DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality

Ref: QSO-25-04-Transplant REVISED

DATE: **October 30**, 2026

TO: State Survey Agency Directors

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

SUBJECT: **REVISED:** Outcome Requirements for Initial Transplant Program Approval

Memo Information:

Memo revision date: **2026-10-30**
Original release date: **2024-10-10**

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.~~
- *This memo is revised to include flexibility in the timing of compliance determinations and the use of raw 1-year patient and graft survival outcomes SRTR data to assess a program's likely compliance. If survival rates are favorable and that data is unlikely to change, CMS may move forward with reviewing the other conditions of participation while the final statistical comparison is pending.*

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 *contained* in the most recent SRTR program-specific report. Upon receipt of a prospective transplant program's request for initial approval including survival data to date and the cohort of transplant patients that have passed their 1 year, 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 is likely to meet 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.~~

Flexibility in timing of compliance determinations

CMS recognizes that the reporting cycle for outcomes data under §482.80(c) and §488.61(a)(2) can create a gap between when a program is survey-ready and when the final published analysis

confirming statistical compliance becomes available. This gap carries real consequences: transplant programs facing prolonged uncertainty may pause or slow transplant activity while awaiting final certification, directly affecting patient access to care at a time when national transplant waitlists already strain capacity. Beneficiaries also bear a tangible cost during extended delays, as cost-sharing exposure is significantly higher under Part D than Part B, meaning administrative timing, not clinical readiness, can translate into real out-of-pocket costs for patients. To reduce this unnecessary delay while preserving the integrity of the outcome review, CMS will apply the following flexibility going forward from the date of this memo's issuance.

Use of raw outcomes data under §488.61(a)(2)

Section 488.61(a)(2) states that CMS will review the data "contained in" the most recent OPTN data report and the 1-year graft and patient survival data in the most recent SRTR program-specific report. Before SRTR completes its statistical methodology and comparative ranking, the underlying raw data is already available to CMS. CMS may use this raw data to assess a program's likely compliance and move forward with reviewing the other conditions of participation while the final statistical comparison is pending. This conditional approval is not a final determination and does not replace or override the final decision; it allows CMS to use the waiting period productively rather than as a hold on all survey activity.

Separating the survey from the compliance determination

Neither §482.80 nor §488.61 specifies when an onsite survey must occur relative to the final outcomes determination. CMS and the SA may conduct the onsite survey for the other Medicare Conditions of Participation and hold the outcome compliance determination open until the applicable SRTR program-specific report is published. This approach allows CMS to complete survey work without waiting idle for the publication cycle.

Effective date under §488.61(a)(5)

Section 488.61(a)(5) ties the effective date of Medicare approval to CMS's determination that a program has met the outcome requirements. CMS's general approach is that the determination of outcome compliance should occur before CMS sets the effective date. Where CMS has already reviewed a program's other Conditions of Participation and is waiting only on SRTR's final published confirmation of the statistical outcome thresholds, CMS may set the effective date as of the date the program completed the onsite survey for the other Conditions and confirms that the outcome requirements were met at the time of the onsite survey (based on the SRTR public report).

Effective date

Once the published SRTR report becomes available, *CMS determines compliance as follows:*

- *If the published SRTR report shows the program was **in compliance** with §482.80, and the other Medicare Conditions of Participation, CMS may set the effective date of certification to the later of:*
  - *The date the program achieved compliance with the data contained in the most recent SRTR program-specific report in accordance with §482.80(c)(1), rather than the later date of the published SRTR report. The program is not penalized for the SRTR reporting lag.*
  - *The date that other Conditions of Participation were shown to have been met either based on the initial survey, or an acceptable plan of correction if Standard-level deficiencies are cited.*

- *If the published SRTR report shows the program was **not in compliance** with §482.80, CMS denies initial approval.*

Scope of this flexibility

This flexibility applies on a case-by-case basis and depends on CMS having sufficient raw SRTR data, at the time of the determination, to support moving forward with a survey. It does not change the underlying requirement that a program must meet all data submission, clinical experience, and outcome requirements before CMS grants initial Medicare certification. The purpose of the memo is to clarify the timing of the onsite survey, the use of raw data, and the establishment of the effective date.

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/

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