

(2) Data furnished by ESRD network organizations and recommendations of the Public Health Service concerning the facility's contribution to the ESRD services of the network.

(3) Data concerning the facility's compliance with professional norms and standards.

(4) Data pertaining to the facility's qualifications for approval or for any expansion of services.

(b) *Determining compliance with minimal utilization rates: Time limitations*—(1) *Unconditional status.* A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements.

(2) *Conditional status.* A conditional status may be granted to a facility for not more than four consecutive calendar years and will not be renewable (see § 405.2122(b) of this chapter). Its status may be examined each calendar year to ascertain its compliance with Subpart U.

(3) *Exception status.* Under unusual circumstances (see § 405.2122 (b) of this chapter) the Secretary may grant a time-limited exception to a facility which is not in compliance with the minimal utilization rate(s) for either unconditional status or conditional status. This exception status may be granted, and may be renewed on an annual basis, under circumstances where rigid application of minimal utilization rate requirements would adversely affect the achievement of ESRD program objectives.

(c) *New applicant.* A facility which has not previously participated in the ESRD program must submit a plan detailing how it expects to meet the conditional minimal utilization rate status by the end of the second calendar year of its operation under the program and meet the unconditional minimal utilization rate status by the end of the fourth calendar year of its operation under the program.

(d) *Notification.* The Secretary will notify each facility and its network coordinating council of its initial and its subsequent minimal utilization rate classification.

(e) *Failure to meet minimal utilization rate.* A facility failing to meet standards for unconditional status or condi-

tional status, or if applicable, for exception status, will be so notified at the time of such classification.

(f) *Interim regulations participant.* A facility previously participating under the interim regulations will not be approved under the program established by subpart U until it has demonstrated that it meets all the applicable requirements of this subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see § 405.2100(c) of this chapter). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this subpart will automatically terminate coverage of such facility's services under the ESRD program at the end of such year.

[41 FR 22510, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and further amended at 45 FR 58124, Sept. 2, 1980. Redesignated and amended at 53 FR 23100, June 17, 1988; 73 FR 20474, Apr. 15, 2008]

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

For the purposes of this subpart, the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A apply to transplant centers, including the periodic review of compliance and approval described at § 488.20.

(a) *Initial approval procedures for transplant centers that are not Medicare-approved as of June 28, 2007.* A transplant center, including a kidney transplant center, may submit a request to CMS for Medicare approval at any time.

(1) The request, signed by a person authorized to represent the center (for example, a chief executive officer), must include:

(i) The hospital's Medicare provider I.D. number;

(ii) Name(s) of the designated primary transplant surgeon and primary transplant physician; and,

(iii) A statement from the OPTN that the center has complied with all data submission requirements.

(2) To determine compliance with the clinical experience and outcome requirements at §§ 482.80(b) and 482.80(c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Beneficiary (SRTR) center-specific report.

(3) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements, CMS may deny the request for approval or may review the center's compliance with the conditions of participation at §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, of the effective date of its approval.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering initial approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements, CMS will review the center's compliance with the conditions of participation contained at §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter using the procedures described at 42 CFR part 488, subpart A. If the transplant center is found to be in compliance with all the conditions of participation at §§ 482.72 through 482.104, except for § 482.82 of

this chapter (Re-approval Requirements), CMS will notify the transplant center in writing of the effective date of its Medicare-approval. CMS will notify the transplant center in writing if it is not Medicare-approved.

(6) A kidney transplant center may submit a request for initial approval after performing at least 3 transplants over a 12-month period.

(7) Transplant centers will be approved for 3 years.

(b) *Initial approval procedures for transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007.* (1) A transplant center that wants to continue to be Medicare approved must be in compliance with the conditions of participation at §§ 482.72 through 482.104 as of June 28, 2007 and submit a request to CMS for Medicare approval under the conditions of participation no later than December 26, 2007, using the process described in paragraph (a)(1) of the section.

(2) CMS will determine whether to approve the transplant center, using the procedures described in paragraphs (a)(2) through (a)(5) of this section. Until CMS makes a determination whether to approve the transplant center under the conditions of participation at §§ 482.72 through 482.104, the transplant center will continue to be Medicare approved under the end stage renal disease (ESRD) conditions for coverage (CfCs) in part 405, subpart U of this chapter for kidney transplant centers or the pertinent national coverage decisions (NCDs) for extra-renal organ transplant centers, as applicable, and the transplant center will continue to be reimbursed for services provided to Medicare beneficiaries.

(3) Once CMS approves a kidney transplant center under the conditions of participation, the ESRD CfCs no longer apply to the center as of the date of its approval. Once CMS approves an extra-renal organ transplant center under the conditions of participation, the NCDs no longer apply to the center as of the date of its approval.

(4) If a transplant center that is Medicare approved as of June 28, 2007 submits a request for approval under the CoPs at §§ 482.72 through 482.104 of

this chapter but CMS does not approve the transplant center, or if the transplant center does not submit its request to CMS for Medicare approval under the CoPs by December 26, 2007, CMS will revoke the transplant center's approval under the conditions for coverage for kidney transplant centers or the national coverage decisions for extra-renal transplant centers, as applicable, and the transplant center will no longer be reimbursed for services provided to Medicare beneficiaries. CMS will notify the transplant center in writing of the effective date of its loss of Medicare approval.

(c) *Re-approval procedures.* Once Medicare-approved, transplant centers, including kidney transplant centers, must be in compliance with all the conditions of participation for transplant centers at §§ 482.72 through 482.104 of this chapter, except for § 482.80 (initial approval requirements) throughout the 3-year approval period.

(1) Prior to the end of the 3-year approval period, CMS will review the transplant center's data in making re-approval determinations.

(i) To determine compliance with the data submission requirements at § 482.82(a) of this chapter, CMS will request data submission data from the OPTN for the previous 3 calendar years.

(ii) To determine compliance with the clinical experience and outcome requirements at § 482.82(b) and § 482.82(c) of this chapter, CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent SRTR center-specific reports.

(2) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements at § 482.82, the transplant center will be reviewed for compliance with §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(3) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements at § 482.82, CMS may choose to review the transplant center for compliance with §§ 482.72 through

482.76 and §§ 482.90 through 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (*e.g.*, natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may re-approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) CMS will notify the transplant center in writing if its approval is being revoked and of the effective date of the revocation.

(d) *Loss of Medicare Approval.* Centers that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A center that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in § 488.61(a);

(2) Be in compliance with §§ 482.72 through 482.104 of this chapter, except for § 482.82 (Re-approval Requirements), at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the center as a result of the loss of its Medicare approval status.

(e) *Transplant Center Inactivity.* A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months during the 3-year approval cycle. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(d) of this chapter.

[72 FR 15278, Mar. 30, 2007]

§ 488.64 Remote facility variances for utilization review requirements.

(a) As used in this section: