

§ 405.2123

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 §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 (§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.

[43 FR 48951, Oct. 19, 1978, as amended at 45 FR 58124, Sept. 2, 1980; 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 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

42 CFR Ch. IV (10–1–06 Edition)

and the number performed during each of the preceding 2 calendar years.

[55 FR 23441, June 8, 1990]

§ 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.

§ 405.2130 Condition: Minimum utilization rates.

Unless a renal transplantation center is granted an exception under §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.

[55 FR 23441, June 8, 1990]

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

A renal transplantation center or a renal dialysis center (§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.

§ 405.2132 [Reserved]

§ 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).

[53 FR 6548, Mar. 1, 1988]

§ 405.2134 Condition: Participation in network activities.

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

[51 FR 30362, Aug. 26, 1986]

§ 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.

§ 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 pa-

tients' 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 (§ 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 percent 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.