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

Ref: QSO-24-04-[OPO]

DATE: January 18, 2024

TO: CMS Location Offices

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

SUBJECT: Organ Procurement Organization (OPO) Conditions for Coverage – Definition Clarification

Memorandum Summary

- **Donor Definition:** CMS is clarifying the definition of "donor" in the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs). This clarification addresses the *use* of the pancreata for *islet cell research* that are included in the definition (emphasis added).
- **Data Verification:** OPOs must maintain information on the disposition of pancreas organs and islet cells submitted for pancreatic islet cell research.

Background:

The OPO CfCs are intended to drive improvements in organ procurement and transplantation through, among other provisions, the donor and transplantation outcome measures. OPOs are required to report data related to pancreata procured for research, and this data is incorporated into calculations used to assess compliance with the donor and transplant outcome measures and are used for re-certification purposes. To facilitate accurate reporting of data related to pancreata donors, the term "donor" is defined in CMS regulation to specify that, among other requirements, an individual would be considered a donor even if only the pancreas is procured and is used for research or islet cell transplantation.

CMS has noted a significant increase in the number of pancreata procured since this definition was revised in 2020, raising questions about the interpretation of this definition by OPOs and how this definition is applied to reporting data related to donors of pancreata used for islet cell research. There is a concern that the increase in pancreata procured may not reflect a meaningful increase in pancreata being actually used for islet cell research, and instead may reflect pancreata procured for other purposes. This memo is clarifying that the pancreata must be used for islet cell research.

Discussion:

1. Islet Cell Research.

The Pancreatic Islet Cell Transplantation Act of 2004 amended section 371 of the Public Health Service Act to require that "Pancreata procured by an OPO and *used* for *islet cell transplantation or research* shall be counted for purposes of certification or recertification." (emphasis added). This requirement is codified in the definition of "donor" in the OPO regulations at § 486.302, stating that a donor is "a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and *is used for research or islet cell transplantation*." (emphasis added).

To avoid any potential confusion by OPOs, we are clarifying that in the definition of "donor", the reference to pancreata "*research*" specifically refers to research for islet cell transplantation, consistent with the statutory requirements. Although the order of the words "research" and "islet cell transplantation" are reversed in the regulation as compared to the order in which they appear in the statute, the overall meaning and intent are the same.

Pancreata used for islet cell research was explained in the preamble to the recent proposed and final rules. In the 2019 proposed rule, we stated that, "We are excluding organs procured for research, but not transplanted, from our definition, except for pancreata that are procured for islet cell transplantation or research (transplanted or not transplanted), as this is required by section 371(c) of the Public Health Service (PHS) Act."[1] We reaffirmed our commitment to excluding all organs procured for research, other than pancreata procured for islet cell research, in the December 2, 2020 final rule where we stated that, "Except for pancreata when procured for research, as noted in the December 2019 OPO proposed rule, we are not adopting the commenters' suggestion to include organs donated for research in the outcomes measures."[2] and "Pancreata procured for islet cell research are included in the outcome measures of this final rule."[3] The final rule further stated that this inclusion is directly related to implementation of the PHS Act requirement.

Consistent with the requirements of the Pancreatic Islet Cell Transplantation Act of 2004 (PHS Act section 371(c)) and we continue to include pancreata procured for islet cell research in the outcome measures in the definition of "donor." We do not include pancreata procured for uses beyond islet cell research or other organs procured for research in the outcome measures, and they are likewise not included in the definition of "donor."

2. Used for Islet Cell Research

To be included in the outcome measures, the statute requires that, in addition to procurement, the pancreas must be *used* for islet cell transplantation or research (emphasis added). This requirement is codified in the definition of "donor" in the OPO regulations at § 486.302, stating

[1] 84 FR 70631
[2] 85 FR 77902
[3] 85 FR 77902

that a donor is "a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and is *used* for research or islet cell transplantation." (emphasis added).

OPOs should report all procurements, including pancreata; however, procurement for purposes of potential pancreatic islet cell research alone is insufficient for the organ to count, nor donors of unused pancreata to count as donors, if the pancreata are not used as prescribed, and the OPO cannot validate the actual use of the organ for islet cell research. This requirement is consistent with requirements for all other organs, in that a donor cannot be counted for inclusion in the donor measure until an organ from that donor is used for transplant.

In summary, this memo is clarifying that consistent with the Pancreatic Islet Cell Transplantation Act of 2004, only pancreata procured by an OPO and *used* for islet cell transplantation or research shall be counted. CMS anticipates clarifying the regulatory text in upcoming rulemaking so the regulatory text is identical to the Pancreatic Islet Cell Transplantation Act of 2004.

In addition, CMS intends to develop a means to validate OPO reporting of pancreata for research and approaches are under review.

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

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/

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Director, Survey & Operations Group	Director, Quality, Safety & Oversight Group

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