

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5030-N]

Frontier Extended Stay Clinic Demonstration

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

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply for the Frontier Extended Stay Clinic (FESC) demonstration, which is mandated by section 434 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. A FESC is designed to address the needs of seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred to acute care hospitals, or patients who do not need a hospital level of care but need monitoring and observation for limited periods of time.

DATES: Applications will be considered timely if we receive them no later than 5 p.m., Eastern Standard Time (e.s.t), on November 24, 2006.

ADDRESSES: Mail or deliver applications to the following address:

Centers for Medicare & Medicaid Services,

Attention: Sid Mazumdar

Mail Stop: C4-15-27

7500 Security Boulevard

Baltimore, MD 21244

Siddhartha.Mazumdar@cms.hhs.gov

FAX: 410-786-1048

Because of staff and resource limitations, we cannot accept applications by facsimile (FAX) transmission or by e-mail.

FOR FURTHER INFORMATION CONTACT:

Sid Mazumdar at (410) 786-6673. Interested parties can obtain the complete application on the CMS Web site at <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS061689>. Paper copies can be obtained by writing to Sid Mazumdar at the address listed in the "**ADDRESSES**" section of this notice.

SUPPLEMENTARY INFORMATION:

I. Background

We have previously developed alternative provider types designed to make available basic acute care and emergency services in remote geographic areas. In response to Congressional mandates, in 1991 we piloted the Montana Medical Assistance Facility (MAF) Demonstration and in 1993 implemented the Essential Access Community Hospital/Rural Primary Care Hospital (EACH/RPCH) Program. These programs tested the concept of a limited service hospital, including lower required levels of physician and nurse staffing than full service hospitals. In the Balanced Budget Act of 1997,

Congress mandated a nationwide program called "Rural Hospital Flexibility Program", the purpose of which is the provision of needed acute care services by a new type of provider type known as a "critical access hospital" (CAH). CAHs are entities in rural areas that generally provide limited services.

Now under section 434 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) the Congress established "The Frontier Extended Stay Clinic Demonstration Project," to test the feasibility of providing extended stay services to remote frontier areas under Medicare payment and regulations. In remote frontier areas, weather and distance can prevent patients who experience severe injury or illness from obtaining immediate transport to an acute care hospital. In some instances, when patients are unable to be transported, local clinics staffed by physicians or other health professionals may offer observation services until the patient can be transferred or is no longer in need of transport. This type of extended stay service is not currently reimbursed by Medicare, Medicaid, or most third-party payers. For several years, officials in the State of Alaska and several state offices of Rural Health, Primary Care Offices, and Primary Care

Associations have explored the development of a new provider type that would enable reimbursement of these services.

In designing the demonstration, the goal is to allow flexibility for these remote clinics to serve the needs of a range of patients for whom transportation to a full-service acute care hospital is problematic. In addition, this demonstration also attempts to ensure safety in clinics that have neither the institutional experience nor the level of technological sophistication of hospitals. As authorized by statute, we are defining requirements for providers to participate in the Frontier Extended Stay Clinic (FESC) demonstration.

Specifically, section 434(a) of the MMA allows waiver of provisions of the Medicare program as are necessary to conduct the demonstration project, under which a FESC is treated as a provider of items and services under the Medicare program. The FESC must be located in a community which is—(1) at least 75 miles away from the nearest acute care hospital, critical access hospital, or (2) is inaccessible by public road. The distance requirement is in relation to the nearest acute care or critical access hospital, regardless of whether patients are generally transferred to that hospital. In addition, we are

determining mileage as measured in terms of the shortest distance by road.

We believe the FESC should be designed to address the needs of seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred to acute care hospitals, or patients who do not meet CMS inpatient hospital admission criteria and who need monitoring and observation for a limited period of time. We believe that the FESC should provide extended stay services under circumstances when weather and transportation conditions prevent transfer, but apart from such circumstances when a patient's condition warrants hospitalization, he or she should be transported to an acute care hospital.

According to section 434(e) of the MMA, the FESC demonstration will last for three years. Unless reauthorized, at the end of this period, the FESCs will lose their certification as Medicare providers. Moreover, pursuant to section 434(d)(2) of the MMA, the demonstration is to be budget neutral.

II. Provisions of the Notice

A. Eligible Organizations

Potentially qualifying applicants are currently operational primary care clinics, including clinics operated

by the Indian Health Service or tribal authorities. Other clinics may be eligible if they propose plans to adopt the features of a FESC. To be eligible for the Frontier Extended Stay Clinic demonstration, a clinic must be located in a community which is at least 75 miles from the nearest acute care hospital or critical access hospital, or which is inaccessible by public road. Mileage is measured in terms of the shortest distance by road.

B. Conditions of Participation

This notice solicits applications for demonstration projects to enable participating remote clinics to provide services to seriously or critically ill or injured patients who, due to adverse weather conditions, or other reasons, cannot be transferred quickly to an acute care hospital, and to patients who do not meet hospital admission criteria but who need monitoring and observation for a limited period of time.

FESCs may vary as far as their architectural design and original type of clinic. At a minimum, an interested clinic must be able to provide primary care, ambulatory care, and extended stay services, but there are no requirements that an interested clinic be of any particular type. For example, Rural Health Clinics (RHCs) and federally qualified health centers (FQHCs), which are separately certified under

Medicare, are especially appropriate for the FESC model. We will require each such clinic to explain how its staff and equipment will meet the needs of emergency and overnight patients.

Given the wide variety of clinical conditions that a clinic will face, it is vital that each FESC maintain stable, effective transfer relationships with acute care hospitals. All clinics participating in the FESC demonstration will be required to keep all billable items under the demonstration separate from those of the existing outpatient clinic. The FESC portion of a clinic participating in the demonstration will be able to share staff and resources with its non-FESC portion as long as billing for staff and resources is kept distinct during discrete blocks of time. An applicant must also describe its transfer agreements with acute care hospitals.

In addition, we expect all participants in the demonstration to have a physically separate area dedicated to extended stay FESC patients. A more specific listing of the FESC requirements are found in the application package at web address identified above.

C. Evaluation Process and Criteria

If the application meets the basic eligibility requirements and responds to all components of the

application, it will be referred to a technical review panel for evaluation and scoring for an independent review. The comments and evaluations of the panelists will be transcribed into a summary statement that will serve as the basis for award decisions. The evaluations of the panelists will contain numerical ratings based on the rating criteria specified in this section, the ranking of all applications, and a written assessment of each application. In addition, we will conduct a financial analysis of the recommended proposals and evaluate the proposed projects to ensure that they are budget neutral. CMS will make the final selection.

The evaluation criteria and weights are detailed in the complete application package. These criteria will be used to evaluate the applications for the FESC demonstration. Applications will be scored on an absolute basis. The application package, as well as the Medicare Waiver Demonstration Application, are available on the CMS website.

III. Requirements for Submission of Applications

Individual clinics or consortia that represent several clinics may submit applications. Each applicant organization is to submit one application, regardless of the number of proposed demonstration sites. The application is to be coordinated and submitted by an organizational

component that has the authority to determine the financial and clinical service policy of an applicant body. If applicable, variations related to proposed sites should be outlined in the application text or supplemental materials.

Applications should be a maximum of 40 typewritten pages, excluding appendices. The complete application package is at the CMS website at

<http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS061689>. Hard copies can be obtained by calling Sid Mazumdar (410) 786-6673 or by e-mail at Siddhartha.Mazumdar@cms.hhs.gov.

In order to be considered for review by the technical review panel, applicants must complete, sign, date and return the Medicare Waiver Demonstration Applicant Data Sheet found on this web page. The Medicare Waiver Demonstration Application, on the web page, serves as the required outline for submitting information in the application. The required narrative portion is to consist of responses to the questions under "Evaluation Process and Criteria." Queries for the narrative portion of the application may be submitted in writing by mail, fax, or e-mail. (Please see the ADDRESSED section of this notice for necessary information.)

IV. Collection of Information Requirements

This information collection requirement is subject to the Paperwork Reduction Act of 1995 (PRA); however, the collection is currently approved under OMB control number 0938-0880 entitled "Medicare Demonstration Waiver Application" with a current expiration date of July 31, 2006.

Authority: Section 434 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Pub. L. 108-173.

Dated: May 18, 2006

Mark B. McClellan,

Administrator,

Centers for Medicare & Medicaid

Services

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