§488.64  [42 CFR Ch. IV (10–1–10 Edition)]

(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:

(1) An “available” individual is one who:

(i) Possesses the necessary professional qualifications;

(ii) Is not precluded from participating by reason of financial interest in any such facility or direct responsibility for the care of the patients being reviewed or, in the case of a skilled nursing facility, employment by the facility; and

(iii) Is not precluded from effective participation by the distance between the facility and his residence, office, or other place of work. An individual whose residence, office, or other place of work is more than approximately one hour’s travel time from the facility shall be considered precluded from effective participation.

(2) “Adjacent facility” means a health care facility located within a 50-mile radius of the facility which requests a variance.

(b) The Secretary may grant a requesting facility a variance from the time frames set forth in §§405.1137(d) of this chapter and 482.30 as applicable, within which reviews of cases must
Centers for Medicare & Medicaid Services, HHS  
§ 488.68 State Agency responsibilities for OASIS collection and data base requirements.

As part of State agency survey responsibilities, the State agency or other entity designated by CMS has overall responsibility for fulfilling the following requirements for operating the OASIS system:

(a) Establish and maintain an OASIS database. The State agency or other entity designated by CMS must—

(1) Establish and maintain an OASIS database.

(2) Document the requesting facility’s inability to meet the requirements for which a variance is requested and the facility’s good faith efforts to comply with the requirements contained in §405.1137 of this chapter or §482.30 of this chapter, as applicable.

(3) The request shall include an assurance by the requesting facility that it will continue its good faith efforts to meet the requirements contained in §405.1137 of this chapter or §482.30 of this chapter, as applicable.

(4) The request shall include the names of all physicians on the active staff of the facility and the names of all other professional personnel on the staff of the facility, or both.

(5) The name, location, and type of each adjacent facility (e.g., hospital, skilled nursing facility);

(6) The distance and average travel time between the facility and each adjacent facility;

(7) As relevant to the request, the location of practice of available physicians and the estimated number of other available professional personnel, or both (see paragraph (a)(1)(iii) of this section);

(8) Documentation by the facility of its attempt to obtain the services of available physicians or other professional personnel, or both; and

(9) A statement of whether a QIO exists in the area where the facility is located.

(g) The Secretary shall promptly notify the facility of the action taken on the request. Where a variance is in effect, the validation of utilization review pursuant to §405.1137 of this chapter or §482.30 shall be made with reference to the revised utilization review plan submitted with the request for variance.

(h) The Secretary, in granting a variance, will specify the period for which the variance has been granted; such period will not exceed one year. A request for a renewal shall be submitted not later than 30 days prior to the expiration of the variance and shall contain all information required by paragraphs (c), (d), and (f) of this section. Renewal of the variance will be contingent upon the facility’s continuing to meet the provisions of this section.