

## **FRONTIER EXTENDED STAY CLINIC DEMONSTRATION**

### **I. Background**

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 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.

To test the feasibility of providing these services in these remote areas under Medicare payment and regulations, Congress established "The Frontier Extended Stay Clinic Demonstration Project," under section 434 of the Medicare Modernization Act. The law mandates that the project last for 3 years. This request for proposals describes Centers for Medicare & Medicaid Services' (CMS) project guidelines,

conditions of participation, and application instructions for the demonstration.

The law allows waiver of provisions of the Medicare program as are necessary to conduct the demonstration project, under which a Frontier Extended Stay clinic, or FESC, is treated as a provider of items and services under the Medicare program. The FESC must be located in a community which is at least 75 miles away from the nearest acute care hospital or critical access hospital or which is inaccessible by public 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 the Medicare inpatient hospital admission criteria, but who need monitoring and observation for a limited period of time. We believe that the FESC should provide extended stay services under circumstances where weather and transportation conditions prevent transfers, but apart from such circumstances patients whose condition warrants hospitalization should be transferred to an acute care hospital.

CMS has 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 the agency 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 for critical access hospitals, which provide limited services in rural areas.

Section 434 allows clinics, which are currently not licensed to provide inpatient services, to provide services to patients for more extended periods than are entailed in routine physician visits. In designing the program, CMS faces the challenge of allowing 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 due to adverse weather conditions, and of ensuring safety in clinics that have neither the institutional experience nor the level of technological sophistication of hospitals. As authorized by Section 434, we are defining requirements for providers to participate in the FESC Program.

We are soliciting each applicant for the demonstration project to describe its treatment of Medicare patients.

## **II. FESC Model**

### A. Provider Features

The FESC provider model is targeted at clinics located in remote rural areas that currently provide diagnosis and treatment for outpatients, that is, individuals who generally visit the clinic during the day for a brief period for each encounter. Rural health clinics (RHCs) and federally qualified health centers (FQHCs), which are separately certified under Medicare, are especially appropriate for the FESC model, but there is no requirement that a provider seeking to participate in the demonstration be of any particular clinic type, so long as it can provide primary care, ambulatory care, and extended stay services.

An essential goal of the demonstration is 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 the hospital admission level of care but need monitoring and observation for a limited period of time. Examples of patients who could receive limited monitoring and observation services include patients suffering from acute migraines, acute asthma, acute allergic reactions, seizure disorders, exposure to heat or cold; patients who require IV therapy such

as rehydration, chemotherapy or IV antibiotics; and patients with acute alcohol intoxication without comorbidities that would require hospitalization.

FESCs may vary as far as their architectural design and original type of provider. We expect applicants for the demonstration to have a dedicated physically separate area for extended stay FESC patients. CMS will require each such clinic to explain how its staff and equipment will meet the needs of extended stay patients.

All clinics participating in the FESC demonstration will be required to keep all billable items under the demonstration separate from those of its existing outpatient services. The FESC portion of a clinic participating in the demonstration will be able to share staff and resources with its non-FESC portion, so long as billing for staff and resources is kept distinct during discrete blocks of time.

A clinic under the demonstration shall demonstrate a detailed protocol of how it will use its clinics and resources to treat:

- patients with an emergency medical condition who require an extended stay due to weather or other conditions that preclude transport to an acute care hospital; and
- ill or injured patients who receive an extended stay

because a physician (Doctor of Medicine or Doctor of Osteopathy("MD/DO")), nurse practitioner or physician assistant using prudent clinical judgment determines that they do not meet Medicare inpatient hospital admission criteria but do need monitoring and observation, and details how they can be discharged within 48 hours.

Given the wide variety of clinical conditions that a FESC will face, it is vital that each FESC maintain stable, effective transfer relationships with acute care hospitals. In the application, a clinic must describe its transfer agreements with acute care hospitals.

As authorized by section 434 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.

#### B. Medicare Payments for the FESCs

According to section 434(d)(2) of the MMA, this demonstration must be budget neutral. This means that the expected Medicare payments for the care of Medicare patients treated by FESCs under the demonstration may be no more than the Medicare payments for such patients in the absence of the demonstration. Before awards are made, CMS will make calculations based on submitted data to support budget

neutrality calculations. CMS will work with prospective demonstration sites to identify, from historical data, the numbers of Medicare patients expected to be treated by the FESC and the potential savings from avoided medical costs, including air ambulance transfers and acute care hospitalizations. We are asking applicants to estimate their costs and identify payment rates appropriate to ensure budget neutrality. We request that applicants provide this information in accordance with the following Medicare payment methodology.

CMS' payment model for Medicare patients treated in the FESCs incorporates the following features:

- We will not make a FESC payment during the initial four hours of a stay. We believe this policy clearly differentiates between routine office visits and extended stays, thus reducing the number of Medicare payments and enhancing the case for budget neutrality while simplifying the system.
- For stays up to four hours, the FESC will receive the customary Medicare payment for an office visit. In most cases, this will be the Rural Health Clinic or Federally Qualified Health Center payment rate for Medicare.

- The payments for extended stays would be in addition to the customary payments for an office visit.
- We will pay a prospective rate that is the same for each FESC provider.
- We will pay for blocks of time rather than hourly. For example, payments for each stay longer than 4 hours may consist of a single rate for each four-hour period. The rate for each clinic participating in the demonstration will be identical within a state.

Individual applicants should estimate the costs of FESC services to its Medicare patients. That is, the applicant should itemize all costs. In addition, the applicant should project the number of patients and volume of services, justifying these estimates from historical data.

Given this information, applicants should propose an itemized budget with expenses for services that it expects to furnish, the cost per patient for either an hour or a 4-hour block of time, and the number of patients projected. We seek to understand current clinic costs for purposes of establishing payment rates, but we are not planning to adopt cost-based reimbursement of FESC services. We will review these financial data on the basis of overall budget neutrality constraints and comparability with similar services provided

in other settings. As a point of reference, we note that the rate that would be paid under the Medicare Hospital Outpatient Prospective Payment System for observation services in calendar year 2006 is approximately \$500 for the patient's stay.

To make the prospective payment operational, CMS will define a code to distinguish the patient visits authorized by the FESC demonstration. The code will be applied to the bills that the FESC will submit to its fiscal intermediary or carrier. The type of primary care clinic sharing location with the FESC and its customary billing arrangements will determine to which fiscal intermediary or carrier the FESC will submit billing information. Claims will be required to be submitted electronically. In addition, remittances would be required to be received electronically. Current Medicare and Medicaid payment for RHCs, FQHCs, Indian Health Service and tribal providers will not be affected by the FESC payment system. CMS will provide instructions on billing for different types of providers, including Indian Health Service and tribally owned clinics.

In preparing their proposals, applicants should recognize that the demonstration is mandated by statute to be budget neutral. We will perform a formal budget neutrality analysis after preliminary site selection, and are interested in the

applicants' own estimates of how the FESCs may be able to reduce Medicare spending for other services sufficient to offset FESC payments. CMS will identify payment rates in the demonstration terms and conditions at the time of final award.

Applicants should describe how the FESC program would be budget neutral. For example, based on historical data, applicants could note the fraction of FESC patients for whom hospitalizations could be avoided in a year, the hours that these patients were kept at the applicant FESC, and the extent that hospital, physician, and ambulance payments could be avoided by Medicare for these patients.

### **III. FESC Conditions of Participation**

CMS plans to collaborate on certification of FESC providers with the licensure department of each state in which a FESC is awarded a demonstration. At a minimum, Medicare providers are to comply with CMS requirements. In instances where State law is more stringent than CMS requirements, providers must comply with State law. For Indian Health Service or tribally owned clinics, which a state might choose not to license, CMS will apply criteria for certification based on the following principles. Similarly, if a state does not establish the FESC as a licensure category, CMS will use the following principles for certification.

The following are the CMS requirements for participation in the FESC Demonstration program. For ease of reference, we have categorized the requirements as conditions of participation to track the general, traditional requirements for provider certification. These requirements have been compiled in consultation with technical experts on rural health care, with the purpose of allowing flexibility to the FESC while at the same time maximizing patient safety.

A. Condition of Participation: Scope of services

(1) The FESC provides urgently needed care, as long as these services are necessary and reasonable and allowable under the following conditions of participation.

(2) Services for urgently needed care are available in the FESC on an as-needed basis 24 hours a day. Outside regular clinic operating hours, staff are required to be present to provide services whenever a patient is there.

(3) Equipment, supplies, and medications used in treating emergency medical conditions are kept at the FESC and are readily available for treating patients. The items available must include, but not be limited to, the following:

(i) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, inhalation

therapy drugs, antihypertensives, diuretics, and electrolytes and replacement solutions.

(ii) Equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, nebulizers, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

(4) The FESC provides training for staff in the provision of these emergency procedures according to the clinic's policies which are consistent with nationally accepted standards of practice as well as in accordance with applicable Federal, State, and local laws.

(5) Surgeries will not be allowed in the FESC beyond what is allowable in physician offices. Repair of simple and complex lacerations will be allowed. CMS will also not allow general or epidural anesthesia, deep sedation, or planned delivery of newborn babies.

(6) Extended stays of patients for more than 4 hours will be limited to two types of situations:

(i) The patient who meets Medicare criteria for acute hospital admission and cannot be transported to an acute care hospital (as defined in Section 1861(e) of the Social Security Act) because of adverse weather conditions or other

transportation problems such as a delay in air transportation. In such cases, the patient is required to be transferred as soon as possible, once weather conditions permit or transportation is available.

(ii) Prudent clinical judgment determines that a patient does not meet Medicare criteria for acute hospital admission, and the patient needs monitoring and observation and can be treated and safely discharged within 48 hours of arrival at the clinic.

(7) Except in the case of a patient who cannot be transported to an acute care hospital due to adverse weather conditions, extended stay patients must be discharged within 48 hours. Any repeat extended stay within 24 hours will be included as part of the total time of the original admission.

(8) Barring a situation where weather prevents transfer, there can be no more than 4 patients who meet the extended stay definition in the FESC at any time.

B. Condition of Participation: FESC Staff Coverage

(1) An MD/DO, physician assistant, or nurse practitioner must be in charge of every patient's treatment and is responsible for determining that the patient must stay in the clinic at least 4 hours or longer.

(2) At all times, an MD/DO must be on-site or immediately available to the FESC staff by phone or radio or

teleconferencing.

(3) An MD/DO, physician assistant, or nurse practitioner must be immediately available by telephone and on-site at the FESC within 30 minutes of a patient's arrival.

(4) For after-hours situations when a person needing assistance appears at the clinic and no one is present, there must be a notification system (that is, buzzer or alarm or outside telephone) by which the MD/DO, physician assistant, nurse practitioner, or registered nurse who is providing coverage will be immediately available for response by telephone, intercom, or radio and on site within 30 minutes.

(5) Every FESC patient must be assessed by either a registered nurse, physician assistant, nurse practitioner, or an MD/DO within 30 minutes of arrival at the FESC. If the initial assessment was performed by a registered nurse, the FESC patient must be assessed by a physician assistant, nurse practitioner, or MD/DO within 60 minutes of the initial assessment.

(6) Any time there is an extended stay patient in the FESC, a qualified registered nurse, nurse practitioner, physician assistant, or MD/DO must be immediately available for the bedside care of the patient.

(7) In situations when patients are being treated, a Community Health Aide or EMT is able to participate in the

patient's care to the degree provided by and in accordance with State law, but a registered nurse, physician assistant, nurse practitioner, or MD/DO must supervise all care by such individuals and be immediately available for the bedside care of the patient.

(8) The FESC must meet the emergency needs of its patients. The FESC must have written policies and procedures for the appraisal of emergencies, initial treatment, and referral when appropriate. The FESC must ensure that all staff are qualified to carry out their roles and duties as addressed in the FESC's emergency preparedness policies and procedures.

### C. Condition of Participation: Staff and Staff Responsibilities

Staff that furnish services in a FESC must meet the following requirements:

(1) Staff of the FESC are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

(2) The FESC must ensure and maintain documentation that all clinical personnel, for whom licensure is required, have valid and current licenses.

(3) All staff who provide a medical level of care (including at a minimum MD/DOs, physician assistants, and nurse practitioners) must be individually evaluated and

determined qualified to conduct any and all care for which they are granted privileges. Only the FESC governing body may grant privileges.

(4) There must be a doctor of medicine or osteopathy, with training or experience in emergency care, on call and immediately available in person or by telephone or radio contact.

(5) The FESC, in coordination with emergency response systems in the area, must establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hour a day basis to receive emergency calls, and provide information on treatment of emergency patients.

(6) The FESC has a professional health care staff that includes one or more doctors of medicine or osteopathy on staff or on contract and who may or may not be in the community of the FESC but who are available to the FESC for patient care, chart review, and consultation, and one or more physician assistants or nurse practitioners who are in the community.

(7) Any ancillary personnel are supervised by the professional staff (that is, MD/DO, physician assistant, nurse practitioner.)

(8) The staff is sufficient in number and skill mix to provide the services essential to the operation of the FESC.

(9) An MD/DO, nurse practitioner, or physician assistant is available to furnish patient care services. (Available means that the practitioner is located in the community, within a short commute to the clinic.)

(10) A doctor of medicine or osteopathy is present for consultation on patient care issues for which the nonphysician staff seeks input. The MD/DO is on site at the clinic for sufficient periods of time to provide medical direction for a patient-focused and data driven quality assurance program.

(11) The physician assistant or nurse practitioner performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the FESC's policies and within the scope of the State's practice act.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the FESC, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(iii) Ensures adequate staff including registered nurses and other nursing staff are on-site to provide safe and adequate bedside care that meets patient needs when there are one or more FESC patients in the clinic. If the level of care

needed exceeds the training, experience, capability or scope of practice of available staff, the physician assistant or nurse practitioner must be on-site to provide adequate supervision and immediate intervention when needed.

D. Condition of Participation: Compliance with Applicable Federal, State, and Local Laws and Regulations.

The FESC and its staff are in compliance with the following:

(1) The FESC is licensed in accordance with applicable State and local laws and regulations.

(2) The FESC is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

E. Condition of Participation: Agreements

The FESC must effect an agreement with at least one acute care hospital that is of sufficient capacity to support patient needs for--

(1) Patient referral and transfer; and

(2) Ensuring that the FESC has the ability to transfer and transport patients to appropriate hospitals. If the agreements or arrangements are not in writing, the FESC is able to present evidence that patients referred by the FESC are being accepted and treated. Each FESC other than those that are currently Federally Qualified Health Centers shall

have an agreement with respect to credentialing of staff and quality assurance activities with at least--

(i) One acute-care hospital; or

(ii) One other appropriate and qualified entity

identified in the state rural health care plan.

Federally Qualified Health Centers will adhere to current Bureau of Primary Health Care rules, as contained in the document, "Credentialing and Privileging of Health Center Practitioners," dated July 17, 2001.

F. Condition of Participation: FESC Requirements

The following are requirements of the FESC, apart from its capacity for staffing and provision of care:

(1) The FESC must provide dietary services either directly or under contract that ensure nutritious meals to patients, including sanitary processes and methods for storing and preserving food on the premises or in the vicinity.

(2) Medications must be ordered, dispensed, and administered by qualified and licensed staff in a manner that is safe and that minimizes errors, and that is in accordance with state law and nationally accepted principles of practice.

(3) The FESC must adhere to the requirements in the Ambulatory Health Care Occupancy chapters of the National Fire Prevention Association 101 Life Safety Code, 2000 edition. In addition, sprinklers are required for fire safety.

(4) The FESC must develop, implement, evaluate, maintain and document an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. The FESC QAPI program must identify patient safety and quality of care problems and areas for performance improvement, implement corrective or performance improvement actions, and track, monitor and sustain those implemented actions. The self-assessment and performance improvement must be appropriate for the complexity of the FESC's organization and services. The program must focus on maximizing outcomes by improving patient safety, quality of care, and patient satisfaction. The FESC must maintain records of its QAPI activities.

(5) The FESC must have an infection control program that ensures the prevention and control of communicable diseases in accordance with nationally accepted standards of practice.

G. Condition of participation: Physical Plant and Environment.

(1) The FESC is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(2) The FESC must have appropriate clinics, equipment and supplies for the services it provides. It must maintain its

equipment in accordance with the manufacturer's directions and in a manner that ensures safe and proper functioning.

(3) The FESC has housekeeping and preventive maintenance programs to ensure that--

(i) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(ii) There is proper routine storage and prompt disposal of trash and infectious and hazardous waste;

(iii) Drugs and biologicals are appropriately, safely, and securely stored;

(iv) The premises are clean and orderly; and

(v) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(4) The FESC assures the safety of patients in internal and external disaster situations by--

(i) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(ii) Providing for emergency power and lighting in the treatment areas and for battery lamps and flashlights in other areas;

(iii) Providing for an adequate emergency fuel and water supply; and

(iv) Taking appropriate emergency preparedness measures that are consistent with the particular conditions of the area in which the FESC is located; and

(v) Developing an emergency preparedness plan, in coordination with local emergency preparedness officials.

H. Condition of participation: Organizational Structure

(1) The FESC has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the FESC's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(2) The FESC discloses the names and addresses of -

(i) Its owners, or those with a controlling interest in the FESC or in any subcontractor in which the FESC directly or indirectly has a 5 percent or more ownership interest; and

(ii) The person principally responsible for the operation of the FESC.

I. Condition of participation: Provision of Services.

(1) The FESC's health care services are furnished in accordance with nationally accepted standards of practice and

appropriate written policies that are consistent with applicable state law.

(2) The FESC must have and implement the following policies regarding its care and services:

(i) A description of the services that the FESC furnishes.

(ii) Policies and procedures for emergency medical services.

(iii) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with nationally accepted professional principles that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(iv) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(v) A system for preventing, identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(3) Laboratory services. The FESC provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of patients that meet the standards

imposed under the Clinical Laboratory Improvement Amendments of 1988 (section 353 of the Public Health Service Act (42 U.S.C. 236a)). At a minimum, the laboratory services provided include:

- (i) Chemical examination of urine by stick or tablet method or both (including urine ketones);
- (ii) Hemoglobin or hematocrit;
- (iii) Blood glucose;
- (iv) Examination of stool specimens for occult blood;
- (v) Primary culturing for transmittal to a certified laboratory;
- (vi) Electrolytes; and
- (vii) PO<sub>2</sub>.

(4) Radiology services. Radiology services furnished at the FESC are provided as direct services by FESC staff qualified under State law, and do not expose FESC patients or staff to radiation hazards.

(5) The FESC has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--

- (i) Inpatient hospital care;
- (ii) Services of doctors of medicine or osteopathy;

(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the FESC; and

(iv) Food and other services to meet patients' nutritional needs to the extent these services are not provided directly by the FESC.

(6) If the agreements or arrangements are not in writing, the FESC is able to present evidence that patients referred by the FESC are being accepted and treated.

(7) The FESC maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(8) The person principally responsible for the operation of the FESC is also responsible for the following:

(i) Services furnished in the FESC.

(ii) Ensuring that a contractor of services furnishes services that enable the FESC to comply with all applicable conditions of participation and standards for the contracted services.

(9) All drugs, biologicals, and intravenous medications must be administered by or under the direct supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, nationally accepted standards of practice, and Federal and State laws.

(10) If State laws governing the administration of drugs are more stringent than Federal laws, then the FESC must abide by these State laws.

J. Condition of participation: Clinical Records.

(1) The FESC maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the FESC maintains a record that includes, as applicable--

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, post release/discharge instructions to the patient, and applicable evidence of appropriate discharge planning.

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All physician and other practitioner orders, consultations, reports of treatments and medications, nursing notes addressing observations, assessments, interventions, and responses to interventions;

(iv) For extended stay patients, the medical record must contain information to explain the weather/transportation problem that prevents transfer to a hospital, and provides information to justify the stay and continued stay, support the diagnosis, and describe the patient's progress and response to interventions, medications, care, and services;

(v) There must be documentation of complications, infections and medication errors and other pertinent information necessary to monitor the patient's progress, such as temperature graphics and progress notes describing the patient's response to treatment.

(4) All orders are dated, timed and authenticated as soon as possible by the doctor of medicine or osteopathy or other health care professional responsible for the order.

(5) The FESC must maintain the confidentiality of records in accordance with the medical privacy rules of the Health Insurance Portability and Accountability Act of 1996.

(6) Written policies and procedures govern the use and removal of records from the FESC and the conditions for the release of information.

(7) The patient's written consent is required for release of information not required by law.

(8) The records are retained for at least 6 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

(9) All entries in the medical record must be dated, timed and authenticated by the person making the entry.

#### **IV. Evaluation and Reporting Requirements**

We plan to award a contract to an independent research organization to evaluate the FESC demonstration. Awardees for the demonstration would agree to cooperate with our evaluation contractor, participate in periodic site visits, and provide information necessary to conduct the evaluation. The specific FESC site requirements related to the evaluation of the demonstration will be finalized once an evaluation contract has been awarded.

#### **V. Submission of Applications**

##### **A. General**

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 policy of a clinic or clinics interested in participating in the demonstration. 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. 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 should be submitted in writing by mail, fax, or e-mail to:

Sid Mazumdar, Project Officer

Medicare Demonstrations Program Group

Centers for Medicare & Medicaid Services

C4-17-27

7500 Security Boulevard, Baltimore, MD 21244-1850

FAX: 410 786-1048

E-mail: [siddhartha.mazumdar@cms.hhs.gov](mailto:siddhartha.mazumdar@cms.hhs.gov).

An unbound original and two copies plus an electronic copy on diskette or CD of the application must be submitted; however, applicants may, but are not required to, submit six additional copies to assure that each review panelist receives the application in the manner intended by the applicant (e.g., collated, tabulated, colorized.) The applications should be MAILED or sent by overnight delivery to Sid Mazumdar, Project Officer, Medicare Demonstrations Program Group, at the street address shown above. The application is due November 24, 2006.

B. Evaluation Process and Criteria

If the application meets the basic eligibility requirements and responds to all components of the solicitation, it will be referred to a technical review panel for evaluation and scoring and 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. CMS will make the final determinations based on these initial evaluations. In addition, we will conduct a financial analysis of the

recommended proposals and evaluate the proposed projects to assure that they are budget neutral.

The evaluation criteria and weights are described below. These criteria will be used to evaluate the applications for the FESC demonstration. Applications will be scored on an absolute basis. Please respond to the criteria carefully and thoroughly. Your responses should be organized according to the format outlined in the Medicare Waiver Demonstration Application, which is available on the website along with this solicitation.

1. Purpose of Project (10 points)

The applicant will be evaluated on how it defines the purpose of its proposal for the FESC Demonstration project: that is, the specific goals and objectives to be achieved and how taking part in the demonstration will lead to these goals. The applicant should describe the population that it serves, along with distinguishing features such as access barriers, health status and conditions, and proneness to injury on account of occupations or activities. The applicant should assess how participating in the demonstration will benefit the community compared to the current situation of how services for the population operate.

2. Description of Clinic or Clinics (30 Points)

The applicant should describe the clinic or clinics that it

proposes to use in implementing the demonstration model.

Descriptions of the clinics will be evaluated on whether they conform to requirements of the section 434 legislation, and also whether the applicant describes a plausible and coherent model of how the clinic will serve the patients targeted in the legislation.

a) For each clinic, the applicant should calculate the shortest distance by passable road to an acute care hospital or CAH and document this distance with a map or computer program printout, such as from MapQuest. The applicant also should describe any item of geography or climate (e.g., a mountain range, a body of water, or regular occurrences of fog) likely to impede transportation to health care clinics for people of the surrounding area. The applicant should describe the community that the clinic serves, and, if possible, the geographic boundary of the community. In the case wherein no passable roads exist, the nearest acute care hospital or CAH should be indicated, along with the primary means of transportation to this clinic.

b) The applicant should describe the physical structure of each clinic, including its adherence to the Life Safety Code. The applicant should detail the spatial arrangements for the primary care outpatient clinic and the distinct FESC

extended stay unit. If any spatial changes to the clinic are planned for the demonstration, the applicant should describe these. The applicant should describe any clinic equipment not usually found in a physician's office or ambulatory clinic and under what circumstances it will be used.

c) For each clinic the applicant should describe the staff serving both the primary care clinic outpatients and the FESC extended stay patients. The applicant should describe each staff member's training and experience. Furthermore, the applicant should describe the extent to which each staff member's time will be committed to the clinic, for the primary care outpatient clinic and for the FESC. The applicant should describe for each clinic its arrangements for the availability of staff when they are not onsite. In particular, the applicants should describe arrangements for availability of MD/DOs, if not regular staff members, in the event of an extended stay patient with urgent needs. As well, the applicant should describe its plans for any new hires.

d) The applicant should assess the extent of its expected caseload of FESC extended stay patients during a typical month during the demonstration period and explain how its staffing arrangements will be adequate during the period. Furthermore, the applicant should identify recruiting,

credentialing and privileging procedures for acquiring new employees.

e) The applicant should describe how clinical staff are alerted and how they respond to patients who are at the clinic and need medical assistance at times when there is no staff at the clinic.3. Proposed Operation of the Frontier Extended Stay Clinic (40 Points)

a) The applicant should estimate the costs of services to its Medicare patients. That is, the applicant should itemize costs. The applicants should propose an itemized budget considering services it expects to furnish, and projected costs per capita. Given this estimate of costs, the applicant should state an appropriate payment rate or rates for Medicare patients. The applicant will not be evaluated specifically on amounts stated; however, CMS expects a thorough accounting of costs.

b) Applicants should describe how the FESC program would be budget neutral. For example, based on historical data, for what fraction of FESC patients could hospitalizations be avoided in a year? How many hours were these patients kept at the applicant FESC? To what extent would hospital, physician, and ambulance payment be avoided by Medicare for these patients? What were the diagnosis codes (ICD-9 codes) of FESC

patients?

c) The applicant should describe the hours of operation of the primary care clinic and the FESC extended stay clinic. In particular the applicant should describe how the clinic or clinics will be staffed so as to ensure there is at all times access to care for patients with emergency medical conditions.

d) As part of the application, the applicant should describe its policies and procedures for treating patients with emergency conditions. In an appendix, the applicant should submit its protocols for treating patients with emergent needs. If a consortium of clinics is applying, it should submit any protocols that exist for the consortium, as well as any that define procedures specifically for individual clinics.

e) The applicant should describe its policies and procedures for monitoring and observation of patients and what conditions each provider commonly encounters and has experience in treating on a short term basis. The applicant should provide a simple description of the clinical methods (e.g., laboratory tests, medications, use of equipment) that are used in monitoring patients. The applicant should state a set of commonly encountered conditions that require transfer and that should not be treated in the FESC, unless weather

situations require such.

f) The applicant should describe its relationship with other providers, including other clinics and acute care hospitals or CAHs. These descriptions should include sharing of staff, equipment, and clinical information. The applicant should provide documentation of transfer agreements and protocols for transferring patients with emergency medical conditions from the clinic to acute care hospitals. The applicant should also describe other arrangements associated with these transfers, such as transportation, accommodations for family members, and return trip transportation to the community.

g) The applicant should give a general account of the staffing of its business office and how it submits financial information to the Medicare fiscal intermediary or carrier. The applicant should describe its capability to provide billing information to Medicare for the types of patients that will be treated by the FESC.4. Relationship with the Community (20 Points)

a) The applicant should describe any formal or informal liaisons between the clinic and governmental or community organizations in the proximate area. The applicant should describe what benefit these relationships have to the

provision of health care services in the area.

b) The applicant should describe how FESC designation will benefit the community in its effort to care for the overall caseload.

c) The applicant should describe the specific mental and behavioral health needs of the community, and clinic policies and procedures in relation to individuals needing assistance. The applicant should describe the extent to which the clinic collaborates with legal authorities on issues of mental and behavioral health and whether the scope of such practices will be affected by Medicare designation as a FESC.

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