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United States Senate

COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

March 20, 2023

Ms. Julie Bergin
Chief Executive Officer
Kentucky Organ Donor Affiliates
10301 Linn Station Rd
Louisville, KY 40223

Dear Ms. Bergin,

We write to request data from your organization, Kentucky Organ Donor Affiliates, on pancreata procured for research. We are concerned that some Organ Procurement Organizations (OPOs) may be attempting to take advantage of a loophole in the Centers for Medicare and Medicaid Services' (CMS) Final Rule, "Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations," [hereinafter the OPO Final Rule]. This loophole allows OPOs to count pancreata procured for research the same as other organs procured for transplants, giving OPOs the ability to falsely inflate their performance.¹ In turn, those inflated performance metrics will assist OPOs in maintaining their contracts with CMS for organ donation.

In the OPO Final Rule, CMS specified that "only bona fide research conducted by a qualified researcher using a pancreas from an organ donor" will be counted in CMS's performance measures and that such research would be counted as a single research project regardless of the number of research activities performed using that one pancreas and its islets. In 2018, the number of pancreas research projects were 1.73 percent of the total number of transplants. In the OPO Final Rule, CMS said they expected a similar fraction of the total organs counted for transplants in future years.² However, in April 2022, we raised concerns with the Department of

¹ 86 FR 7814, available at <https://www.federalregister.gov/documents/2021/02/02/2021-02180/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>

² 85 FR 77898, available at <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to> (In accordance with the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," the final rule entitled, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule" published in the Federal Register on December 2, 2020 was temporarily delayed for 60 days the initial effective date, *see* 86 FR 7814, available at,

Health and Humans Services (HHS) and CMS that OPOs had already begun to exploit this loophole as the, “total number of reported pancreata for research [doubled] in 2021 after remaining steady for years.”³

In 2021, the OPO Final Rule created new objective metrics that relied on an OPO’s procurement and transplant rates to measure OPO performance. The rapid increase of pancreata used for research in 2021 is concerning particularly because 2021 was the first year that OPOs were being measured under the new metrics. This trend raises serious questions about OPO practice regarding procurement of pancreata for transplant in light of the CMS performance metrics. Specifically, we are concerned some OPOs may be reporting pancreas procurements that are not, in fact, meeting the standard of bona fide research consistent with regulation and statute.

Based on communications we have received, we are concerned that many of these pancreata may not have been recovered for legitimate research purposes. For example, emails between OPO employees on the official listserv for the Association of Organ Procurement Organizations (AOPO), sent shortly after the OPO Final Rule was implemented, and under the email subject “Data and Information Management Council: The CMS Final Rule,” one OPO employee appeared to advise other OPO employees on how to game the metric, writing: “If you have a donor with only a pancreas for research, that is an organ donor for the Donor Rate. Otherwise, a donor is any donor with at least 1 organ transplanted. Savvy (or cynical?) OPOs ought to start a pancreas for research program immediately.”⁴

We have also heard from OPO whistleblowers with concerns that some OPOs are flagrantly gaming the OPO Final Rule, including by instructing staff and partner hospitals to create frivolous explanations for recovering pancreata, classifying such pancreata as “research and education.”

To help us evaluate this issue, please provide the following information from your organization no later than April 7, 2023:

1. The total number of pancreata recovered by your OPO, per year, from 2018 to 2022.
2. The total number of pancreata successfully placed for transplant by your OPO, per year, from 2018 to 2022.
3. The total number of pancreata placed for research by your OPO, per year, from 2018 to 2022.

<https://www.federalregister.gov/documents/2021/02/02/2021-02180/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

³ Senate Finance Committee Letter (April 07, 2022),

<https://www.finance.senate.gov/imo/media/doc/040722%20Wyden%20Grassley%20Young%20Transplant%20System%20RFI%20letter.pdf>.

⁴ Document on file with Senate Finance Committee.

4. The total number of pancreata recovered for research and transplant reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.
5. The total number of pancreata recovered for research specifically focused on islet cell transplantation by your OPO, per year, from 2018 to 2022.
6. How many total donors your OPO reported as part of CMS's performance metric calculations, per year, from 2018 to 2022.
7. How many total donors your OPO reported as part of CMS's performance metric calculations who only had a pancreas removed for research, per year, from 2018 to 2022. Any guidance documents on protocol for pancreas recovery produced by the OPO staff from 2018 to 2022.
8. Finally, we request copies of the research protocols, along with documentation of review and approval of these protocols for each study the OPO is providing pancreata for research and the number of pancreata procured for each study, per year, from 2018 to 2022. Please include any financial transactions between your OPO and the associated researchers or their institutions related to this research.

Sincerely,



Ron Wyden
Chairman
Committee on Finance



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Member
Committee on Finance



Benjamin L. Cardin
Member
Committee on Finance



Todd Young
Member
Committee on Finance