

§ 488.56 Temporary waivers applicable to skilled nursing facilities.

(a) *Waiver of 7-day registered nurse requirement.* To the extent that § 483.30 of this chapter requires any skilled nursing facility to engage the services of a registered nurse more than 40 hours a week, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individual patients therein.

(2) Such facility has at least one fulltime registered nurse who is regularly on duty at such facility 40 hours a week, and

(3) Such facility (i) has only patients whose attending physicians have indicated (through physicians' orders or admission notes) that each such patient does not require the services of a registered nurse for a 48-hour period, or (ii) has made arrangements for a registered nurse or a physician to spend such time at the facility as is determined necessary by the patient's attending physician to provide necessary services on days when the regular fulltime registered nurse is not on duty.

(4) Such facility has made and continues to make a good faith effort to comply with the more than 40-hour registered nurse requirement, but such compliance is impeded by the unavailability of registered nurses in the area.

(b) *Waiver of medical director requirement.* To the extent that § 488.75(i) of this chapter requires any skilled nursing facility to engage the services of a medical director either part-time or full-time, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in an area where the supply of physicians is not sufficient to permit compliance with this requirement without seriously reducing the availability of physician services within the area, and

(2) Such facility has made and continues to make a good faith effort to

comply with § 488.75(i) of this chapter, but such compliance is impeded by the unavailability of physicians in the area.

[39 FR 35777, Oct. 3, 1974. Redesignated and amended at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 53 FR 23100, June 17, 1988, and further amended at 56 FR 48879, Sept. 26, 1991; 57 FR 43925, Sept. 23, 1992]

§ 488.60 Special procedures for approving end stage renal disease facilities.

(a) *Consideration for approval.* An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494 of this chapter, must secure a determination by the Secretary. To secure a determination, the facility must submit the following documents and data for consideration by the Secretary:

(1) Certification by the State agency referred to in § 488.12 of this part.

(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

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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 conditional 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 Recipient (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