

PART 405\_FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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Subpart U\_Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

**Sec. 405.2100 Scope of subpart.**

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in Sec. 405.2101, and general definitions are contained in Sec. 405.2102. The provisions of Sec. Sec. 405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

**Sec. 405.2101 Objectives of the end-stage renal disease (ESRD) program.**

The objectives of the end-stage renal disease program are:

- (a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;
- (b) To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care;
- (c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and
- (d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

**Sec. 405.2102 Definitions.**

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

Dialysis. A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of "ESRD service"). Such facilities are:

(a) Renal Transplantation Center. A hospital unit which is approved to furnish directly Transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

(b) Renal dialysis center. A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(c) Renal dialysis facility. A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(d) Self-dialysis unit. A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(e) Special purpose renal dialysis facility. A renal dialysis facility which is approved under Sec. 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(a) Transplantation service. A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

(b) Dialysis service--(1) Inpatient dialysis. Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) Outpatient dialysis. Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) Staff-assisted dialysis. Dialysis performed by the staff of the center or facility.

(ii) Self-dialysis. Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) Home dialysis. Dialysis performed by an appropriately trained patient at home.

(c) Self-dialysis and home dialysis training. A program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through "agreements" or "arrangements").

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (MCE). Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Organ procurement. The process of acquiring donor kidneys. (See definition of Organ procurement organization in Sec. 485.302 of this chapter.)

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) Chief executive officer. A person who:

- (1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or
- (2) Is a registered nurse or physician director as defined in this definition; or
- (3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) Dietitian. A person who:

- (1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or
- (2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) Medical record practitioner. A person who:

- (1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.
- (2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or
- (3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American Medical Record Association under its requirements in effect June 3, 1976.

(d) Nurse responsible for nursing service. A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process;

(3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) Physician-director. A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;

(3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) Social worker. A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.

(g) Transplantation surgeon. A person who:

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

#### **Sec. 405.2110 Designation of ESRD networks.**

CMS designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) Effect on patient choice of facility. The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) Redesignation of networks. CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in Sec. 405.2101, and compatible with efficient program administration.

**Sec. 405.2112 ESRD network organizations.**

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

- (a) Developing network goals for placing patients in settings for self-care and transplantation.
- (b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.
- (c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.
- (d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.
- (e) Making recommendations to member facilities as needed to achieve network goals.
- (f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:
  - (1) A statement of the network goals.
  - (2) The comparative performance of facilities regarding the placement of patients in appropriate settings for--
    - (i) Self-care;
    - (ii) Transplants; and
    - (iii) Vocational rehabilitation programs.
  - (3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.
  - (4) Identification of facilities and providers that are not providing appropriate medical care.
  - (5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.
- (g) Evaluating and resolving patient grievances.
- (h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

**Sec. 405.2113 Medical review board.**

(a) General. The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) Restrictions on medical review board members. (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

**Sec. 405.2120 Minimum utilization rates: general.**

Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) authorizes the Secretary to limit payment for ESRD care to those facilities that meet the requirements that the Secretary may prescribe, including minimum utilization rates for covered transplantations. The minimum utilization rates, which are explained and specified in Sec. Sec. 405.2121 through 405.2130, may be changed from time to time in accordance with program experience. Changes will be published as amendments to these regulations.

**Sec. 405.2121 Basis for determining minimum utilization rates.**

In developing minimum utilization rates, the Secretary takes into account the performance of ESRD facilities, the availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:

**Sec. 405.2122 Types and duration of classification according to utilization rates.**

A renal transplantation center that meets all the other conditions for coverage of ESRD services will be classified according to its utilization rate(s) as follows: Unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see Sec. 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent

classification occurs. (See Sec. 405.2123 for reporting requirements; Sec. 405.2124 for method of calculating rates; Sec. 405.2130 for specific standards.)

(a) Initial classification. (1) A renal transplantation center that has not previously participated in the ESRD program will be granted conditional status if it submits a written plan, detailing how it will achieve the utilization rates for conditional status by the end of the second calendar year of its operation under the ESRD program, and the rates required for unconditional status by the end of its fourth calendar year of operation.

(2) The renal transplantation center's performance will be evaluated at the end of the first calendar year to ascertain whether it is properly implementing the plan.

(b) Exception status. (1) A renal transplantation center that does not meet the minimum utilization rate for unconditional or conditional status may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage under this subpart;

(ii) It is unable to meet the minimum utilization rate because it lacks a sufficient number of patients and is located in an area without a sufficient population base to support a center or facility which would meet the rate; and

(iii) Its absence would adversely affect the achievement of ESRD program objectives.

(2) A hospital that furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under this subpart, but does not meet the utilization standards prescribed in Sec. 405.2130(a), may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage as a renal transplantation center;

(ii) The surgery is performed under the direct supervision of a qualified transplantation surgeon (Sec. 405.2102) who is also performing renal transplantation surgery at an approved renal transplantation center that is primarily oriented to adult nephrology;

(iii) It has an agreement, with the other hospital serviced by the surgeon, for sharing limited resources that are needed for kidney transplantation; and

(iv) There are pediatric patients who need the surgery and who cannot obtain it from any other hospital located within a reasonable distance.

#### **Sec. 405.2123 Reporting of utilization rates for classification.**

Each hospital furnishing renal transplantation services must submit an annual report to CMS on its utilization rates. The report must include both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.

#### **Sec. 405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status.**

For purposes of classification the Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.

**Sec. 405.2130 Condition: Minimum utilization rates.**

Unless a renal transplantation center is granted an exception under Sec. 405.2122(b), the center must meet the following minimum utilization rate(s) for unconditional or conditional status:

(a) Unconditional status: 15 or more transplants performed annually.

(b) Conditional status: 7 to 14 transplants performed annually.

**Sec. 405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center.**

A renal transplantation center or a renal dialysis center (Sec. 405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

**Sec. 405.2133 Condition: Furnishing data and information for ESRD program administration.**

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).

**Sec. 405.2134 Condition: Participation in network activities.**

Each facility must participate in network activities and pursue network goals.

**Sec. 405.2135 Condition: Compliance with Federal, State and local laws and regulations.**

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) Standard: licensure. Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

(1) Licensed pursuant to such law; or

(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) Standard: licensure or registration of personnel. Each staff member is currently licensed or registered in accordance with applicable law.

(c) Standard: conformity with other laws. The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

**Sec. 405.2136 Condition: Governing body and management.**

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer who is responsible for the overall management of the facility.

(a) Standard: disclosure of ownership. The ESRD facility supplies full and complete information to the State survey agency (Sec. 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 per centum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility;

(2) Each officer and director of the corporation, if the facility is organized as a corporation; and

(3) Each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) Standard: Operational objectives. The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.

(3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see Sec. 405.2137).

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(c) Standard: chief executive officer. The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities.

(3) The responsibilities of the chief executive officer include but are not limited to:

(i) Implementing the policies of the facility and coordinating the provision of services, in accordance with delegations by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, re delegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) Standard: personnel policies and procedures. The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing inservice training, including procedures for

infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.

(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.

(e) Standard: use of outside resources. If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) Standard: patient care policies. The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement).

(ii) Admission and discharge policies (in relation to both in-facility care and home care).

(iii) Medical supervision and physician services.

(iv) Patient long term programs, patient care plans and methods of implementation.

(v) Care of patients in medical and other emergencies.

(vi) Pharmaceutical services.

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).

(viii) Administrative records.

(ix) Use and maintenance of the physical plant and equipment.

(x) Consultant qualifications, functions, and responsibilities.

(xi) The provision of home dialysis support services, if offered (see Sec. 405.2163(e)).

(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physician director to (or, in the case of a self-dialysis unit, to another licensed health practitioner) a registered nurse, the physician-director provides medical guidance in such matters.

(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their non-working hours.

(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see Sec. 405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

(g) Standard: medical supervision and emergency coverage. The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) Standard: medical staff. The governing body of the ESRD facility designates a qualified physician (see Sec. 405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

**Sec. 405.2137 Condition: Patient long-term program and patient care plan.**

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved

with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) Standard: patient long-term program. There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see Sec. 405.2161(b)(1) and Sec. 405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) Standard: patient care plan. There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see Sec. 405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate. (See Sec. 405.2163(e).)

(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following:

(i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

(ii) Review of medications to ensure adequate provision of supplemental iron.

(iii) Ongoing evaluations of hematocrit and iron stores.

(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

(v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.

(vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension.

(vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.

**Sec. 405.2138 Condition: Patients' rights and responsibilities.**

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) Standard: informed patients. All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) Standard: participation in planning. All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) Standard: respect and dignity. All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) Standard: confidentiality. All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) Standard: grievance mechanism. All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

**Sec. 405.2139 Condition: Medical records.**

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) Standard: medical record. Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see Sec. 405.2137(a) and (b)); evidence that the patient was

informed of the results of the assessment described in Sec. 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.

(b) Standard: protection of medical record information. The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) Standard: medical records supervisor. A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) Standard: Completion of medical records and centralization of clinical information. Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) Standard: retention and preservation of records. Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) Standard: location and facilities. The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) Standard: transfer of medical information. The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

**Sec. 405.2140 Condition: Physical environment.**

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) Standard: building and equipment. The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.

(4) [Reserved]

(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in "Hemodialysis Systems," second edition, which is incorporated by reference.

(ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

(iii) Incorporation by reference of the AAMI's "Hemodialysis Systems," second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.<sup>1</sup> If any changes in "Hemodialysis Systems," second edition, are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.

(b) Standard: favorable environment for patients. The facility is maintained and equipped to provide a functional sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and

contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items which conform to requirements for reuse in Sec. 405.2150.

(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accommodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency. There is sufficient space in units for safe storage of self-dialysis supplies.

(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made.

(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.

(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see Sec. 405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(c) Standard contamination prevention. The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures. The written patient care policies (see Sec. 405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in Sec. 405.2150.

(d) Standard: emergency preparedness. Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for

orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.

**Sec. 405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.**

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) Standard: Hemodialyzers. If the ESRD facility reuses hemodialyzers, it conforms to the following:

(1) Reuse guidelines. Voluntary guidelines adopted by the AAMI ("Reuse of Hemodialyzers," second edition). Incorporation by reference of the AAMI's "Reuse of Hemodialyzers," second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.<sup>1</sup> If any changes in "Reuse of Hemodialyzers," second edition, are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.

(2) Procedure for chemical germicides. To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) Surveillance of patient reactions. In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility--

- (i) Takes appropriate blood cultures at the time of a febrile response in a patient; and
- (ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) Standard: Transducer filters. To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

(c) Standard: Bloodlines. If the ESRD facility reuses bloodlines, it must--

- (1) Limit the reuse of bloodlines to the same patient;

- (2) Not reuse bloodlines labeled for "single use only";
- (3) Reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and
- (4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.

**Sec. 405.2160 Condition: Affiliation agreement or arrangement.**

(a) A renal dialysis facility and a renal dialysis center (see Sec. 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

- (1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;
- (2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and
- (3) Security and accountability for patients' personal effects are assured.

**Sec. 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.**

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) Standard: qualifications. The director of a dialysis facility is a qualified physician-director. (See Sec. 405.2102.)

(b) Standard: responsibilities. The responsibilities of the physician-director include but are not limited to the following:

- (1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

- (2) Assuring adequate training of nurses and technicians in dialysis techniques;
- (3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;
- (4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and
- (5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

**Sec. 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.**

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

- (a) Standard: Registered nurse. The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See Sec. 405.2102.)
- (b) Standard: On-duty personnel. Whenever patients are undergoing dialysis:
  - (1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;
  - (2) An adequate number of personnel are present so that the patient/ staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and
  - (3) An adequate number of personnel are readily available to meet medical and nonmedical needs.
- (c) Standard: Self-care dialysis training personnel. If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see Sec. 405.2102.)

**Sec. 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.**

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

- (a) Standard: Outpatient dialysis services--(1) Staff-assisted dialysis services. The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) Self-dialysis services. If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) Standard: Laboratory services. The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter.

If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) Standard: Social services. Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (Sec. 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) Standard: Dietetic services. Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (Sec. 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) Standard: Self-dialysis support services. The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A recordkeeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(f) Standard: Participation in recipient registry. The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 486, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.

(g) Use of EPO at home: Patient selection. The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) Pre-selection monitoring. The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) Conditions the patient must meet. The assessment must find that the patient meets the following conditions:

(i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient;

(ii) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.)

(B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.

(iii) Is under the care of--

(A) A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) Conditions the patient or the patient's caregiver must meet. The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) Care and storage of drug. The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) Use of EPO at home: Responsibilities of the physician or the dialysis facility. The patient's physician or dialysis facility must--

- (1) Develop a protocol that follows the drug label instructions;
  - (2) Make the protocol available to the patient to ensure safe and effective home use of EPO;
- and
- (3) Through the amounts prescribed, ensure that the drug "on hand" at any time does not exceed a 2-month supply.

**Sec. 405.2164 Conditions for coverage of special purpose renal dialysis facilities.**

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in Sec. Sec. 405.2130 through 405.2164, with the exception of Sec. Sec. 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under Sec. 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

**Sec. 405.2170 Condition: Director of a renal transplantation center.**

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (Sec. 405.2102) or a qualified physician-director (Sec. 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

- (a) Participating in the selection of a suitable treatment modality for each patient.
- (b) Assuring adequate training, of nurses in the care of transplant patients.
- (c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.
- (d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

**Sec. 405.2171 Condition: Minimal service requirements for a renal transplantation center.**

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by CMS as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.

(a) Standard: participation in recipient registry. The renal transplantation center participates in a patient registry program with an OPO certified or recertified under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.

(b) Standard: social services. Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (Sec. 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(c) Standard: dietetic services. Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (Sec. 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(d) Standard: Laboratory services: (1) The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter.

(2) Laboratory services for crossmatching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.

(e) Standard: Organ procurement. A renal transplantation center using the services of an organ procurement organization designated or redesignated under part 485, subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplantation center agrees to notify CMS in writing within 30 days of the termination of the agreement.

**Sec. 405.2180 Termination of Medicare coverage.**

(a) Except as provided in Sec. 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U will result in termination of Medicare coverage of the services furnished by that supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required by Sec. 405.2134, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

**Sec. 405.2181 Alternative sanctions.**

(a) Basis for application of alternative sanctions. CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that--

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) Alternative sanctions. The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) Duration of sanction. An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

**Sec. 405.2182 Notice of sanction and appeal rights: Termination of coverage.**

(a) Notice of sanction. CMS gives the supplier and the general public notice of sanction and of the effective date of the sanction. The effective date of the sanction is at least 30 days after the date of the notice.

(b) Appeal rights. Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

**Sec. 405.2184 Notice of appeal rights: Alternative sanctions.**

If CMS proposes to apply a sanction specified in Sec. 405.2181(b), the following rules apply:

(a) CMS gives the facility notice of the proposed sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility--

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the sanction, with a written notice that specifies the effective date and the reasons for the sanction.

**Sec. 405.2400 Basis.**

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Source: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

Subpart X is based on the provisions of the following sections of the Act: Section 1833 sets forth the amounts of payment for supplementary medical insurance services. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program.

**Sec. 405.2401 Scope and definitions.**

(a) Scope. This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) Definitions. As used in this subpart, unless the context indicates otherwise:

Act means the Social Security Act.

Allowable costs means costs that are incurred by a clinic or center and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic and Federally qualified health center services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Coinsurance means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

Carrier means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means:

(1) The first \$100 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(2) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See Sec. Sec. 410.160 and 410.161 of this chapter for greater detail.)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under Sec. Sec. 405.2434 and--

(1) Is receiving a grant under section 329, 330, or 340 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330 or 340 of the Public Health Service Act;

(2) Based on the recommendation of the PHS, is determined by CMS to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of part B, as a comprehensive federally funded health center (FFHC) as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

CMS stands for Centers for Medicare & Medicaid Services.

Intermittent nursing care means a medically predictable need for nursing care from time to time, but usually not less frequently than once every 60 days.

Nurse-midwife means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(10)(iv) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

Nurse practitioner and physician assistant means individuals who meet the applicable education, training experience and other requirements of Sec. 491.2 of this chapter.

Part-time nursing care means nursing care that is required on less than a full-time basis, that is, less than 8 hours a day or 40 hours a week.

Physician means the following:

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed.

(2) Within limitations as to the specific services furnished, a doctor of dentistry or dental or oral surgery, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor. (See section 1861(r) of the Act for specific limitations.)

(3) A resident (including residents as defined in Sec. 415.152 of this chapter who meet the requirements in Sec. 415.206(b) of this chapter for payment under the physician fee schedule).

Reporting period means a period of 12 consecutive months specified by the intermediary as the period for which a clinic or center must report its costs and utilization. The first and last reporting periods may be less than 12 months.

Rural health clinic (RHC) means an entity that:

(1) Meets the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval.

(2) Has filed an agreement with CMS that meets the basic requirements described in Sec. 405.2402 to provide RHC services under Medicare.

(3) Does not share space, staff, supplies, records, and other resources during RHC hours of operation with a private Medicare or Medicaid practice operated by the same physicians and nonphysician practitioners working for the RHC. Operation of a multipurpose clinic with other types of health providers or suppliers is permissible subject to the provisions in paragraph (4) of this definition.

(4) Appropriately allocates and excludes from the RHC cost report the net non-RHC costs if it operates at a multipurpose location that involves the sharing of common space, medical support staff, or other physical resources with other health care providers or suppliers.

Secretary means the Secretary of Health and or his delegate.

Visiting nurse services means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered nurse or licensed practical nurse to a homebound patient.

#### **Sec. 405.2402 Basic requirements.**

(a) Certification by the State survey agency. The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) Acceptance of the clinic as qualified to furnish rural health clinic services. If the Secretary, after reviewing the survey agency recommendation and other evidence relating to the qualifications of the rural health clinic, determines that it meets the requirements of this subpart and of part 491 of this chapter, he will send the clinic:

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) Filing of agreement by the rural health clinic. If the rural health clinic wishes to participate in the program, it must:

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) Acceptance by the Secretary. If the Secretary accepts the agreement filed by the rural health clinic, he will return to the clinic one copy of the agreement, with a notice of acceptance specifying the effective date.

(e) Duration of agreement. The agreement shall be for a term of one year and may be renewed annually by mutual consent of the Secretary and the rural health clinic.

(f) Appeal rights. If the Secretary does not certify a rural health clinic, or refuses to enter into or renew an agreement, the facility is entitled to a hearing in accordance with part 498 of this chapter.

#### **Sec. 405.2403 Content and terms of the agreement with the Secretary.**

(a) Under the agreement, the rural health clinic agrees to the following:

(1) Maintaining compliance with conditions. The clinic agrees to maintain compliance with the conditions set forth in part 491 of this chapter and to report promptly to CMS any failure to do so.

(2) Charges to beneficiaries. The clinic agrees not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under

the provisions of this part (or for which the beneficiary would have been entitled if the rural health clinic had filed a request for payment in accordance with Sec. 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under Sec. 405.2410.

(3) Refunds to beneficiaries. (i) The clinic agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, money incorrectly collected means sums collected in excess of the amount for which the beneficiary was liable under Sec. 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

(A) The beneficiary is later determined to have been entitled to Medicare benefits; and

(B) The beneficiary's entitlement period falls within the time the rural health clinic's agreement with the Secretary is in effect.

(4) Beneficiary treatment. (i) The clinic agrees to accept beneficiaries for care and treatment; and

(ii) The clinic agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) Additional provisions. The agreement may contain any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

#### **Sec. 405.2404 Terminations of agreements.**

(a) Termination by rural health clinic. (1) Notice to Secretary. If the clinic wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) Action by the Secretary. (i) The Secretary may approve the date proposed by the clinic, or set a different date no later than 6 months after the date of the clinic's notice.

(ii) The Secretary may approve a date which is less than 6 months after the date of notice if he determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the clinic; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) Cessation of business. If a clinic ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the clinic, effective on the last day of business.

(b) Termination by the Secretary. (1) Cause for termination. The Secretary may terminate an agreement if he determines that the rural health clinic:

(i) No longer meets the conditions for certification under part 491 of this chapter; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

(iii) Has undergone a change of ownership.

(2) Notice of termination. The Secretary will give notice of termination to the rural health clinic at least 15 days before the effective date stated in the notice.

(3) Appeal by the rural health clinic. A rural health clinic may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) Effect of termination. Payment will not be available for rural health clinic services furnished on or after the effective date of termination.

(d) Notice to the public. Prompt notice of the date and effect of termination shall be given to the public, through publication in local newspapers:

(1) By the clinic, after the Secretary has approved or set a termination date; or

(2) By the Secretary, when he has terminated the agreement.

(e) Conditions for reinstatement after termination of agreement by the Secretary. When an agreement with a rural health clinic is terminated by the Secretary, the rural health clinic may not file another agreement to participate in the Medicare program unless the Secretary:

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

**Sec. 405.2410 Application of Part B deductible and coinsurance.**

(a) Application of deductible. (1) Medicare payment for RHC services begins only after the beneficiary has incurred the deductible. Medicare applies the Medicare Part B deductible as follows:

(i) If the deductible is fully met by the beneficiary before the RHC visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible is not fully met by the beneficiary before the visit and the amount of the RHC's reasonable customary charge for the service that is applied to the deductible is--

(A) Less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-inclusive rate and 80 percent of the remainder, if any, is paid to the RHC; or

(B) Equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(2) Medicare payment for FQHC services is not subject to the usual Part B deductible.

(b) Application of coinsurance. (1) The beneficiary is responsible for the coinsurance amount that cannot exceed 20 percent of the clinic's reasonable customary charge for the covered service.

(2) The beneficiary's deductible and coinsurance liability for any one service furnished by the RHC may not exceed a reasonable amount customarily charged by the RHC for that particular service.

(3) For any one service furnished by an FQHC, the coinsurance liability may not exceed 20 percent of reasonable amount customarily charged by the FQHC for that particular service.

**Sec. 405.2411 Scope of benefits.**

(a) Rural health clinic services reimbursable under this subpart are:

- (1) The physicians' services specified in Sec. 405.2412;
- (2) Services and supplies furnished as an incident to a physician's professional service;
- (3) The nurse practitioner or physician assistant services specified in Sec. 405.2414;
- (4) Services and supplies furnished as an incident to a nurse practitioner's or physician

assistant's services; and

(5) Visiting nurse services.

(b) Rural health clinic services are reimbursable when furnished to a patient at the clinic, at a hospital or other medical facility, or at the patient's place of residence.

**Sec. 405.2412 Physicians' services.**

(a) Physicians' services are professional services that are performed by a physician at the clinic or are performed away from the clinic by a physician whose agreement with the clinic provides that he or she will be paid by the clinic for such services.

**Sec. 405.2413 Services and supplies incident to a physician's services.**

(a) Services and supplies incident to a physician's professional service are reimbursable under this subpart if the service or supply is:

- (1) Of a type commonly furnished in physicians' offices;
- (2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;
- (3) Furnished as an incidental, although integral, part of a physician's professional services;
- (4) Furnished under the direct, personal supervision of a physician; and
- (5) In the case of a service, furnished by a member of the clinic's health care staff who is an

employee of the clinic.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

**Sec. 405.2414 Nurse practitioner and physician assistant services.**

(a) Professional services are reimbursable under this subpart if:

(1) Furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner who is employed by, or receives compensation from, the rural health clinic;

- (2) Furnished under the medical supervision of a physician;
  - (3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician;
  - (4) They are of a type which the nurse practitioner, physician assistant, nurse midwife or specialized nurse practitioner who furnished the service is legally permitted to perform by the State in which the service is rendered; and
  - (5) They would be covered if furnished by a physician.
- (b) The physician supervision requirement is met if the conditions specified in Sec. 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.
- (c) The services of nurse practitioners, physician assistants, nurse midwives or specialized nurse practitioners are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

**Sec. 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.**

(a) Services and supplies incident to a nurse practitioner's or physician assistant's services are reimbursable under this subpart if the service or supply is:

- (1) Of a type commonly furnished in physicians' offices;
- (2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;
- (3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner;
- (4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and
- (5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

**Sec. 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.**

(a) Services and supplies incident to a nurse practitioner's or physician assistant's services are reimbursable under this subpart if the service or supply is:

- (1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner;

(4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

**Sec. 405.2416 Visiting nurse services.**

(a) Visiting nurse services are covered if:

(1) The rural health clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies;

(2) The services are rendered to a homebound individual;

(3) The services are furnished by a registered nurse, licensed practical nurse, or licensed vocational nurse who is employed by, or receives compensation for the services from the clinic; and

(4) The services are furnished under a written plan of treatment that is:

(i) Established and reviewed at least every 60 days by a supervising physician of the rural health clinic or established by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner and reviewed at least every 60 days by a supervising physician; and

(ii) Signed by the nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, or the supervising physician of the clinic.

(b) The nursing care covered by this section includes:

(1) Services that must be performed by a registered nurse, licensed practical nurse, or licensed vocational nurse if the safety of the patient is to be assured and the medically desired results achieved; and

(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, homebound means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, "place of residence" does not include a hospital or long term care facility.

**Sec. 405.2417 Visiting nurse services: Determination of shortage of agencies.**

A shortage of home health agencies exists if the Secretary determines that the rural health clinic:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the rural health clinic;

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency; or

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

**Sec. 405.2430 Basic requirements.**

(a) Filing procedures. (1) In response to a request from an entity that wishes to participate in the Medicare program, CMS enters into an agreement with an entity when--

(i) PHS recommends that the entity qualifies as a Federally qualified health center;

(ii) The Federally qualified health center assures CMS that it meets the Federally qualified health center requirements specified in this subpart and part 491, as described in Sec. 405.2434(a); and

(iii) The FQHC terminates other provider agreements, unless the FQHC assures CMS that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

(2) CMS sends the entity a written notice of the disposition of the request.

(3) When the requirement of paragraph (a)(1) of this section is satisfied, CMS sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to CMS.

(4) If CMS accepts the agreement filed by the Federally qualified health center, CMS returns to the center one copy of the agreement with the notice of acceptance specifying the effective date (see Sec. 489.11), as determined under Sec. 405.2434.

(b) Recommendations by PHS about Federally qualified health centers. (1) An entity must--

- (i) Meet the applicable requirements of the PHS Act, as specified in Sec. 405.2401(b); and
- (ii) Be recommended by PHS to CMS as a Federally qualified health center.

(2) The PHS notifies CMS of entities that meet the requirements specified in Sec. 405.2401(b).

(c) Provider-based and freestanding Federally qualified health centers. The requirements and benefits under Medicare for provider-based or freestanding Federally qualified health centers are the same, except that payment methodologies differ, as described in Sec. 405.2462.

(d) Appeals. An entity is entitled to a hearing in accordance with part 498 of this chapter when CMS fails to enter into an agreement with the entity.

**Sec. 405.2434 Content and terms of the agreement.**

Under the agreement, the Federally qualified health center must agree to the following:

(a) Maintain compliance with the requirements. (1) The Federally qualified health center must agree to maintain compliance with the Federally qualified health center requirements set forth in this subpart and part 491, except that the provisions of Sec. 491.3 do not apply.

(2) Centers must promptly report to CMS any changes that result in noncompliance with any of these requirements.

(b) Effective date of agreement. (1) Except as specified in paragraph (b)(2) of this section, the effective date of the agreement is the date CMS accepts the signed agreement, which assures that all Federal requirements are met.

(2) For facilities that met all requirements on October 1, 1991, the effective date of the agreement can be October 1, 1991.

(c) Charges to beneficiaries. (1) The beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the Federally qualified health center for the covered services. There is no coinsurance for a second or third opinion obtained in accordance with section 1164 of the Act or for pneumococcal vaccine and its administration.

(2) The beneficiary is responsible for blood deductible expenses, as specified in Sec. 410.161.

(3) The Federally qualified health center agrees not to charge the beneficiary (or any other person acting on behalf of a beneficiary) for any Federally qualified health center services for which the beneficiary is entitled to have payment made on his or her behalf by the Medicare program (or for which the beneficiary would have been entitled if the Federally qualified health center had filed a request for payment in accordance with Sec. 410.165 of this chapter), except for coinsurance amounts.

(4) The Federally qualified health center may charge the beneficiary for items and services that are not Federally qualified health center services. However, if the item or service is covered under Part B of Medicare, and the Federally qualified health center agrees to receive Part B payment under the assignment method, the Federally qualified health center may not charge the beneficiary more than 20 percent of the Part B payment.

(d) Refunds to beneficiaries. (1) The Federally qualified health center must agree to refund as promptly as possible any money incorrectly collected from Medicare beneficiaries or from someone on their behalf.

(2) As used in this section, "money incorrectly collected" means any amount for covered services that is greater than the amount for which the beneficiary was liable because of the coinsurance requirements specified in part 410, subpart E.

(3) Amounts also are considered incorrectly collected if the Federally qualified health center believed the beneficiary was not entitled to Medicare benefits but--

(i) The beneficiary was later determined to have been so entitled;

(ii) The beneficiary's entitlement period fell within the time the Federally qualified health center's agreement with CMS was in effect; and

(iii) The amounts exceed the beneficiary's coinsurance liability.

(e) Treatment of beneficiaries. (1) The Federally qualified health center must agree to accept Medicare beneficiaries for care and treatment.

(2) The Federally qualified health center may not impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose upon all other persons seeking care and treatment from the Federally qualified health center. Failure to comply with this requirement is a cause for termination of the Federally qualified health center's agreement with CMS in accordance with Sec. 405.2436(d).

(3) If the Federally qualified health center does not furnish treatment for certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries.

**Sec. 405.2436 Termination of agreement.**

(a) Termination by Federally qualified health center. The Federally qualified health center may terminate its agreement by--

(1) Filing with CMS a written notice stating its intention to terminate the agreement; and

(2) Notifying CMS of the date on which the Federally qualified health center requests that the termination take effect.

(b) Effective date. (1) Upon receiving a Federally qualified health center's notice of intention to terminate the agreement, CMS will set a date upon which the termination takes effect. This effective date may be--

- (i) The date proposed by the Federally qualified health center in its notice of intention to terminate, if that date is acceptable to CMS; or
  - (ii) Except as specified in paragraph (2) of this section, a date set by CMS, which is no later than 6 months after the date CMS receives the Federally qualified health center's notice of intention to terminate.
- (2) The effective date of termination may be less than 6 months following CMS's receipt of the Federally qualified health center's notice of intention to terminate if CMS determines that termination on such a date would not--
- (i) Unduly disrupt the furnishing of Federally qualified health center services to the community; or
  - (ii) Otherwise interfere with the effective and efficient administration of the Medicare program.
- (3) The termination is effective at the end of the last day of business as a Federally qualified health center.
- (c) Termination by CMS. (1) CMS may terminate an agreement with a Federally qualified health center if it finds that the Federally qualified health center--
- (i) No longer meets the requirements specified in this subpart; or
  - (ii) Is not in substantial compliance with--
    - (A) The provisions of the agreement; or
    - (B) The requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act.
- (2) Notice by CMS. CMS will notify the Federally qualified health center in writing of its intention to terminate an agreement at least 15 days before the effective date stated in the written notice.
- (3) Appeal. A Federally qualified health center may appeal CMS's decision to terminate the agreement in accordance with part 498 of this chapter.
- (d) Effect of termination. When a Federally qualified health center's agreement is terminated whether by the Federally qualified health center or CMS, payment will not be available for Federally qualified health center services furnished on or after the effective date of termination.

**Sec. 405.2440 Conditions for reinstatement after termination by CMS.**

When CMS has terminated an agreement with a Federally qualified health center, CMS will not enter into another agreement with the Federally qualified health center to participate in the Medicare program unless CMS--

- (a) Finds that the reason for the termination no longer exists; and
- (b) Is assured that the reason for the termination of the prior agreement will not recur.

**Sec. 405.2442 Notice to the public.**

(a) When the Federally qualified health center voluntarily terminates the agreement and an effective date is set for the termination, the Federally qualified health center must notify the public prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set, through publication in at least one newspaper in general circulation in the area serviced by the Federally qualified health center of the--

- (1) Effective date of termination of the provision of services; and
- (2) Effect of termination of the agreement.

(b) When CMS terminates the agreement, CMS will notify the public through publication in at least one newspaper in general circulation in the Federally qualified health center's service area.

**Sec. 405.2444 Change of ownership.**

(a) What constitutes change of ownership--(1) Incorporation. The incorporation of an unincorporated FQHC constitutes change of ownership.

(2) Merger. The merger of the center corporation into another corporation, or the consolidation of two or more corporations, one of which is the center corporation, resulting in the creation of a new corporation, constitutes a change of ownership. (The merger of another corporation into the center corporation does not constitute change of ownership.)

(3) Leasing. The lease of all or part of an entity constitutes a change of ownership of the leased portion.

(b) Notice to CMS. A center which is contemplating or negotiating change of ownership must notify CMS.

(c) Assignment of agreement. When there is a change of ownership as specified in paragraph (a) of this section, the agreement with the existing center is automatically assigned to the new owner if it continues to meet the conditions to be a Federally qualified health center.

(d) Conditions that apply to assigned agreements. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

- (1) Compliance with applicable health and safety standards.
- (2) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C of this subchapter.

**Sec. 405.2446 Scope of services.**

(a) For purposes of this section, the terms rural health clinic and clinic when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers.

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

- (1) Physician services specified in Sec. 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional services, as specified in Sec. 405.2413.

(3) Nurse practitioner or physician assistant services specified in Sec. 405.2414.

(4) Services and supplies furnished as an incident to a nurse practitioner or physician assistant services, as specified in Sec. 405.2415.

(5) Clinical psychologist and clinical social worker services specified in Sec. 405.2450.

(6) Services and supplies furnished as an incident to a clinical psychologist or clinical social worker services, as specified in Sec. 405.2452.

(7) Visiting nurse services specified in Sec. 405.2416.

(8) Nurse-midwife services specified in Sec. 405.2401.

(9) Preventive primary services specified in Sec. 405.2448 of this subpart.

(c) Federally qualified health center services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility or other institution used as a patient's home.

(d) Federally qualified health center services are not covered in a hospital, as defined in section 1861(e)(1) of the Act.

**Sec. 405.2448 Preventive primary services.**

(a) Preventive primary services are those health services that--

(1) A center is required to provide as preventive primary health services under section 329, 330, and 340 of the Public Health Service Act;

(2) Are furnished by or under the direct supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, clinical psychologist, clinical social worker, or a physician;

(3) In the case of a service, are furnished by a member of the center's health care staff who is an employee of the center or by a physician under arrangements with the center; and

(4) Except as specifically provided in section 1861(s) of the Act, include only drugs and biologicals that cannot be self-administered.

(b) Preventive primary services which may be paid for when provided by Federally qualified health centers are the following:

(1) Medical social services.

(2) Nutritional assessment and referral.

(3) Preventive health education.

(4) Children's eye and ear examinations.

(5) Prenatal and post-partum care.

(6) Perinatal services.

(7) Well child care, including periodic screening.

(8) Immunizations, including tetanus-diphtheria booster and influenza vaccine.

(9) Voluntary family planning services.

(10) Taking patient history.

(11) Blood pressure measurement.

(12) Weight.

(13) Physical examination targeted to risk.

(14) Visual acuity screening.

(15) Hearing screening.

(16) Cholesterol screening.

(17) Stool testing for occult blood.

(18) Dipstick urinalysis.

(19) Risk assessment and initial counseling regarding risks.

(20) Tuberculosis testing for high risk patients.

(21) For women only.

(i) Clinical breast exam.

(ii) Referral for mammography; and

(iii) Thyroid function test.

(c) Preventive primary services do not include group or mass information programs, health education classes, or group education activities, including media productions and publications.

(d) Screening mammography is not considered a Federally qualified health center service, but may be provided at a Federally qualified health center if the center meets the requirements applicable to that service specified in Sec. 410.34 of this subchapter. Payment is made under applicable Medicare requirements.

(e) Preventive primary services do not include eyeglasses, hearing aids, or preventive dental services.

**Sec. 405.2450 Clinical psychologist and clinical social worker services.**

(a) For clinical psychologist or clinical social worker professional services to be payable under this subpart, the services must be--

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

(2) Of a type that the clinical psychologist or clinical social worker who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker or clinical psychologist who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

(4) Covered if furnished by a physician.

(b) If State law prescribes a physician supervision requirement, it is met if the conditions specified in Sec. 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of clinical psychologists or clinical social workers are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

**Sec. 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.**

(a) Services and supplies incident to a clinical psychologist's or clinical social worker's services are reimbursable under this subpart if the service or supply is--

(1) Of a type commonly furnished in a physician's office;

(2) Of a type commonly furnished either without charge or included in the Federally qualified health center's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist or clinical social worker;

(4) Furnished under the direct, personal supervision of a clinical psychologist, clinical social worker or physician; and

(5) In the case of a service, furnished by a member of the center's health care staff who is an employee of the center.

(b) The direct personal supervision requirement in paragraph (a)(4) of this section is met only if the clinical psychologist or clinical social worker is permitted to supervise such services under the written policies governing the Federally qualified health center.

**Sec. 405.2460 Applicability of general payment exclusions.**

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for services provided by rural health clinics and Federally qualified health centers, except that preventive primary services, as defined in Sec. 405.2448, are covered in Federally qualified health centers and not excluded by the provisions of section 1862(a) of the Act.

**Sec. 405.2462** Payment for rural health clinic services and Federally qualified health clinic services.

(a) General rules. (1) RHCs and FQHCs are paid on the basis of 80 percent of an all-inclusive rate per visit determined by the fiscal intermediary for each beneficiary visit for covered services, subject to an annual payment limit.

(2) The fiscal intermediary determines the all-inclusive rate in accordance with this subpart and instructions issued by CMS.

(3) If an RHC is an integral and subordinate part of a hospital, it can receive an exception to the per-visit payment limit if the hospital has fewer than 50 beds as determined by using one of the following methods:

(i) The determination of the number of beds at Sec. 412.105(b) of this chapter.

(ii) The hospital's average daily patient census count of those beds described in Sec. 412.105(b) of this chapter, and the hospital meets all of the following conditions:

(A) It is a sole community hospital as determined in accordance with Sec. 412.92 or 412.109(a) of this chapter.

(B) It is located in a level 8 or level 9 nonmetropolitan county using urban influence codes as defined by the U.S. Department of Agriculture.

(C) It has an average daily patient census that does not exceed 40.

(b) Payment procedures. To receive payment, an RHC or FQHC must follow the payment procedures specified in Sec. 410.165 of this chapter.

(c) Mental health limitation. Payment for the outpatient treatment of mental, psychoneurotic, or personality disorders is subject to the limitations on payment in Sec. 410.155(c) of this chapter.

**Sec. 405.2463 What constitutes a visit.**

(a) Visit. (1) A visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(2) For FQHCs, a visit also means a face-to-face encounter between a patient and a qualified clinical psychologist or clinical social worker.

(3) Encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when one of the following conditions exist:

(i) After the first encounter, the patient suffers illness or injury requiring additional diagnosis or treatment.

(ii) For FQHCs, the patient has a medical visit and an other health visit, as defined in paragraphs (b) and (c) of this section.

(4) Payment. (i) Medicare pays for two visits per day when the conditions in paragraph (a)(3) of this section are met.

(ii) In all other cases, payment is limited to one visit per day.

(b) Medical visit. For purposes of paragraph (a)(3) of this section, a medical visit is a face-to-face encounter between an FQHC patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(c) Other health visit. For purposes of paragraph (a)(3) of this section, an other health visit is a face-to-face encounter between an FQHC patient and a clinical psychologist, clinical social worker, or other health professional for mental health services.

**Sec. 405.2464 All-inclusive rate.**

(a) Determination of rate. (1) An all-inclusive rate is determined by the intermediary at the beginning of the reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for rural health clinic or Federally qualified health center services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(b) Adjustment of rate. (1) The intermediary, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits for rural health clinic or Federally qualified health center services and adjusts the rate if:

(i) There is a significant change in the utilization of clinic or center services;

(ii) Actual allowable costs vary materially from the clinic or center's allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(2) The clinic or center may request the intermediary to review the rate to determine whether adjustment is required.

**Sec. 405.2466 Annual reconciliation.**

(a) General. Payments made to a rural health clinic or a Federally qualified health center during a reporting period are subject to reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) Calculation of reconciliation. (1) The total reimbursement amount due the clinic or center for covered services furnished to Medicare beneficiaries is based on the report specified in Sec. 405.2470(c)(2) and is calculated by the intermediary as follows:

(i) The average cost per visit is calculated by dividing the total allowable cost incurred for the reporting period by total visits for rural health clinic or Federally qualified health center services furnished during the period. The average cost per visit is subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of rural health clinic or Federally qualified health center services furnished to Medicare beneficiaries is calculated by multiplying the average cost per visit by the number of visits for covered rural health clinic or Federally qualified health center services by beneficiaries.

(iii) For rural health clinics, the total reimbursement due the clinic is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to rural health clinic services from the cost of these services. The reimbursement computation for

Federally qualified health centers does not include a reduction related to the deductible because Federally qualified health center services are not subject to a deductible.

(iv) For rural health clinics and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost.

(2) The total reimbursement amount due is compared with total payments made to the clinic or center for the reporting period, and the difference constitutes the amount of the reconciliation.

(c) Notice of program reimbursement. The intermediary sends written notice to the clinic or center:

(1) Setting forth its determination of the total reimbursement amount due the clinic or center for the reporting period and the amount, if any, of the reconciliation; and

(2) Informing the clinic or center of its right to have the determination reviewed at a hearing under the procedures set forth in subpart R of this part.

(d) Payment of reconciliation amount--(1) Underpayments. If the total reimbursement due the clinic or center exceeds the payments made for the reporting period, the intermediary makes a lump-sum payment to the clinic or center to bring total payments into agreement with total reimbursement due the clinic or center.

(2) Overpayments. If the total payments made to a clinic or center for the reporting period exceed the total reimbursement due the clinic or center for the period, the intermediary arranges with the clinic or center for repayment through a lump-sum refund, or, if that poses a hardship for the clinic or center, through offset against subsequent payments or a combination of offset and refund. The repayment must be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the intermediary if the intermediary is satisfied that unusual circumstances exist which warrant a longer period.

**Sec. 405.2468 Allowable costs.**

(a) Applicability of general Medicare principles. In determining whether and to what extent a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the intermediary applies the principles for reimbursement of provider costs, as set forth in part 413 of this subchapter.

(b) Typical rural health clinic and Federally qualified health center costs. The following types and items of cost are included in allowable costs to the extent that they are covered and reasonable:

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, nurse-midwife, visiting nurse, qualified clinical psychologist, and clinical social worker who owns, is employed by, or furnishes services under contract to an FQHC. (RHCs are not paid for services furnished by contracted individuals other than physicians.)

(2) Compensation for the duties that a supervising physician is required to perform under the agreement specified in Sec. 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, or clinical social worker.

(4) Overhead costs, including clinic or center administration, costs applicable to use and maintenance of the entity, and depreciation costs.

(5) Costs of services purchased by the clinic or center.

(c) Tests of reasonableness for rural health clinic cost and utilization. Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by CMS or the carrier with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. Those tests include, but are not limited to, screening guidelines and payment limitations.

(d) Screening guidelines. (1) Costs in excess of amounts established by the guidelines are not included unless the clinic or center provides reasonable justification satisfactory to the intermediary.

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, and clinical social workers.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other clinic or center personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the clinic or center, subject to the limitation that the costs of physician services purchased by the clinic or center may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

(e) Payment limitations. Limits on payments may be set by CMS, on the basis of costs estimated to be reasonable for the provision of such services.

(f) Graduate medical education. (1) Effective for that portion of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs "all or substantially all" of the costs for the training program in the nonhospital setting as defined in Sec. 413.86(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents.

(2) Direct graduate medical education costs are not included as allowable cost under Sec. 405.2466(b)(1)(i); and therefore, are not subject to the limit on the all-inclusive rate for allowable costs.

(3) Allowable graduate medical education costs must be reported on the RHC's or the FQHC's cost report under a separate cost center.

(4) Allowable graduate medical education costs are non-reimbursable if payment for these costs are received from a hospital or a Medicare+Choice organization.

(5) Allowable direct graduate medical education costs under paragraphs (f)(6) and (f)(7)(i) of this section, are subject to reasonable cost principles under part 413 and the reasonable compensation equivalency limits in Sec. Sec. 415.60 and 415.70 of this chapter.

(6) The allowable direct graduate medical education costs are those costs incurred by the nonhospital site for the educational activities associated with patient care services of an approved program, subject to the redistribution and community support principles in Sec. 413.85(c).

(i) The following costs are allowable direct graduate medical education costs to the extent that they are reasonable--

(A) The costs of the residents' salaries and fringe benefits (including travel and lodging expenses where applicable).

(B) The portion of teaching physicians' salaries and fringe benefits that are related to the time spent teaching and supervising residents.

(C) Facility overhead costs that are allocated to direct graduate medical education.

(ii) The following costs are not allowable graduate medical education costs--

(A) Costs associated with training, but not related to patient care services.

(B) Normal operating and capital-related costs.

(C) The marginal increase in patient care costs that the RHC or FQHC experiences as a result of having an approved program.

(D) The costs associated with activities described in Sec. 413.85(h) of this chapter.

(7) Payment is equal to the product of--

(i) The RHC's or the FQHC's allowable direct graduate medical education costs; and

(ii) Medicare's share, which is equal to the ratio of Medicare visits to the total number of visits (as defined in Sec. 405.2463).

(8) Direct graduate medical education payments to RHCs and FQHCs made under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

**Sec. 405.2470 Reports and maintenance of records.**

(a) Maintenance and availability of records. The rural health clinic or Federally qualified health center must:

(1) Maintain adequate financial and statistical records, in the form and containing the data required by CMS, to allow the intermediary to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets is allowable rather than the expenditure for the capital asset.

(b) Adequacy of records. (1) The intermediary may suspend reimbursement if it determines that the clinic or center does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension continues until the clinic or center demonstrates to the intermediary's satisfaction that it does, and will continue to, maintain adequate records.

(c) Reporting requirements--(1) Initial report. At the beginning of its initial reporting period, the clinic or center must submit an estimate of budgeted costs and visits for rural health clinic or Federally qualified health center services for the reporting period, in the form and detail required by CMS, and such other information as CMS may require to establish the payment rate.

(2) Annual reports. Within 90 days after the end of its reporting period, the clinic or center must submit, in such form and detail as may be required by CMS, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for rural health clinic or Federally qualified health center services furnished during the period; and

(ii) The estimated costs and visits for rural health clinic services or Federally qualified health center services for the succeeding reporting period and such other information as CMS may require to establish the payment rate.

(3) Late reports. If the clinic or center does not submit an adequate annual report on time, the intermediary may reduce or suspend payments to preclude excess payment to the clinic or center.

(4) Inadequate reports. If the clinic or center does not furnish a report or furnishes a report that is inadequate for the intermediary to make a determination of program payment, CMS may deem all payments for the reporting period to be overpayments.

(5) Postponement of due date. For good cause shown by the clinic or center, the intermediary may, with CMS's approval, grant a 30-day postponement of the due date for the annual report.

(6) Reports following termination of agreement or change of ownership. The report from a clinic or center which voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change in ownership (see Sec. Sec. 405.2436-405.2438) is due no later than 45 days following the effective date of the termination of agreement or change of ownership.

#### **Sec. 405.2472 Beneficiary appeals.**

A beneficiary may request a hearing by an intermediary (subject to the limitations and conditions set forth in subpart H of this part) if:

(a) The beneficiary is dissatisfied with an intermediary's determination denying a request for payment made on his or her behalf by a rural health clinic or Federally qualified health center; or

- (b) The beneficiary is dissatisfied with the amount of payment; or
- (c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.