C, including linking liver enzyme test results with laboratory markers for hepatitis C infection (antibody to HCV, and HCV RNA (PCR)).

c. Chronic Hepatitis B and C (optional activity in first year).

(1) Develop an unduplicated database of laboratory reports of markers of chronic hepatitis B and C infection (antibody to HCV, HBsAg).

(2) Develop a prioritized algorithm for follow-up of laboratory reports of markers of chronic hepatitis B and C infection. Contact prioritized cases of chronic hepatitis B and C for counseling and preventive services.

2. CDC Activities (for both projects).

a. Provide consultation and scientific and technical assistance as needed in general operations of the studies and in designing and conducting individual projects.

b. Assist in developing collaborative relationships and facilitate multi-site collaboration as needed to support the successful completion of the project.

c. Participate in analysis and interpretation of data from the project.

d. As needed, assist in monitoring and evaluating scientific and operational

accomplishments of the project and progress in achieving the purpose and overall goals of the program.

e. If a proposed project involves research with human subjects and CDC scientists will be co-investigators in that research, assist in the development of a research protocol for IRB review by all institutions participating in the research project. The CDC IRB will review and approve the project initially and on, at least, an annual basis until the research project is completed.

F. Application Content

Grantees may apply for supplemental funds for one or both of the two described projects. If applying for both projects (A-SARS and B-Hepatitis), a separate narrative, budget, and budget justification must be submitted for each. On Form 424 and in the budget justification, applicants should provide a 12-month budget that clearly distinguishes the resources requested for "Project A" activities and/or "Project B" activities. The line item budgets for Project A—Surveillance for SARS and Severe Pneumonia and for Project B—Hepatitis, should separate costs by the separate activities as broken out in the Recipient Activities section, above.

For all activities proposed, the requested budget should be for a 12-month period; however funding will be awarded only for items that can be obligated by the end of the current EIP budget period (December 29, 2003).

If requesting funds for any contracts, provide the following information for each proposed contract: (1) Name of proposed contractor; (2) breakdown and justification for estimated costs; (3) description and scope of activities to be performed by contractor; (4) period of performance; and (5) method of contractor selection (*e.g.* sole-source or competitive solicitation).

Use the information in the Program Requirements section to develop the application content. Narratives for each Project (A-SARS or B-Hepatitis), should be no more than five single-spaced pages (not including budget and appendices for items such as curricula vitae, letters of support, and other similar supporting information). Material or information that should be part of the narrative will not be accepted if placed in the appendices. Do NOT solicit or submit letters of support from CDC personnel.

G. Submission and Deadline

Application Forms

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 August 14, 2003. Submit the application to: Technical Information Management—PA#03188, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146.

Applications may not be submitted electronically.

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 p.m. 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 identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goal 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.

An independent review group appointed by CDC will evaluate each application (separately reviewing Project A—SARS and Project B—Hepatitis) against the following criteria:

1. Operational Plan (60 points)

a. Extent to which applicant presents an operational plan for initiating and conducting the project, which clearly and appropriately addresses all Recipient Activities in the application.

b. Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel.

c. Extent to which the plan clearly describes the applicant's technical approach and method for conducting the proposed project and the extent to which the plan is adequate to accomplish the objectives.

d. Extent to which the applicant proposes specific draft study protocols or plans for the development of study protocols that are appropriate for achieving project objectives.

e. Extent to which the applicant describes plans for collaboration with CDC in initiating the project, developing final protocols, and ongoing operation of the project.

f. Extent to which the applicant describes how they will integrate the project(s) with related projects currently being conducted by the EIPs (such as with Unexplained Deaths and Critical Illnesses projects).

g. Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

2. Description of Capacity (15 points)

a. Extent to which applicant demonstrates past experience in conducting activities similar to those proposed and that the new activities will complement current ones. Applicants that are already engaged in the Unexplained Deaths and Critical Illnesses project should demonstrate that Surveillance for SARS and Severe

Pneumonia Syndrome activities will be integrated with ongoing activities.

b. Extent to which applicant provides evidence that this activity can be accomplished while satisfactorily maintaining their ongoing EIP activities.

Extent to which applicant documents accomplishments in conducting active surveillance, applied epidemiologic research, laboratory research, and prevention research.

c. Extent to which applicant identifies key personnel with appropriate experience for the project.

Extent to which applicant includes letters of support from proposed collaborators indicating essential collaborating organizations or individuals and their willingness to participate as proposed. Do not include letters of support from CDC personnel.

3. Background (10 points)

a. Extent to which applicant demonstrates a clear understanding of the subject area, particularly as it relates to the local situation.

b. Extent to which applicant illustrates and justifies the need for the proposed project and demonstrates how the project is consistent with the purpose and objectives of the EIP and of this cooperative agreement supplement.

4. Evaluation (10 points)

Extent to which applicant provides a detailed and adequate plan for evaluating progress toward achieving project process and outcome objectives.

5. Measures of Effectiveness (5 points)

Does the applicant provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant? Are the measures objective/quantitative and do they adequately measure the intended outcome?

6. Budget (not scored)

Extent to which the proposed budget is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds.

7. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

I. Other Requirements

Technical Reporting Requirements

Technical reporting requirements are the same as those under grantee's existing EIP cooperative agreement award.

The following additional requirements are applicable to this

program. For a complete description of each, see Appendix 3 of the program announcement as posted on the CDC Web site.

AR-1 Human Subjects Requirements

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7 Executive Order 12372 Review

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, 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 Road, Atlanta, GA
30341-4146, Telephone: 770-488-2700.

For business management and budget assistance, contact:

Lynn Walling, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, e-mail address: Lwalling@cdc.gov.

For program technical assistance, contact:

Cathy Rebmann, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., NE, Mailstop D-59, Atlanta, GA 30333, Telephone (404) 371-5363, e-mail address: csr9@cdc.gov.

or

Angela Slaughter, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., NE, Mailstop D-59, Atlanta, GA 30333, Telephone (404) 371-5357, e-mail address: aslaughter@cdc.gov.

Dated: July 9, 2003.

Sandra R. Manning,

*Director, Procurement and Grants Office,
Center for Disease Control and Prevention.*

[FR Doc. 03-17805 Filed 7-14-03; 8:45 am]

BILLING CODE 4163-18-P