

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 in accordance with paragraphs (f), (g), and (h) of this section.

(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.

(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,

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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 continuous 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).

(1) CMS will review the transplant center's data on an on-going basis and 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 (c) of this chapter, CMS will review the data contained in the most recent OPTN Data Report for the previous 3 years and 1-year patient and graft survival data contained in the most recent SRTR center-specific reports.

(2) 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.

(3) CMS will consider mitigating factors in accordance with paragraphs (f), (g), and (h) of this section.

(4) 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. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(a)(3) of this chapter.

(f) *Consideration of mitigating factors in initial approval and re-approval survey, certification, and enforcement actions for transplant centers—(1) Factors.* Except for situations of immediate jeopardy or deficiencies other than failure to meet requirements of § 482.80 or § 482.82 of this chapter, CMS will consider such mitigating factors as may be appropriate in light of the nature of the deficiency and circumstances, including (but not limited to) the following, in making a decision of initial and re-approval of a transplant center that does not meet the data submission, clinical experience, or outcome requirements:

(i) The extent to which outcome measures are not met or exceeded;

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

(iii) Extenuating circumstances (for example, natural disaster) that have a temporary effect on meeting the conditions of participation;

(iv) Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available SRTR report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at § 482.80(c)(2)(ii)(C) or § 482.82(c)(2)(ii)(C) of this chapter;

(v) Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone a Fontan procedure compared to most other transplant programs, where CMS finds that the innovative practices are supported by evidence-based published research literature or nationally recognized standards or Institution Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and

(vi) Whether the program's performance, based on the OPTN method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy.

(2) *Content.* A request for consideration of mitigating factors must include sufficient information to permit an adequate review and understanding of the transplant program, the factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and in the case of natural disasters, the recovery actions planned. Examples of information to be submitted with each request include (but are not limited to) the following:

(i) The name and contact information for the transplant hospital and the

names and roles of key personnel of the transplant program;

(ii) The type of organ transplant program(s) for which approval is requested;

(iii) The conditions of participation that the program does not meet for which the transplant center is requesting CMS' review for mitigating factors;

(iv) The program's organizational chart with full-time equivalent levels, roles, and structure for reporting to hospital leadership;

(v) For applications involving substandard patient or graft survival, the rationale and supporting evidence for CMS' review includes, but is not limited to—

(A) Root Cause Analysis for patient deaths and graft failures, including factors the program has identified as likely causal or contributing factors for patient deaths and graft failures;

(B) Program improvements that have been implemented and improvements that are planned;

(C) Patient and donor/organ selection criteria and evaluation protocols, including methods for pre-transplant patient evaluation by cardiologists, hematologists, nephrologists, and psychiatrists or psychologists to the extent applicable;

(D) Waitlist management protocols and practices relevant to outcomes;

(E) Pre-operative management protocols and practices;

(F) Immunosuppression/infection prophylaxis protocols;

(G) Post-transplant monitoring and management protocols and practices;

(H) Quality Assessment and Performance Improvement (QAPI) Program meeting minutes from the most recent four meetings and attendance rosters from the most recent 12 months;

(I) Quality dashboard and other performance indicators; and

(J) The most recent data regarding transplants that have been made and for outcomes in terms of both patient survival and graft survival;

(vi) For mitigating factors requests based on innovative practice:

(A) A description of the innovations that have been implemented and identification of the specific cases for which the innovative practices are relevant so as to enable the patient and

graft survival data for such cases to be compared with all other transplants for at least the period covered by the latest available SRTR report.

(B) The literature, research, or other evidentiary basis that supports consideration of the practice(s) as innovative.

(vii) For requests based on natural disasters or public health emergency:

(A) A description of the disaster or emergency, the specific impact on the program, the time periods of the event(s) and of its immediate recovery aftermath;

(B) Identification of the transplants that occurred during the period for which the request is being made; and

(C) The approximate date when the program believes it substantially recovered from the event(s), or believes it will recover if substantial recovery has not been accomplished at the time of the request.

(3) *Timing.* Within 14 calendar days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval or re-approval, and receive all information for consideration of mitigating factors within 120 calendar days of the CMS written notification for a deficiency due to data submission, clinical experience or outcomes at § 482.80 or § 482.82 of this chapter. Failure to meet these timeframes may be the basis for denial of mitigating factors. However, CMS may permit an extension of the timeline for good cause, such as a declared public health emergency.

(g) *Results of mitigating factors review—(1) Actions.* Upon review of the request to consider mitigating factors, CMS may take the following actions:

(i) Approve initial approval or re-approval of a program's Medicare participation based upon approval of mitigating factors;

(ii) Deny the program's request for Medicare approval or re-approval based on mitigating factors.

(iii) Offer a time-limited Systems Improvement Agreement, in accordance with paragraph (h) of this section, when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institution-

ally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the Systems Improvement Agreement or a CMS finding that the hospital has failed to meet the terms of the Agreement, CMS makes a final determination of whether to approve or deny a program's request for Medicare approval or re-approval based on mitigating factors. A Systems Improvement Agreement follows the process specified in paragraph (h) of this section.

(2) *Limitation.* 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.

(h) *Transplant Systems Improvement Agreement.* A Systems Improvement Agreement is a binding agreement, entered into voluntarily by the hospital and CMS, through which CMS extends a prospective Medicare termination date and offers the program additional time to achieve compliance with the conditions of participation, contingent on the hospital's agreement to participate in a structured regimen of quality improvement activities, demonstrate improved outcomes, and waive the right to appeal termination based on the identified deficiency or deficiencies (that led to the Agreement) in consideration for more time to demonstrate compliance. In some cases, transplant programs may enter a period of inactivity—voluntarily, or imposed as a condition of the Systems Improvement Agreement.

(1) *Content.* In exchange for the additional time to initiate or continue activities to achieve compliance with the conditions of participation, the hospital must agree to a regimen of specified activities, including (but not limited to) all of the following:

(i) Patient notification about the degree and type of noncompliance by the program, an explanation of what the program improvement efforts mean for patients, and financial assistance to defray the out-of-pocket costs of co-payments and testing expenses for any

wait-listed individual who wishes to be listed with another program;

(ii) An external independent peer review team that conducts an onsite assessment of the program. The peer review must include—

(A) Review of policies, staffing, operations, relationship to hospital services, and factors that contribute to program outcomes;

(B) Suggestions for quality improvements the hospital should consider;

(C) Both verbal and written feedback provided directly to the hospital;

(D) Verbal debriefing provided directly to CMS; neither the hospital nor the peer review team is required to provide a written report to CMS; and

(E) Onsite review by a multidisciplinary team that includes a transplant surgeon with expertise in the relevant organ type(s), a transplant administrator, an individual with expertise in transplant QAPI systems, a social worker or psychologist or psychiatrist, and a specialty physician with expertise in conditions particularly relevant to the applicable organ types(s) such as a cardiologist, nephrologist, or hepatologist. Except for the transplant surgeon, CMS may permit substitution of one type of expertise for another individual who has expertise particularly needed for the type of challenges experienced by the program, such as substitution of an infection control specialist in lieu of, or in addition to, a social worker;

(iii) An action plan that addresses systemic quality improvements and is updated after the onsite peer review;

(iv) An onsite consultant whose qualifications are approved by CMS, and who provides services for 8 days per month on average for the duration of the agreement, except that CMS may permit a portion of the time to be spent offsite and may agree to fewer consultant days each month after the first 3 months of the Systems Improvement Agreement;

(v) A comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs;

(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 paragraphs (h)(1)(v), (h)(1)(vi), (h)(1)(vii), or (h)(1)(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

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

transplant program in writing if it is not Medicare-approved.

[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]

EFFECTIVE DATE NOTE: At 84 FR 51831, Sept. 30, 2019, § 488.61 was amended—

- a. By revising the section heading;
- b. In the introductory text by removing the phrase “transplant centers” and adding in its place the phrase “transplant programs”;
- c. In paragraph (a) introductory text by removing the words “centers” and “center” each time they appear and adding in their place the words “programs” and “program,” respectively;
- d. In paragraph (a)(2) by removing the phrase “Scientific Registry of Transplant Beneficiary (SRTR) center-specific” and adding in its place the phrase “Scientific Registry of Transplant Recipient (SRTR) program-specific”;
- e. By revising paragraph (a)(5);
- f. By removing paragraph (c);
- g. By redesignating paragraphs (d) through (h) as paragraphs (c) through (g), respectively;
- h. By revising newly redesignated paragraphs (c) and (d), the newly redesignated paragraph (e) subject heading, and newly redesignated paragraphs (e)(1) introductory text, (e)(1)(iv), (e)(3), and (f)(1)(i) through (iii); and
- i. In newly redesignated paragraph (g)(1)(x) by removing the reference “paragraphs (h)(1)(v), (h)(1)(vi), (h)(1)(vii) or (h)(1)(viii)” and adding in its place the reference “paragraph (g)(1)(v), (vi), (vii) or (viii)”.

The amendments are effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

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

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(a) * * *

(5) If CMS determines that a transplant program has met the data submission, clinical experience, and outcome requirements, CMS will review the program’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 in subpart A of this part. If the transplant program is found to be in compliance with all the conditions of participation at §§ 482.72 through 482.104 of this chapter, CMS will notify the transplant program in writing of the effective date of its Medicare-approval. CMS will notify the

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

- (1) Request initial approval using the procedures described in paragraph (a) of this section;
- (2) Be in compliance with §§ 482.72 through 482.104 of this chapter 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 program as a result of the loss of its Medicare approval status.

(d) *Transplant program inactivity.* A transplant program may remain inactive and retain its Medicare approval for a period not to exceed 12 months. A transplant program must notify CMS upon its voluntary inactivation as required by § 482.74(a)(3) of this chapter.

(e) *Consideration of mitigating factors in initial approval survey, certification, and enforcement actions for transplant programs—(1) Factors.* Except for situations of immediate jeopardy or deficiencies other than failure to meet requirements at § 482.80 of this chapter, CMS will consider such mitigating factors as may be appropriate in light of the nature of the deficiency and circumstances, including (but not limited to) the following, in making a decision of initial approval of a transplant program that does not meet the data submission, clinical experience, or outcome requirements:

* * * * *

(iv) Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available SRTR report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at § 482.80(c)(2)(ii)(C) of this chapter;

* * * * *

(3) *Timing.* Within 14 calendar days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program’s intent to seek mitigating factors approval, and receive all information for consideration of mitigating factors within 120

calendar days of the CMS written notification for a deficiency due to data submission, clinical experience or outcomes at § 482.80 of this chapter. Failure to meet these timeframes may be the basis for denial of mitigating factors. CMS may permit an extension of the timeline for good cause, such as a declared public health emergency.

(f) * * *

(1) * * *

(i) Approve initial approval of a program's Medicare participation based upon approval of mitigating factors.

(ii) Deny the program's request for Medicare approval based on mitigating factors.

(iii) Offer a time-limited Systems Improvement Agreement, in accordance with paragraph (g) of this section, when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the Systems Improvement Agreement or a CMS finding that the hospital has failed to meet the terms of the Agreement, CMS makes a final determination of whether to approve or deny a program's request for Medicare approval based on mitigating factors. A Systems Improvement Agreement follows the process specified in paragraph (g) of this section.

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§ 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