



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-04-Transplant
REVISED 09.08.2017

DATE: October 28, 2016
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

SUBJECT: Transplant Centers: Clinical Experience Requirements

****Revised to clarify the volume requirement for initial adult kidney only transplant approval****

Memorandum Summary

- ***Initial Certification:*** *Some* 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 12 months prior to the application should be cited for non-compliance 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.
- **Re-approval:** Some transplant 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 for non-compliance at the Standard level. The program may be reapproved with an acceptable plan of correction 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. Heart/lung, intestine, pancreas, and pediatric transplant programs are exempt from this requirement. In addition, a kidney transplant center, that is not Medicare-approved, is only required to perform at least three transplants over a 12-month period prior to its request for initial Medicare approval.

42 CFR 482.82(b) *Clinical Experience* also requires 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. Again, heart/lung, intestine, pancreas, and pediatric transplant programs are exempt from this requirement for re-approval. Kidney transplant programs are not exempt from this re-approval volume requirement.

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 12 months prior to the initial application it may not be certified for Medicare participation. If the program has performed at least eight but less than 10 transplants in the same 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. (Heart/lung, intestine, pancreas, and pediatric transplant programs are exempt from this requirement. In addition, a kidney transplant center, that is not Medicare-approved, is only required to perform at least three transplants over a 12-month period prior to its request for initial Medicare approval.)

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 (previous 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. (Heart/lung, intestine, pancreas, and pediatric transplant programs are exempt from this requirement for re-approval. Kidney transplant programs are not exempt from this re-approval volume requirement.)

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.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management