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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-13-Transplant
EXPIRED EFFECTIVE: 11/18/2024

DATE: December 16, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: ***EXPIRED:*** Transplant Centers: Citation for Outcome Requirements
***This policy memorandum superseded policy memorandums S&C: 10-16-Transplant and
S&C 08-17-Transplant ***

Memo Expiration Information:

Expiration Date: 11/18/2024

Expiration Information: Refer to *QSO-25-03-Transplant: Revisions to the State Operations Manual (SOM), Chapter 2- The Certification Process; SOM Appendix X, Guidance to Surveyors: Organ Transplant Programs; and SOM Chapter 9- Exhibits – Advance Copy for current guidance.*

Memorandum Summary

- **Background:** Certain Medicare-approved organ transplant center programs must maintain one-year patient and graft survival rates consistent with the Standard: *Outcome requirements* within the Transplant Center Conditions of Participation (CoP) at 42 CFR §482.82. The Centers for Medicare & Medicaid Services (CMS) uses risk-adjusted statistical reports, released semi-annually by the Scientific Registry of Transplant Recipients (SRTR), to measure and determine program compliance.
- **Enforcement of the Outcomes Requirement:** Beginning with the January 2017 SRTR center-specific reports, CMS will identify those transplant programs who cross CMS' thresholds for one-year patient and/or graft survival rates, in accordance with 42 CFR §482.82(c). Simultaneously, CMS will review more recent SRTR data to determine whether the program's one year patient/graft survival rate is improving, static or declining. If the program is out of compliance upon the release of the next SRTR report **and** is not showing improvement in more recent data, CMS will consider the program to be non-compliant at a Condition level and may conduct an on-site survey to determine whether there are deficiencies with other requirements.

Background

The Transplant Center regulations at §482.82(c) address patient and graft survival. The regulation requires that CMS compare each transplant program's *observed* number of patient deaths and graft failures one year post transplant to the program's *expected* number of patient deaths and graft failures one year post transplant (O/E). CMS uses data contained in the most recent SRTR center-specific report to make these comparisons. CMS receives data on the one year patient/graft survival rates for transplant programs every six months from the SRTR and each report covers a rolling, retrospective 2.5-year period.

CMS will not consider a program's patient and graft survival rates to be acceptable if a program's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate and all three of the following thresholds are crossed over:

- 1) The one-sided p-value is less than 0.05;
- 2) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3; and
- 3) The O/E ratio is greater than 1.85.

Note: Through the rule-making process, CMS adjusted the performance threshold at §§ 482.80(c)(2)(ii)(C) and 482.82(c)(2)(ii)(C) from 1.5 to 1.85 as of November 14, 2016.

There are some exceptions to the above outcome requirements. These exceptions are noted at §482.82 (d) and include heart/lung programs, intestine transplant centers and pancreas transplant centers.

Enforcement of the Outcome Requirements

Since 2007, CMS identified a Condition level non-compliance with the Outcome requirements using the Two-Flag Classification. This meant that if SRTR center-specific data indicated a patient and graft survival rate to be lower than expected with all three thresholds crossed over in:

(a) the most recent SRTR report; *and* (b) one in the previous four bi-annual SRTR reports, the program was considered to be out of compliance at the Condition level.

CMS is revising its methodology for determining non-compliance with the transplant program outcome requirements at §482.82(c) using the following process:

- Beginning with the January, 2017 SRTR report, CMS will identify all transplant programs with an O/E ratio greater than 1.85; O-E greater than 3; and a one-sided P-value less than 0.05 at the time of each bi-annual SRTR center specific data report. CMS will share this information with the transplant programs.

- Since the SRTR reports encompass data that is up to 3.5 years old, CMS will review more recent SRTR data, as it becomes available, to determine if the trend of performance for each identified program appears to be improving, declining, or static.
- At the time of the *next* bi-annual SRTR report, if a program continues to exceed the acceptable patient and graft survival rate, with all thresholds crossed over, more recent SRTR data will again be requested and reviewed. If the more recent data indicates that the program's outcomes are not improving, CMS will consider the program to be non-compliant at a Condition level and an on-site survey may be scheduled to review/identify associated process requirement concerns.
- Deficiencies for non-compliance with the outcome requirements, as well as any additional deficiencies identified at the time of the on-site survey, will be cited upon completion of the survey. If an on-site survey is not conducted, the program will be notified of its non-compliance with the outcome requirements by letter to include a form CMS-2567.

Contact: Please submit any questions you may have regarding the information in this memo to SCG_TransplantTeam@cms.hhs.gov.

Effective Date: This procedure will be effective upon the release of the January 2017 SRTR center-specific report. The information provided in this memorandum should be communicated to all Survey and Certification managers and staff and the State/Regional Office Training Coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management

The contents of this letter support activities or actions to improve patient or resident safety and increase quality and reliability of care for better outcomes.