

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-19-05-Transplant
EXPIRED EFFECTIVE: 11/18/2024

DATE: February 1, 2019

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: ***EXPIRED:*** Survey and Approval of Pancreas and Intestine Transplant Centers

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

- **Pancreas Transplant Centers** - An adult or pediatric pancreas transplant center may be Medicare approved, with no independent survey activity, if the program operates as a component of a Medicare approved kidney transplant center.
- **Intestine Transplant Centers** - An adult or pediatric intestine transplant center may be Medicare approved, with no independent survey activity, if the program operates as a component of a Medicare approved liver transplant center.
- **Pancreas and intestine transplant patients** will be incorporated into the kidney and liver program survey reviews. Noncompliance with the care or services to pancreas or intestine transplant patients will result in noncompliance by the associated kidney or liver programs, respectively.

Background

The Centers for Medicare & Medicaid Services (CMS) regulations as outlined under 42 CFR §482.70 *Definitions*, defines a pancreas transplant center as a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney

transplant as well as kidney-pancreas transplants. Section 482.70 *Definitions*, also defines an intestine transplant center as a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

Discussion

While CMS has historically surveyed and approved pancreas and intestine (pediatric or adult) transplant centers as independent entities, the State Operations Manual is being updated to revise this process. Pancreas and Intestine transplant programs must continue to apply for initial Medicare approval. This approval will be contingent upon Medicare approval for the associated kidney or liver transplant center within which they operate. Pancreas and intestine transplant centers are not automatically approved simply because they operate as a component of an approved kidney or liver program. However, if the program is operating as a component of an already Medicare approved kidney or liver transplant program, which is in compliance with the Conditions of Participation (CoPs) (42 CFR §§482.72-482.104), no on-site survey activity will be required for approval. No review of the outcome performance measures at §482.80 will be required before approval for either center type. However, any intestine transplant program applying for Medicare approval must be in compliance with the clinical experience requirements at §482.80 before initial approval may be granted, and remain in compliance and at the time of each re-approval of the associated liver transplant center. Upon approval by the CMS Regional Office, the pancreas or intestine transplant center will be listed as an approved program.

While no separate surveys will be conducted for pancreas and intestine transplant centers, during the survey of the associated kidney or liver center, pancreas or intestine transplant patients will be included in the kidney or liver center patient samples. Care and services to the patients being served by the pancreas and intestine centers must also meet the requirements of the CoPs. Non-compliance in a pancreas or intestine center will result in a non-compliance in the associated kidney or liver program. In the event that Medicare approval for the associated kidney or liver center is either voluntarily or involuntarily terminated, the Medicare approval for the associated pancreas or intestine center will also be terminated.

Contact: For questions or concerns, please contact SCG_Transplantteam@cms.hhs.gov

Effective Date: Immediately. This policy 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/
Karen Tritz
Acting Director

cc: Survey and Certification Regional Office Management