

FOR FURTHER INFORMATION CONTACT: Tim McGrath, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, rm. 12-41, Rockville, MD 20857, 301-827-1028, email: timothy.mcgrath@fda.hhs.gov; or Camille R. Peake, Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301-827-7168, FAX: 301-827-7101, email: Camille.Peake@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

For more information on the original funding opportunity announcement (FOA) for the FERN Microbiological Laboratories, please refer to the full FOA located at <http://grants.nih.gov/grants/guide/pa-files/PA-09-215.html>. The program is further described in the Catalog of Federal Domestic Assistance under 93.103.

A. Background

This **Federal Register** announcement issued by FDA under the FERN Microbiological Cooperative Agreement Program Grant mechanism (U18) is to solicit applications from existing FERN Microbiology Laboratories to enhance current Cooperative Agreement Program (CAP) capabilities. The FERN cooperative agreements are to enable the analyses of foods and food products in the event that laboratory surge capacity is needed by FERN and FDA for analyses related to microbiological contamination, either through intentional or unintentional means. The supplemental grant funds will enable analyses of human pathogenic bacteria found in animal feed, for samples collected by Federal, State, or local agencies. Numbers of samples and scheduling of samples will be done by the FERN National Program Office (NPO) in coordination with State/local lab authorities.

These supplemental grant funds will also be utilized to enhance animal feed analysis results through the usage of standardized methods, equipment platforms (provided by the grant), analytical worksheets, and electronic reporting. The supplemental funds will also provide training and proficiency testing for each method/platform. Minimal quality management systems will be initiated for each lab, based on existing systems in place in each lab and consultations between the FERN NPO and each lab management group.

Each laboratory shall develop its own consensus decisionmaking, size, and format. Federal agency representatives may be invited to be nonmember liaisons or advisors to the laboratory

and its meetings. Supplemental funds may not be used for Federal employees to travel to or participate in these meetings.

B. Research Objectives

Selected FDA FERN Microbiological Cooperative Agreement Laboratories (CAP labs) will participate in a special Cooperative Agreement program to enhance their ability to handle human pathogenic bacteria in animal feed. This additional program will be compatible with other FERN Cooperative Agreement work that the selected laboratories will be performing. This special program will involve screening and detection studies for selected pathogens (*Listeria*, *Salmonella*, *Escherichia coli* O157:H7 and generic *E. coli*). The isolates will be tested using methods agreed upon in consultation with the Center for Veterinary Medicine's (CVM) Office of Research, most of which are already being used to isolate these organisms from human foods. The selected labs will participate in FERN food defense/food safety assignments. The participation in this cooperative agreement will expand the ability of FERN to screen for potential foodborne pathogens in these feed matrices. In addition, this project will provide CVM with information needed to assess future testing needs.

C. Eligibility Information

These supplemental grant funds are only available to existing grant recipients from State, local, and tribal government FERN laboratories and are authorized by section 312 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) (42 U.S.C. 247b-20). This program is described in the Catalog of Federal Assistance under number 93.448. All projects developed with these funds at State, local, and tribal levels must have national implication or application that can enhance Federal food and feed safety and security programs.

D. Requirements

Laboratories will be selected based on the following criteria:

- If it's an existing FDA FERN Microbiological Cooperative Agreement Laboratory;
- If it has routine microbiological capabilities as demonstrated through established, ongoing State testing programs, preferably those involving animal feed testing;
- If it participates in FERN Food Safety/Food Defense surveillance assignments;

- If it participates in FERN proficiency testing; and
- If it has a geographically balanced distribution of the selected laboratories.

II. Award Information/Funds Available

A. Award Amount

FDA anticipates providing approximately \$50,000 total costs (direct costs only) in support of this supplemental program in fiscal year 2010. It is estimated that up to six microbiological laboratories will be supplemented at the level requested, but not exceeding \$50,000 total costs (direct costs only) for a 1-year minor program expansion.

B. Length of Support

The initial award will be for a 1-year performance period and any additional funding related to this supplement will be dependant on successful performance and fiscal appropriations.

III. Paper Application and Submission Information

To submit an application in response to this supplemental notice, applicants should download the PHS-398 form at <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

Submit the paper application to:
Camille R. Peake, Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301-827-7168; and
Jenny Gabb, Office of Regulatory Affairs (HFC-150), Food and Drug Administration, 5600 Fishers Lane, rm. 12-07, Rockville, MD 20857, 301-827-8299.

Dated: August 24, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for Members of the U.S. Preventive Services Task Force (USPSTF)

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Solicits nominations for new members of USPSTF.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) invites nominations of individuals qualified to serve as members of the U.S. Preventive Services Task Force (USPSTF).

The USPSTF, a standing, independent panel of non-Federal experts that makes evidence-based recommendations to the health care community and the public regarding the provision of clinical preventive services, see 42 U.S.C. 299b–4(a), is composed of members appointed to serve for four-year terms with an option for reappointment. New members are selected each year to replace approximately one fourth of the USPSTF members, *i.e.*, those who are completing their appointments. Individuals nominated but not appointed in previous years, as well as those newly nominated, are considered in the annual selection process.

USPSTF members meet three times a year for two days in the Washington, DC area. Between meetings, member duties include reviewing and preparing comments (off site) on systematic evidence reviews prior to discussing and making recommendations on preventive services, drafting final recommendation documents, and participating in workgroups on specific topics or methods.

A diversity of perspectives is valuable to the work of the USPSTF. To help obtain a diversity of perspectives among nominees, AHRQ particularly encourages nominations of women, members of minority populations, and persons with disabilities. Interested individuals can self nominate. Organizations and individuals may nominate one or more persons qualified for membership on the USPSTF.

Qualification Requirements: The mission of the USPSTF is to review the scientific evidence related to the effectiveness and appropriateness of clinical preventive services for the purpose of developing recommendations for the health care community. Therefore, in order to qualify for the USPSTF, an applicant or nominee MUST demonstrate the following:

1. Knowledge and experience in the critical evaluation of research published in peer reviewed literature and in the methods of evidence review;
2. Understanding and experience in the application of synthesized evidence to clinical decisionmaking and/or policy;
3. Expertise in disease prevention and health promotion;
4. Ability to work collaboratively with peers; and
5. Clinical expertise in the primary health care of children and/or adults, and/or expertise in counseling and behavioral interventions for primary care patients.

Some USPSTF members without primary health care clinical experience

may be selected based on their expertise in methodological issues such as medical decisionmaking, clinical epidemiology, behavioral medicine, health equity, and health economics. For individuals with clinical expertise in primary health care, additional qualifications in one or more of these areas would enhance their candidacy.

Consideration will be given to individuals who are recognized nationally for scientific leadership within their field of expertise. Applicants must have no substantial conflicts of interest, whether financial, professional, or other conflicts, that would impair the scientific integrity of the work of the USPSTF.

DATES: All nominations submitted in writing or electronically, and received by Friday, October 1, 2010, will be considered for appointment to the USPSTF.

Nominated individuals will be selected for the USPSTF on the basis of their qualifications (in particular, those that address the required qualifications, outlined above) and the current expertise needs of the USPSTF. It is anticipated that two or three individuals will be invited to serve on the USPSTF beginning in January, 2011. All individuals will be considered; however, strongest consideration will be given to individuals with demonstrated training and expertise in a specific area such as family medicine, internal medicine, obstetrics/gynecology, pediatrics, nursing, behavioral medicine, health equity or methodology. AHRQ will retain and consider for future vacancies the nominations of those not selected during this cycle.

ADDRESSES: Submit your responses either in writing or electronically to: Gloria Washington, ATTN: USPSTF Nominations, Center for Primary Care, Prevention, and Clinical Partnerships, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, uspstfnominations@AHRQ.hhs.gov.

Nomination Submissions

Nominations may be submitted in writing or electronically, but must include:

(1) The applicant's current curriculum vitae and contact information, including mailing address, e-mail address, and telephone number and

(2) A letter explaining how this individual meets the qualification requirements and how he/she would contribute to the USPSTF. The letter should also attest to the nominee's willingness to serve as a member of the USPSTF.

AHRQ will later ask persons under serious consideration for membership to provide detailed information that will permit evaluation of possible significant conflicts of interest. Such information will concern matters such as financial holdings, consultancies, and research grants or contracts.

Nominee Selection

Appointments to the USPSTF will be made on the basis of qualifications as outlined above (see Qualification Requirements) and the current expertise needs of the USPSTF.

Arrangement for Public Inspection

Nominations and applications are kept on file at the Center for Primary Care, Prevention, and Clinical Partnerships, AHRQ, and are available for review during business hours. AHRQ does not reply to individual nominations, but considers all nominations in selecting members. Information regarded as private and personal, such as a nominee's social security number, home and e-mail addresses, home telephone and fax numbers, or names of family members will not be disclosed to the public. This is in accord with AHRQ confidentiality policies and Department of Health and Human Services regulations (45 CFR 5.67).

FOR FURTHER INFORMATION CONTACT: Gloria Washington at uspstfnominations@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

Under Title IX of the Public Health Service Act, AHRQ is charged with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. 42 U.S.C. 299(b). AHRQ accomplishes these goals through scientific research and promotion of improvements in clinical practice, including clinical prevention of diseases and other health conditions, and improvements in the organization, financing, and delivery of health care services. See 42 U.S.C. 299(b).

The USPSTF is a panel of non-Federal experts that makes independent evidence-based recommendations regarding the provision of clinical preventive services. See 42 U.S.C. 299b–4(a). The USPSTF was first established in 1984 under the auspices of the U.S. Public Health Service. Currently, the USPSTF is convened by the Director of AHRQ, and AHRQ provides ongoing administrative, research and technical support for the USPSTF's operation. The USPSTF is charged with rigorously evaluating the effectiveness and

appropriateness of clinical preventive services and formulating or updating recommendations for primary care clinicians regarding the appropriate provision of preventive services. See 42 U.S.C. 299b-4(a)(1). AHRQ is charged with the dissemination of recommendations. In addition to hard copy materials (that may be obtained from the Publications Clearing house), current USPSTF recommendations and associated evidence reviews are available on the Internet (<http://www.preventiveservices@AHRQ.gov>).

Dated: August 18, 2010.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5051-N]

Medicare Program; Rural Community Hospital Demonstration Program; Solicitation of Additional Participants

AGENCY: Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice.

SUMMARY: This notice announces a solicitation for up to 20 additional eligible hospitals to participate in the Rural Community Hospital Demonstration program for a 5-year period.

DATES: *Application Submission Deadline:* Applications must be received by 5 p.m. on or before October 14, 2010. Only applications that are considered "timely" will be reviewed and considered by the technical panel.

ADDRESSES: The applications should be mailed or sent by an overnight delivery service to the following address: Centers for Medicare & Medicaid Services, ATTN: Sid Mazumdar, Rural Community Hospital Demonstration, Medicare Demonstrations Program Group, Mail Stop C4-17-27, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed information to be received in a timely manner in the event of delivery delays. Because of staffing and resource limitations, and because we require an application containing an original signature, we cannot accept applications by facsimile (Fax) transmission.

FOR FURTHER INFORMATION CONTACT: Sid Mazumdar at (410) 786-6673 or by

e-mail at Siddhartha.mazumdar@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 410A(a) of Public Law 108-173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing cost-based reimbursement for "rural community hospitals" to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals for such services under a cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1) of Public Law 108-173, is a hospital that—

- Has fewer than 51 acute care inpatient beds (excluding beds in a distinct psychiatric or rehabilitation unit of the hospital) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a critical access hospital under section 1820 of the Social Security Act (the Act).

Section 410A(a)(4) of Public Law 108-173 specified that the Secretary was to select for participation from among the applicants no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S. Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We solicited eligible hospitals among these States in 2004 and again in 2008. There are currently 10 hospitals participating in the demonstration.

The demonstration is designed to test the feasibility and advisability of reasonable cost reimbursement for inpatient services to small rural hospitals. The demonstration is aimed at increasing the capability of the selected rural hospitals to meet the needs of their service areas.

Section 410A(a)(5) of Public Law 108-173 required a 5-year demonstration period of participation. The 5-year periods of performance for the hospitals originally selected will end by June 30, 2010. For the hospitals selected in 2008,

the initial period of performance is scheduled to end on September 30, 2010. Section 10313 of the Patient Protection and Affordable Care Act (ACA), (Pub. L. 111-148) mandates an extension and expansion of the Rural Community Hospital demonstration for 5 years. In order for other hospitals to begin participation in this new demonstration for the 5-year extension period, rural community hospitals must be located among the 20 States with the lowest population density—according to the same criteria and data as the original demonstration. These States are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). The statute States that no more than 30 rural community hospitals can participate, and that those hospitals participating in the demonstration program as of the date of the last day of the initial 5-year period will be allowed to continue in the program. Up to 20 additional hospitals will be able to begin participation in the demonstration.

II. Provisions of the Notice

This notice announces the solicitation for up to 20 additional hospitals to participate in the Rural Community Hospital Demonstration Program. Hospitals that enter the demonstration under this solicitation will be able to participate for 5 years.

A. Demonstration Payment Methodology

Hospitals selected for the demonstration will be paid the reasonable costs of providing covered inpatient hospital services, with the exclusion of services furnished in a psychiatric or rehabilitation unit that is a distinct part of the hospital, using the following rules. For discharges occurring—

- In the first cost report period upon the hospital's participation in the demonstration, reasonable costs for covered inpatient services; or
- During the second or subsequent cost reporting period, the lesser of their reasonable costs or a target amount. The target amount in the second cost reporting period is defined as the reasonable costs of providing covered inpatient hospital services in the first cost reporting period, increased by the inpatient prospective payment system update factor (as defined in section 1886(b)(3)(B) of the Act) for that particular cost reporting period. The target amount in subsequent cost