United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

June 6, 2024

VIA ELECTRONIC TRANSMISSION

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

Dear Administrator Brooks-LaSure:

On January 18, 2024, the Center for Medicare & Medicaid Services (CMS) published a memorandum clarifying the regulatory intent regarding procurement of pancreata for islet cell transplantation research in relation to 42 C.F.R. § 486.302. As you are aware, CMS clarified that "in the definition of 'donor', the reference to pancreata 'research' specifically refers to research for islet cell transplantation, consistent with the statutory requirements."[1] However, a memorandum is insufficient to fully address the potential for Organ Procurement Organizations (OPOs) to abuse the pancreata research provision in the OPO conditions for coverage (CfCs). CMS should amend the existing regulation making explicit the requirement that research for purposes of OPO recertification is defined as islet cell transplantation. We further recommend that the research must be done under a Food and Drug Administration (FDA) approved clinical trial for recertification purposes. This approach would be consistent with existing CMS policy regarding use of pancreatic islet cells for transplantation in the context of National Institutes of Health (NIH) clinical trials.[2]

We also urge CMS to identify reporting requirements for OPOs or other mechanisms to validate and monitor the accuracy of the data submitted by OPOs consistent with the definition of pancreata recovered for research. Such requirements should include OPO submissions or

[1] CMS Memorandum, Organ Procurement Organization (OPO) Conditions for Coverage – Definition Clarification (January 18, 2024), https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos-states/organ-procurement-organization-opo-conditions-coverage-definition-clarification.
[2] 42 CFR 413.406. This regulation already limits payment for pancreata procured for the purpose of islet cell transplantation to those procedures conducted by transplant centers "participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003."

other validation of relevant research protocols, agreements between OPOs and research entities regarding pancreas islet cell transplantation research, and any other data necessary to validate utilization.

These recommendations are consistent with the preliminary findings from an ongoing bipartisan investigation into the dramatically increasing rates of pancreata recovered for research reported by OPOs – increases which CMS acknowledged in the January 18, 2024, memorandum.[3] We are concerned these increases are evidence of exploitation of a loophole in the OPO CfCs and that this loophole may continue to be abused without further guidance.

Specifically, our bipartisan investigation discovered that, among the 10 OPOs currently under investigation, the total number of pancreata recovered for research increased from 169 in 2018 to 1606 in 2022, representing an 850% increase.[4] These 10 OPOs reported that in 2018, prior to the creation of the CMS metric, 148 of 169 (87.6%) pancreata recovered for research were used on research specific to islet cell transplantation.[5] However, in 2022, one year after the final rule was enacted, the same 10 OPOs self-reported that only 769 of 1606 (47.9%) pancreata recovered for research were used on research specific to islet cell transplantation.[6] Abuse of the pancreata loophole has serious implications for generous donor families who may have consented to donation based on misrepresentations made by OPOs, as well as patients on the organ waiting list whose lives depend on CMS holding OPOs accountable in the upcoming contracting process. Additionally, we are concerned that the language of the rule, and the demonstrable practices of OPOs, has resulted in a framework that is inconsistent with the legislative requirements at 42 U.S.C. § 273(c).

The Senate Finance Committee has long sounded the alarm on this issue. In April 2022, we wrote to the Department of Health and Human Services (HHS) in response to CMS's transplant system request for information (RFI).[7] Our letter requested CMS remove the loophole in the 2020 regulations that enabled OPOs to count pancreata for research in the metrics when that research was not used for islet cell transplantation.[8] In July 2020, Secretary Becerra responded, echoing our concerns, writing, "…CMS will be monitoring the procurement of pancreata to evaluate for potential gaming of the metrics by OPOs and will take actions as needed."[9] Then, in March 2023, we wrote oversight letters to 10 OPOs seeking data on

---

[3] *Supra* note 1.
[4] Document on file with Senate Committee on Finance.
[5] Document on file with Senate Committee on Finance.
[6] Document on file with Senate Committee on Finance.
[7] Letter from Senate Finance Committee to Secretary Becerra and Administrator Brooks LaSure (April 07, 2022), https://www.finance.senate.gov/imo/media/doc/040722%20Wyden%20Grassley%20Young%20Transplant%20System%20RFI%20letter.pdf (noting that "OPOs have already begun to exploit this loophole, with the total number of reported pancreata for research doubling in 2021 after remaining steady for years.")
[8] *Id*. (Noting that "OPOs have already begun to exploit this loophole, with the total number of reported pancreata for research doubling in 2021 after remaining steady for years."); *see also* Goldberg DS et al., JAMA Network Open, *Procurement of Pancreatic Tissue for Research From Deceased Donors Before vs After the CMS Final Rule in 2020* (Sep. 6, 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10483317/.
[9] Document on file with Senate Committee on Finance.

pancreata recovery and research rates, and the legitimacy of that research,[10] as well as raised preliminary findings with senior CMS officials at a July transplant roundtable.[11]

The legislative history pertaining to the inclusion of this requirement makes clear Congress's intent that only pancreata procured to facilitate research into pancreatic islet cell transplantation should be counted for the purposes of OPO recertification. In fact, the bill resulting in 42 U.S.C. § 273(c), Public Law 108-362 titled Pancreatic Islet Cell Transplantation Act of 2004, states clearly that the intent of the Act is to,

> [A]mend the Public Health Service Act to increase the supply of pancreatic **islet cells** for research, and to provide for better coordination of Federal efforts and information on islet cell transplantation. (emphasis added)

Furthermore, the House of Representatives report accompanying the House Bill, H.R. 3858, Pancreatic Islet Cell Transplantation Act of 2004, states the goal of the legislation is to expand 'the capabilities of pancreatic islet cell research.' Finally, CMS's own language in the preamble to the December 2020 final rule notice (FRN) states:

> **Pancreata procured for islet cell research** are included in the outcome measures of this final rule. We carefully considered other options to address pancreata procured for research, such as creating a process measure for these organs, creating a unique outcome measure, and counting these organs in the outcome measures of this final rule as less than the full value of a transplanted organ. However, these alternative policy approaches did not meet the PHS Act, which states that "Pancreata procured by an organ procurement organization (OPO) and used for islet cell transplantation or research shall be counted for purposes of certification or recertification . . . ."[12]

CMS continued clarifying the intent in the 2020 Final Rule, stating that the "impact of pancreata for research on the overall rankings of OPOs will continue to be minimal"[13] because "only bona

---

[10] Letter from Senate Finance Committee to Select Organ Procurement Organizations (March 20, 2023) https://www.finance.senate.gov/imo/media/doc/03.20.23%20SFC%20to%20OPOs.pdf; *see also* Press Release, *Wyden, Grassley, Cardin, Young Raise Alarm Over Dramatic Increase in Pancreata Procurement* (March 21, 2023) https://www.finance.senate.gov/chairmans-news/wyden-grassley-cardin-young-raise-alarm-over-dramatic-increase-in-pancreata-procurement-; *see also* Press Release, *Bipartisan Senators Meet With HRSA, CMS Officials To Discuss Organ Transplant Modernization And Reform* (July 11, 2023) https://www.grassley.senate.gov/news/news-releases/bipartisan-senators-meet-with-hrsa-cms-officials-to-discuss-organ-transplant-modernization-and-reform. In July 2023, the Committee also raised the preliminary findings of our investigation with senior CMS officials at the Transplant roundtable.

[11] *Id*.

[12] 42 C.F.R. § 486 (2021).

[13] *Id*.

fide research conducted by a qualified researcher using a pancreas from an organ donor would be counted, and it would be counted as a single research project regardless of the number of research activities performed using **that one pancreas and its islets.**"[14] Finally, CMS stated that it intends to, "continue to monitor the trends of pancreata procured for research and will use the survey process to conduct further investigation into any anomalies that such monitoring reveal," making clear the need to monitor this requirement for potential abuse and issue clarification as necessary.[15]

Despite CMS's belief that this requirement would continue to have minimal impact, our investigation has shown that OPOs are reporting pancreata procured for research at a concerningly high number and that many of the reported organs are not supporting bona fide research consistent with the legislative intent. Since the rule was finalized, pancreata for research recovery has increased by more than four-fold, with some OPOs recovering hundreds of pancreata and labeling them as "research," not "islet cell research."[16] This alone is a shocking indication that OPOs are abusing the regulatory language.

Finally, it appears that OPOs may be using taxpayer dollars to create demand rather than meet existing research needs, which could represent conflicts of interest or self-dealing. In fact, within days after the Final Rule's implementation, one OPO executive advised the rest of the industry on the trade association listserv that, "Savvy (or cynical?) OPOs ought to start a pancreas for research program immediately," making clear the belief that the pancreata recovered for research could have a very significant impact.[17] This has serious consequences as OPOs that are otherwise failing or underperforming may be able to keep their government certifications based on highly questionable practices and reporting, harming taxpayers and costing patients' lives.[18]

These findings make clear that OPOs have been and may continue to abuse the current pancreata for research loophole in CMS's regulation. The Committee specifically notes that the intention behind CMS's changes to the OPO CfC in 2020 were to eliminate OPO self-reporting, which had historically been used to game performance metrics. In fact, the ultimate disposition of all organs, other than pancreata recovered for islet cell transplant, that are counted toward recertification can be validated through data reported to the Organ Procurement and Transplantation Network (OPTN). Yet, it is unclear how CMS will validate this data through the survey process, as current regulatory guidance relies on self-reported data for pancreata recovered for transplant with little, if any, apparent effort to validate these data.[19]

---

[14] *Id*
[15] *Id*.
[16] Goldberg DS et al. *supra* note 8.
[17] Document on file with Senate Finance Committee.
[18] Goldberg DS et al. *supra* note 8.
[19] Centers for Medicare and Medicaid Services, "New Organ Procurement Organization (OPO) Survey Protocol and Guidance Revisions in Appendix Y of the State Operations Manual (SOM)," (Aug. 10, 2018) https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-23-OPO.pdf.

As you are aware, 2024 is the year OPO performance will be judged for the 2026 contracting cycle.[20] Given that CMS noted in 2020 its intent to monitor the trends and impact of pancreata recovered for research in the OPO metrics, we urge CMS to immediately begin work to clarify by rule that only pancreata recovered for research focused on pancreatic islet cell transplantation and conducted under FDA approved clinical research be counted toward recertification. We also urge CMS put in place oversight mechanisms to ensure the data OPOs are submitting can be verified.

These steps will help close the pancreata loophole, and by doing so CMS will protect patients, preserve Medicare integrity, and ensure equitable application of the metrics across OPOs so that all parts of the country will be served by high performing OPOs by 2026.

Thank you for your attention to this important matter.

Sincerely,

Ron Wyden
United States Senator
Chairman, Committee on Finance

Charles E. Grassley
United States Senator
Member, Committee on Finance

Benjamin L. Cardin
United States Senator

Todd Young
United States Senator

[20] *Supra* note 12.