

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid
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Center for Clinical Standards and Quality/Survey & Certification Group

**Ref: S&C: 17-04-Transplant
EXPIRED EFFECTIVE: 11/18/2024**

DATE: October 28, 2016

TO: State Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **EXPIRED:** Transplant Centers: Clinical Experience Requirements

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

- **Citing Non-Compliance with Clinical Experience:** Transplant programs are required per 42 CFR 482.80 (b) to *generally* perform 10 transplants within the past 12 months for initial certification with Medicare. Programs applying for initial Medicare certification that performed at least eight but less than 10 transplants in the previous 12 months should be cited at the Standard level. The program may still be certified with an acceptable plan of correction for clinical experience requirements if all Conditions of Participation (CoPs) are in compliance.
- **For re-approval:** Programs are required per 42 CFR 482.82 (b) to perform an average of 10 transplants per year during the prior three years. Programs not meeting this average should be cited at the Standard level, and the program must submit an acceptable plan of correction. The program may be reapproved if all CoPs are in compliance. Voluntary program inactivity does not affect these evaluation periods.

Background

The Transplant Center CoPs at 42 CFR 482.80(b) *Clinical Experience* require that in order for a transplant program to be considered for initial Medicare certification it must generally perform

10 transplants over a 12 month period. The CoPs at 42 CFR 482.82(b) *Clinical Experience* require that in order for a certified transplant program to be considered for re-approval it must generally perform an average of 10 transplants per year during the prior three years.

Compliance with the Clinical Experience requirements is evaluated by the Centers for Medicare & Medicaid Services (CMS) using data reported by the transplant programs to the Scientific Registry of Transplant Recipients (SRTR). This data is incorporated into the CMS Transplant Program Quarterly Report (TPQR). CMS provides the TPQR as a part of the pre-survey preparation for every transplant program survey. During the on-site survey, the surveyor verifies that the TPQR is current and if the minimum number of transplant surveys have not been completed, a deficiency is cited.

Clinical Experience: Determining the Level of Non-Compliance

Initial Approval of Transplant Programs under §482.80(b):

If the transplant program has not performed at least eight transplants in the past 12 months it may not be certified for Medicare participation. If the program has performed at least eight but less than 10 transplants in that time period, a deficiency should be cited at the Standard level. The program may still be Medicare certified with a Standard level citation for Clinical Experience if an acceptable plan of correction is received and all CoPs are in compliance.

Re-approval of Transplant Programs under §482.82(b):

If the transplant program has performed an average of less than 10 transplants per year over the re-approval period (three years), a deficiency should be cited at the Standard level. The program may be re-approved with a Standard level citation for Clinical Experience if an acceptable plan of correction is received and all CoPs are in compliance.

The determination of Condition level non-compliance is made based upon the extent of non-compliance with the Standards of the Condition. A finding of non-compliance for the Standard Clinical Experience alone with no other non-compliance within the Condition would generally not result in a Condition level non-compliance for §482.80 or §482.82.

Although a certified transplant program may choose to go “inactive” for a certain period of time, the program must still meet the Clinical Experience requirements without consideration of the inactivity period.

Contact: If you have any questions or concerns about this guidance, please contact Danielle Miller at SCG_TransplantTeam@cms.hhs.gov.

Effective Date: Immediately. The information provided in this memorandum should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

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/s/
David R. Wright

cc: Survey and Certification Regional Office Management