DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Ref: QSO-25-04-Transplant

DATE: October 10, 2024

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Outcome Requirements for Initial Transplant Program Approval

Memorandum Summary

- **Outcome requirements:** The transplant program Conditions of Participation (CoPs) for initial approval at 42 C.F.R. §488.61 require compliance with all data submission, clinical experience, and outcome requirements under §482.80, with limited exceptions.
- **Data delay:** Since the outcome requirements §482.80(c) must include one-year post transplant data, there may be a delay in the availability of the outcomes data at the time of the applicant program's request for initial Medicare approval.
- **Data availability**: Centers for Medicare & Medicaid Services (CMS) and State Survey Agencies (SA) must confirm the availability of outcomes data before initiating an onsite survey. If the outcomes data is not available, an onsite survey cannot be initiated and the SA should notify the prospective provider that the initial survey will occur once the data becomes available.

Background:

Transplant programs must meet all data submission, clinical experience, and outcome requirements at 42 CFR §482.80 for CMS to grant initial program certification (except as specified at §482.80(d)), as required under §488.61. These measures are essential for ensuring quality care and protecting the health and safety of Medicare beneficiaries who require transplantation as a life-saving treatment for end-organ failure.

CMS and SAs that receive requests for initial approval from transplant programs must ensure that outcomes data is available to determine compliance with CMS requirements. Therefore, **CMS and SAs may not perform an initial survey unless data are available for review**. If the outcomes data is unavailable, the SA should notify the provider that the initial survey will occur once the data becomes available.

CMS uses the Scientific Registry of Transplant Recipient's (SRTR) program-specific reports as

the foundation of the outcome evaluation system. The SRTR updates its program-specific reports every six months for each solid organ transplant program. However, since the outcome requirements §482.80(c) include one-year post-transplant data, there is a delay in compiling and reporting the data. It may be up to 18 months after the first transplant is performed before the data (e.g., one-year post-transplant outcomes data) are reported and available in the required regulatory format.

The SA will schedule an onsite survey for initial Medicare approval once data to determine compliance with all requirements of §482.80 are available. The State Operations Manual, Chapter 2, Section 2062B contains operational guidance for the initial approval survey once the outcomes data becomes available.

Discussion:

A transplant program must submit a request to CMS for Medicare approval (see §488.61). Initial approval requirements at §482.80 stipulate that "…transplant programs must meet **all** data submission, clinical experience, and outcome requirements to be granted initial approval by CMS." If the outcomes data are unavailable, CMS cannot determine compliance with this requirement, and transplant programs will experience a waiting period before an onsite federal survey for initial approval can be performed. Intestine and pancreas transplant programs are exempt from meeting the outcome requirements under§482.80(d).

To determine compliance with the outcome requirements at §482.80(c), CMS will review 1-year patient and graft survival data in the most recent SRTR program-specific report. Upon receipt of a prospective transplant program's request for initial approval, surveyors must request and obtain CMS' Initial Transplant Report (ITR) to determine whether the applicant program meets the criteria specified by §482.80. Once the request is received, CMS Baltimore will provide the CMS Location and SA with the ITR. This report contains data that measures the program's data submission percentage, volume (clinical experience), patient/graft survival rates (outcomes), and whether the transplant program under review has met these requirements. To ensure that the initial approval determinations of the prospective transplant program are made per existing regulations, have updated the State Operations Manual, Chapter 2, to clearly state that CMS and SAs should only perform an initial approval survey when all data are available for review.

Contact:

For questions or concerns relating to this memorandum, please contact QSOG_TransplantTeam@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS' new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to specific provider types and intended to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.

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