identified through regional public hearings, written comments from the public, and consultation with HHS staff. All meetings and hearings of the Committee are open to the general public. During each meeting, invited witnesses will address how regulations affect health-related issues. Meeting agendas will also allow some time for public comment. Additional information on each meeting’s agenda and list of participating witnesses will be posted on the Committee’s Web site prior to the meetings (http://www.regform.hhs.gov).

DATES: The second full meeting of the Secretary’s Advisory Committee on Regulatory Reform will be held on Wednesday, May 15, 2002, from 8:00 a.m. to 5:00 p.m. and on Wednesday, May 16, from 8:00 a.m. to 3:00 p.m.

ADDRESSES: The hearing will be held in Ballroom “E” at the Marriott Denver City Center, 1701 California Street, Denver, Colorado, 80202.

FOR FURTHER INFORMATION CONTACT: Christy Schmidt, Executive Coordinator, Secretary’s Advisory Committee on Regulatory Reform, Office of the Assistant Secretary for Planning and Evaluation, 200 Independence Avenue, SW., Room 344G, Washington, DC, 20201, (202) 401–5182.

SUPPLEMENTARY INFORMATION: The Marriott Denver City Center is in compliance with the Americans with Disabilities Act. Anyone planning to attend the meeting who requires special disability-related arrangements such as sign-language interpretation should provide notice of their need by Monday, May 14, 2002. Please make any request to Michael Starkweather—phone: 301–628–3141; fax: 301–628–3101; e-mail: mstarkweather@s-3.com.

On June 8, 2001, HHS Secretary Thompson announced a Department-wide initiative to reduce regulatory burdens in health care, to improve patient care, and to respond to the concerns of health care providers and industry, State and local Governments, and individual Americans who are affected by HHS rules. Common sense approaches and careful balancing of needs can help improve patient care. As part of this initiative, the Department is establishing the Secretary’s Advisory Committee on Regulatory Reform to provide findings and recommendations regarding potential regulatory changes. These changes would enable HHS programs to reduce burdens and costs associated with departmental regulations and paperwork, while at the same time enhancing the effectiveness, efficiency, impact, and access of HHS programs.

William Raub,
Deputy Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[Program Announcement 02148]
Building Regional Coalitions to Promote Patient Safety; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for building regional coalitions to promote patient safety. This program addresses the “Healthy People 2010” focus areas of Access to Quality Health Services and Immunization and Infectious Diseases.

The purpose of the program is to support and develop a regional coalition that combines the efforts of major healthcare stakeholders to promote patient safety by preventing adverse events associated with healthcare, including evaluation of prevention effectiveness and cost effectiveness. Adverse events associated with healthcare to be targeted for prevention include, but are not limited to, healthcare associated infections, including those caused by antimicrobial resistant organisms. The goals of this program are to: (1) Support further development of an existing regional infrastructure to address issues of patient safety in a geographic area encompassing a major metropolitan area; (2) support implementation of interventions on a regional level designed to prevent adverse events associated with healthcare; (3) support interventions that address problems with current systems of healthcare delivery and their role in contributing to adverse events; (4) support the development of an existing region-wide system of surveillance for adverse events associated with healthcare; (5) support the development of a common information platform which can be used to collect electronic information on a regional level; and (6) evaluate the prevention effectiveness and cost effectiveness of regional interventions.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations. Faith-based organizations are eligible to submit an application.

Applicants will need to have access to a coalition that actively engages a broad spectrum of healthcare quality stakeholders, including, but not limited to, healthcare facilities, major insurers, healthcare purchasers, physicians, corporate and civic leaders, organized labor, and State government.

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.

A. Availability of Funds

Approximately $100,000 is available in FY 2002 to fund one award. It is expected that the award will begin on or about September 1, 2002 and will be made for a 12 month budget period within a project period of up to three years. The funding estimate may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Funding Preferences

1. Funding preference will be given to applicants who demonstrate the presence of an existing regional healthcare coalition with documented active engagement of a broad spectrum of healthcare quality stakeholders, including, but not limited to, healthcare facilities, major insurers, healthcare purchasers, physicians, corporate and civic leaders, organized labor, and State government. Applicants should have existing community charters signed by senior executive officers of at least 25 regional healthcare facilities, insurance companies representing at least 50 percent of the privately insured lives in the region, and at least 15 of the 30 largest employers in the region. These charters should specifically outline participatory actions to which the chief executive officers commit.

2. Funding preference will be given to applicants who can demonstrate the existence of a region-wide system of...
surveillance for healthcare-associated infections. The surveillance system should include a method of reporting infections back to individual participating facilities. The method should utilize definitions and methods consistent with CDC’s National Nosocomial Infection Surveillance System (NNIS).

3. Funding preference will be given to regional coalitions that can document prior and ongoing participation of at least 25 healthcare facilities in the geographic region, including the sharing of healthcare-associated infection surveillance data with all other participating institutions.

4. Funding preference will be given to applicants who demonstrate a prior interest in interventions which take a systems-based approach to improving healthcare quality.

5. Funding preference will be given to applicants who have experience in implementing quality improvement techniques adopted from non-healthcare industries to prevent adverse events associated with healthcare including, but not limited to, healthcare associated infections.

6. Funding preference will be given to applicants who have developed a common electronic information platform which has been used to collect electronic medical data from at least 20 healthcare facilities region-wide. The electronic information platform should be compliant with the functional and technical specifications of the National Electronic Disease Surveillance System (NEDSS) information architecture http://www.cdc.gov/neds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2. CDC Activities.

1. Recipient Activities

a. Further develop and implement a regional program to improve healthcare quality and assure patient safety by preventing adverse events associated with healthcare including, but not limited to, healthcare-associated infections.

b. Regional Program: Continue to build and develop the existing regional program designed to reduce healthcare-associated adverse events. Establish active involvement of a broad spectrum of stakeholders in healthcare quality, including healthcare facilities, major insurers, healthcare purchasers, physicians, corporate and civic leaders, organized labor, and State government.

c. Regional Surveillance system: Maintain an established regional system for surveillance of healthcare-associated adverse events, and a method for reporting the data back to individual healthcare facilities.

d. Coordination and networking of regional healthcare information systems: The regional program should have infrastructure in place that allows for electronic information networking and data sharing. Continue to develop the network for the purpose of collecting and sharing information that promotes healthcare quality in the region, including the development and validation of novel strategies for surveillance using electronic data.

e. Development and application of novel intervention strategies: Study novel interventions that address problems in healthcare delivery systems that contribute to adverse events associated with healthcare. Interventions should include strategies adopted from industries other than healthcare.

f. Evaluate prevention effectiveness and cost-effectiveness: Develop methods for evaluating the prevention effectiveness and cost-effectiveness of interventions at both the facility and regional level.

2. CDC Activities

a. Collaborate, as appropriate, with the recipient in all stages of the program, and provide programmatic and technical assistance.

b. Assist in data collection, analysis, and interpretation of data from the project, as requested.

c. Participate in improving program performance through consultation based on information and activities of other projects.

d. Collaborate on appropriate aspects of the program, preventive measures, and program strategies for the prevention of adverse healthcare-associated events, as needed.

e. Assist, as needed, in the reporting and dissemination of research and other results and relevant healthcare quality prevention education and training information, to appropriate Federal, State, and local agencies, health-care providers, the scientific community, and prevention and service organizations with an interest in healthcare quality, and the general public.

f. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Content

Letter of Intent (LOI)

An LOI is optional for this program. The narrative should be no more than three single spaced pages, printed on one side, with one inch margins, and unreduced font. Your letter of intent will be used to enable CDC to determine the level of interest in the program.

Your letter of intent should identify the program announcement number 02148, and should include the following information: (1) name and address of institution, and (2) name, address, telephone number, e-mail address, and fax number of a contact person.

Application

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 25 double-spaced pages, printed on one side, with one-inch margins, and unreduced font, and should include the following information:

1. Provide a line-item budget and narrative justification for all requested costs. Budgets should be consistent with the purpose, objectives and research activities, and include:

   a. Line-item breakdown and justification for all personnel, i.e., name, position title, annual salary, percentage of time and effort, and amount requested.

   b. For each 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, (5) method of contractor selection (e.g., sole source or competitive solicitation), and (6) method of accountability.

   c. A brief five year budget projection should be submitted that clearly separates and distinguishes direct from indirect costs.

   d. A description of any financial and in-kind contributions from nonfederal sources.

   Additionally, include a one page, single spaced, typed abstract. The heading should include the title of the cooperative agreement, project title, organization, name and address, project director, and telephone number. This abstract should include a work plan identifying activities to be developed, activities to be completed, and a time line for completion of these activities.

Economic Development

The regional program should have the ability to conduct surveillance using electronic data.

Electronic Disease Surveillance System (NEDSS) information architecture http://www.cdc.gov/neds.

The recipient should include a method of accountability.
F. Submission and Deadline

Letter of Intent (LOI)

On or before June 10, 2002, submit the letter of intent (original and two copies) to the Grants Management Specialist identified in the “Where to Obtain Additional Information” section of this announcement.

Application

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available at the following Internet address: www.cdc.gov/od/ppo/forminfo.htm, or in the application kit.

On or before July 5, 2002, submit the application to: Technical Information Management-PAO2148, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd., Room 3000, Atlanta, GA 30341–4146.

Deadline: Applications shall be considered as meeting the deadline if they are received on or before the deadline date.

Late Applications: Applications which do not meet the criteria above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Understanding the objectives of the Building Regional Coalitions to Promote Patient Safety Program (5 points)
   a. Demonstration of a clear understanding of the background and objectives of this cooperative agreement program.
   b. Demonstration of a clear understanding of the requirements, responsibilities, problems, constraints, and complexities that may be encountered in establishing and operating the regional coalition.
   c. Demonstration of a clear understanding of the roles and responsibilities of participation in the program.

2. Description of the existing regional coalition (40 points)
   a. Clear description of the regional coalition participants, including the specific role of each and evidence of active participation. (10 points)
   b. Clear description of the region wide system of surveillance for adverse events associated with healthcare, including the methods of reporting data back to individual participating facilities. The applicant should provide documentation of participation of a large proportion of healthcare facilities in the geographic region. (10 points)
   c. Clear description of the common electronic information platform which has been used to collect electronic medical data from healthcare facilities region-wide. (10 points)
   d. Clear description of the degree to which the applicant has exhibited an ability to comply with the NEDSS information technology architecture in the collection of electronic medical data from healthcare facilities participating in the regional coalition. (10 points)

3. Description of Existing Capacity to Actively Engage the Regional Participants in Implementing Activities That Support Patient Safety by Preventing Adverse Events Associated With Healthcare (25 points)
   a. Description of applicants experience and documentation of accomplishments in conducting quality improvement activities.
   b. Description of applicants experience and documentation of accomplishments in conducting surveillance and prevention activity in the areas of healthcare-associated infections and other adverse events.
   c. Demonstration of the applicants interest and expertise in interventions which take a systems based approach to improving healthcare quality.
   d. Demonstrate the applicants experience and expertise in quality improvement techniques adapted from non-healthcare industries.
   e. Demonstration of applicants ability to develop and maintain strong cooperative regional relationships with medical, public health, laboratory, academic, and community organizations that are either public or private.
   f. Demonstration of support from non-applicant participating agencies, institutions, organizations, laboratories, individuals, consultants, etc., mentioned in the operational plan. Applicant should provide (in an appendix) letters of support which clearly indicate each collaborator’s willingness to participate in the activities of the regional coalition.

4. Operational Plan (20 points)
   a. The extent to which the applicants plan for operating and maintaining the regional coalition clearly describes the proposed activities and clearly identifies the roles and responsibilities of all participating individuals, agencies, organizations, and institutions.
   b. Description of the applicants plan for implementing interventions designed to promote patient safety through the prevention of adverse events associated with healthcare, including healthcare-associated infections.
   c. Description of the applicants plan to develop and validate novel strategies for using electronic surveillance data for improving patient safety.
   d. Description of the applicants plan to utilize quality improvement techniques adapted from non-healthcare industries to promote patient safety.
   e. Consistency of the proposed projects with regard to program goals.
   f. Identification of applicant’s key professional personnel to be assigned to the program and to specific projects as well as key professional personnel from other participating or collaborating institutions, agencies, and organizations outside of the applicants agency that will be assigned to activities (provide curriculum vitae for each in an appendix). Clear identification of applicants’ respective roles in the management and operation of the regional coalition.
   g. Description of all support staff and services assigned to the regional coalition.
   h. The degree to which the applicant has met 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 community (or communities) and recognition of mutual benefits.

5. Evaluation (5 points)
   a. Quality of plan for monitoring and evaluating the prevention effectiveness and the cost effectiveness of the interventions.
   b. Quality of plan for monitoring and evaluating progress in achieving the purpose and overall goals of this cooperative agreement program.

6. Measures of Effectiveness (5 points)

The extent to which the applicant provides Measures of Effectiveness that
If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Yolanda Sledge, Grants Management Specialist, Acquisition and Assistance, Team B, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000 Mailstop K–75, Atlanta, GA 30341–4146, Telephone number: 770–488–2787, Fax number: 770–488–2777, E-mail address: yis0@cdc.gov.

For program technical assistance, contact: John Jernigan, M.D., Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Healthcare Quality and Promotion, Executive Park 57, Suite 4109 Mailstop E–68, Telephone number: (404) 498–1257, Fax number: 404–498–1244, E-mail address: Jjernigan@cdc.gov.

Dated: May 1, 2002.

Sandra R. Manning, CGFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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