

Center for Medicaid and State Operations/Survey and Certification Group

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DATE: April 4, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Transplant Surveys: Guidance for Citing Condition and Standard-Level Deficiencies For Certain Regulatory Requirements and Allowing Additional Time to Correct the Deficiency

Memorandum Summary

- **Consistency in Citing the Level of Deficiency:** This memorandum provides guidelines for determining the level of non-compliance when deficiencies are cited under the clinical experience (volume) requirements or the survival outcome requirements in organ transplant programs.
- **Time for Correcting Deficiencies:** Organ transplant programs that are surveyed for the first time under the new transplant regulations and receive Condition-level deficiencies in the areas of clinical experience (volume) or outcomes will be given a specific timeframe to come into compliance with the Condition before Medicare approval is terminated.

A. Background:

In the organ transplant Conditions of Participation (CoPs) certain types of transplant programs have minimum requirements for the number of transplants they must perform in a given period (42 CFR 482.80(b) and 42 CFR 482.82(b)), and for the patient and graft survival outcome rates (42 CFR 482.80(c) and 42 CFR 482.82(b)). Compliance with these requirements is evaluated using the objective values that are reported by the transplant programs to the national Scientific Registry of Transplant Recipients (SRTR). These are objective values measured against objective regulatory criteria. Therefore, to promote consistency across the surveyor community in making determinations as regards the level of non-compliance (Condition-level and Standard-level) for these values, we are incorporating guidelines for these determinations within our State Operations Manual (SOM) for transplant program surveys. This letter outlines those guidelines that must be used by surveyors for the initial approval surveys in determining the level of deficiency for volume and outcome in anticipation of the soon to be cleared SOM sections.

The objective values to which we refer in this letter are provided to every surveyor via the Transplant Program Quarterly Report (TPQR). The TPQR is shared with the survey team in advance of each transplant program survey. The TPQR conveys key information about the transplant program as regards most recent SRTR calculations of volume and outcome as well as other areas. In the case of volume, the surveyor may need to verify onsite that additional, more recent information is not available at the transplant program as it pertains to compliance with this regulatory requirement.

B. Clinical Experience Requirements: Determining the Level of Non-Compliance

The clinical experience requirements of the transplant program CoPs are as follows:

- Section 42 CFR 482.80(b) requires certain transplant programs to have performed 10 transplants over a 12-month period to be considered for initial approval.
- Section 42 CFR 482.82(b) requires certain transplant programs to have performed an average of 10 transplants during the re-approval period to be considered for re-approval.

To determine the level of the deficiency for the clinical experience (volume) requirement outlined under 42 CFR 482.80(b) and 42 CFR 482.82(b), surveyors must adhere to the following:

For Initial Approval under 42 CFR 482.80(b):

Part 1: If the transplant program has done 8 or more transplants in the past 12 months, cite a deficiency at the *Standard Level*.

Part 2: If the transplant program has done less than 8 transplants in the past 12 months cite a deficiency at the *Condition Level*.

For Re-approval under 42 CFR 482.82(b):

If the transplant program has done an average of 8 or more per year over the re-approval period and has done at least 4 transplants in the past 12 months, cite a deficiency at the *Standard Level*. Otherwise, cite the deficiency at the *Condition Level*.

Transplant programs will be given an extended timeframe to come into compliance with Condition-level deficiencies in this area. This extended timeframe is discussed in more detail below. Please note that a program's inactivation does not create an exception to the clinical experience requirements.

C. Outcome Requirements: Determining the Level of Non-Compliance

The outcome requirements for the regulation do not differentiate between the process for initial approval and the process for re-approval. The outcome requirements within the transplant program Conditions of Participation are as follows:

- The regulation specifies a transplant program's 1-year post-transplant patient and graft survival rates to be unacceptable if the observed survival is lower than the expected survival to such an extent that (1) the one-sided p-value is less than .05; (2) the number of observed events minus the expected events is greater than 3; and (3) the number of observed events divided by the number of expected events is greater than 1.5.

The regulation requires that the outcome measures used for survey evaluation are from the most recent Center-Specific Report from the SRTR. The “expected” patient and graft survival rate is calculated by the SRTR which considers transplant patient and donor characteristics to establish a risk-adjusted outcome measure. A transplant program cannot calculate on its own what their “expected” survival rate should be.

Since the outcome measures are reported 1-year post transplant, the risk-adjusted outcomes that are published by the SRTR are based on transplants that were performed between 1 year and 3.5 years prior to the publication date of the most recent report. This has implications for a surveyor’s assessment of the outcome requirements. To determine the level of non-compliance for the outcome measure surveyors should follow the guidance below:

Part 1 for Out-of-Compliance Cases: In cases where the program is out of compliance with the outcome requirement of the regulation but has had recent *unadjusted* survival rates that are very favorable, the surveyor may consider these survival rates in determining the level of the deficiency to cite. In these cases, surveyors should review the unadjusted patient and graft survival rate reported by the transplant program over the most recent 2 year period to determine if both patient and graft survival was at 100%. (This will allow for the consideration of improvements that may not yet be evident from the SRTR reports.)

- A. If both patient and graft survival have been 100% for both of the previous 2 years, cite a deficiency at the ***Standard Level*** since the regulatory requirements are still not met, but the program has made recent improvements.
- B. If patient and/or graft survival were below 100% for either of the past 2 years, go to Part 2 below.

Note: The standard for Part 1A of 100% survival may seem quite rigorous. It is set at 100% to avoid the need to evaluate unadjusted survival rates. If the program meets Part 1A, cite a Standard level deficiency (since the program still does not meet the regulatory outcome requirements) but do not go to Part 2. If the program does not meet Part 1A, proceed to Part 2.

Part 2: Surveyors use the criteria in the Table below to review the pervasiveness and duration of the transplant program outcomes from the Center-Specific SRTR reports using the criteria below to determine whether a Condition-level finding is warranted.

Table: Pervasiveness & Duration of Outcome Deficiency

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|---|
| Area of Evaluation - Number of Recent SRTR Center-Specific Reports that Do Not Meet the Outcome Requirements |
| Method of Receiving Information - To be provided by CMS CO in the Transplant Program Quarterly Report (TPQR) |
| Standard - The most recent SRTR report shows that the program did not meet outcome requirements, <u>but</u> none of the four outcome reports prior to the most recent show that the program was not in compliance, <i>then cite at the Standard Level</i> |
| Condition - The most recent SRTR report shows that the program did not meet outcome requirements, <u>and</u> 1 or more of the four outcome reports prior to the most recent show noncompliance, <i>then cite at the Condition Level</i> |

If, based on the criteria above, the pervasiveness of poor outcomes indicate that a Condition-level deficiency is warranted, then a Condition-level deficiency should be cited.

Notwithstanding the above table, a Condition-level finding may be cited if more than one Standard under this Condition (i.e., data submission, clinical experience, and outcomes) is out of compliance.

D. Time Allowed for Correction of Condition-Level Deficiencies Due to Non-Compliance with Clinical Experience and/or Outcomes Measurements

A provider that does not substantially meet the CoPs is considered to be limited in its capacity to furnish services at an adequate level or quality. CoPs (i.e., Condition-level deficiencies) must be corrected before a transplant program can be approved or re-approved.

For transplant programs that have not been previously Medicare-approved and do not comply with the transplant program CoPs, the State Survey Agency (SA) and CMS Regional Office (RO) should follow the procedures outlined in Section 3001 of the SOM.

The termination process for currently participating organ transplant programs (i.e., programs previously approved by CMS that have not yet been approved under the CoPs) that do not comply with one or more CoP (i.e., has Condition-level deficiencies) is generally consistent with the 90 calendar-day timeframe used for termination of other provider types; however in two cases, the transplant programs should be allowed additional time for *initial approval only under the CoPs* to accomplish the corrective action necessary to attain compliance with the regulation. Please note that the termination would not affect the *hospital's* Medicare provider agreement; it would only apply to a hospital's Medicare approval for a given transplant program.

- (1) If the transplant program does not meet Condition 42 CFR §482.80 because of the clinical experience (volume) requirements outlined in (b) of this Section, the program will be given **210 days** to come into compliance with this Condition, contingent upon CMS receipt of an acceptable and implemented plan of correction. This timeframe is derived from our experience with the corrective action plans (CAPs) recently undertaken by a number of transplant programs under auspices of the National Coverage Determination authority.
- (2) If the transplant program does not meet Condition 42 CFR §482.80 because of the outcome requirements outlined in (c) of this Section, the program will be given **210 days** to come into compliance with this Condition, contingent upon CMS receipt of an acceptable and implemented plan of correction. This additional time will also allow for the release of the next SRTR Center-Specific Report which occurs every 6 months and sufficient time to provide the necessary steps regarding public notification, etc.

The additional time to come into compliance with the clinical experience or outcome requirements does not eliminate a transplant program's responsibility to immediately develop and implement a comprehensive plan of correction that address these issues. Similar to other types of deficiencies, this plan of correction should be submitted within 10 calendar days of the program's receipt of the CMS-2567 form. A plan of correction for these deficiencies must include an analysis of why the clinical experience and/or outcomes are not in compliance, an

outline of the specific steps that the program will put in place to come into compliance, and the timeframe for when these steps will be accomplished. A general note that the program will wait until the next round of outcome or volume data become available, or that the program is working with the Organ Procurement Transplantation Network to improve its outcomes does not provide sufficient evidence that the program is taking the necessary steps to come into compliance with these requirements.

Organ transplant surveys in some states are being conducted by CMS contract surveyors. Due to the additional administrative process of the contractor forwarding survey findings to the RO and Central Office for review, day one (1) of the termination timeframe should begin on the date the RO receives a complete form CMS-2567 report from the Contractor. Day one of the termination timeframe for state surveyors begins once CMS RO has reviewed and considered the CMS-2567 acceptable and able to be sent to the provider.

Contacts

If you have any questions or concerns about this guidance, please contact Karen Tritz at Karen.Tritz@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with applicable all survey and certification staff, their managers, and the State/RO training coordinators.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management