

§ 488.64

42 CFR Ch. IV (10–1–23 Edition)

(vi) Development of increased proficiency, or demonstration of current proficiency, with patient-level data from the Scientific Registry of Transplant Recipients and the use of registry data to analyze outcomes and inform quality improvement efforts;

(vii) A staffing analysis that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate training and credentialing of staff;

(viii) Activities to strengthen performance of the Quality Assessment and Performance Improvement Program to ensure full compliance with the requirements of § 482.96 and § 482.21 of this chapter;

(ix) Monthly (unless otherwise specified) reporting and conference calls with CMS regarding the status of programmatic improvements, results of the deliverables in the Systems Improvement Agreement, and the number of transplants, deaths, and graft failures that occur within 1 year post-transplant; and

(x) Additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances. CMS may waive the content elements at paragraph (g)(1)(v), (vi), (vii) or (viii) of this section if it finds that the program has already adequately conducted the activity, the program is already proficient in the function, or the activity is clearly inapplicable to the deficiencies that led to the Agreement.

(2) *Timeframe.* A Systems Improvement Agreement will be established for up to a 12-month period, subject to CMS' discretion to determine if a shorter timeframe may suffice. At the hospital's request, CMS may extend the agreement for up to an additional 6-month period. A signed Systems Improvement Agreement remains in force even if a subsequent SRTR report indicates that the program has restored compliance with the CMS conditions of participation, except that CMS in its sole discretion may shorten the timeframe or allow modification to any

portion of the elements of the Agreement in such a case.

[72 FR 15278, Mar. 30, 2007, as amended at 79 FR 27156, May 12, 2014; 79 FR 50359, Aug. 22, 2014; 81 FR 79881, Nov. 14, 2016; 84 FR 51831, Sept. 30, 2019]

§ 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 all of cases must be commenced and completed, upon a showing satisfactory to the Secretary that the requesting facility has been unable to meet one or more of the requirements of § 405.1137 of this chapter or § 482.30 of this chapter, as applicable, by reason of insufficient medical and other professional personnel available to conduct the utilization review required by § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(c) The request for variance shall 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.

(d) 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.

(e) A revised utilization review plan for the requesting facility shall be submitted concurrently with the request for a variance. The revised plan shall specify the methods and procedures which the requesting facility will use, if a variance is granted, to assure:

(1) That effective and timely control will be maintained over the utilization of services; and

(2) That reviews will be conducted so as to improve the quality of care provided to patients.

(f) The request for a variance shall include:

(1) The name, location, and type (e.g., hospital, skilled nursing facility) of the facility for which the variance is requested;

(2) The total number of patient admissions and average daily patient census at the facility within the previous six months;

(3) The total number of title XVIII and title XIX patient admissions and the average daily patient census of title XVIII and title XIX patients in the facility within the previous six months;

(4) As relevant to the request, 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.

[40 FR 30818, July 23, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977; 51 FR 22041, June 17, 1986; 51 FR 27847, Aug. 4, 1986; 51 FR 43197, Dec. 1, 1986. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 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) Use a standard system developed or approved by CMS to collect, store, and analyze data;

(2) Conduct basic system management activities including hardware and software maintenance, system back-up, and monitoring the status of the database; and

(3) Obtain CMS approval before modifying any parts of the CMS standard system including, but not limited to, standard CMS-approved—

(i) OASIS data items;

(ii) Record formats and validation edits; and

(iii) Agency encoding and transmission methods.

(b) *Analyze and edit OASIS data.* The State agency or other entity designated by CMS must—