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 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.

(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...
§ 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;

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—

1. Upon receipt of data from an HHA, edit the data as specified by CMS and ensure that the HHA resolves errors within the limits specified by CMS;

2. At least monthly, make available for retrieval by CMS all edited OASIS records received during that period, according to formats specified by CMS, and correct and retransmit previously rejected data as needed; and

3. Analyze data and generate reports as specified by CMS.

(c) Ensure accuracy of OASIS data. The State agency must audit the accuracy of the OASIS data through the survey process.

(d) Restrict access to OASIS data. The State agency or other entity designated by CMS must do the following:

1. Ensure that access to data is restricted except for the transmission of data and reports to—

(i) CMS;

(ii) The State agency component that conducts surveys for purposes related to this function; and

(iii) Other entities if authorized by CMS.

2. Ensure that patient identifiable OASIS data is released only to the extent that it is permitted under the Privacy Act of 1974.