

Centers for Medicare & Medicaid Services, HHS

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(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.

[53 FR 1620, Jan. 21, 1988]

§ 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).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§ 405.2114 [Reserved]

§ 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 §§ 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.

[55 FR 23440, June 8, 1990]

§ 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:

(a) Information on the geographic distribution of ESRD patients and facilities;

(b) Information on quality of care; and

(c) Information on operational and management efficiency.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 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 § 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent classification occurs. (See § 405.2123 for reporting requirements; § 405.2124 for method of calculating rates; § 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

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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

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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,