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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

April 07, 2022

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
The Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, M.D. 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

We write today in support of the Centers for Medicare & Medicaid Services' (CMS) recent request for information (RFI) titled, "Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities."¹ Every American, regardless of race, ethnicity, or geography deserves to be treated equally in regards to organ donation and transplantation. While CMS's RFI is an important step in the Administration's pursuit to improve the U.S. organ transplant network, an effort that first began under the Trump Administration and now continues under the Biden Administration, we would like to take this opportunity to emphasize provisions that we believe are critical to fostering equitable changes in this system.

¹ Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities, Centers for Medicare and Medicaid (Dec. 03, 2021) <https://www.federalregister.gov/documents/2021/12/03/2021-26146/request-for-information-health-and-safety-requirements-for-transplant-programs-organ-procurement>.

In our July 19, 2021 letter, we commended the Department of Health and Human Services (HHS) and CMS for their efforts to improve the U.S. organ procurement system.² We believe the final rule entitled, “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations,” which aims to increase the number of successful organ transplants performed in the U.S., is an important first step towards ensuring organ procurement organizations (OPOs) are held accountable.³ However, in that same letter, we also voiced our concern with the protracted timeline for enforcement and encouraged CMS to consider ways to hold OPOs accountable during the interim.⁴ We must ensure that the U.S. organ procurement and transplantation system functions at its optimal level to prevent any missed opportunity for organ donation, as no American should die while waiting for a transplant.⁵

We are also concerned that the COVID-19 pandemic continues to exacerbate the need for organ transplants, and communities of color and rural residents remain disproportionately impacted by the failures of the current organ donation system and the effects of COVID-19. In order to reduce disparities and increase the overall number of organ transplants, we believe it is critical that HHS, through CMS, the Health Resources and Services Administration (HRSA), and other relevant agencies, make OPO reform an immediate priority, as highlighted in our July 19, 2021 letter.⁶ To that end, we would like to highlight several priorities that are critical to addressing our concerns.

First, CMS should ensure that the new OPO performance metrics use objective data to hold underperforming OPOs accountable. To accomplish this, we ask CMS to consider the following:

- Maintain its earlier correct judgment disallowing race-based risk adjustments to the metrics;
- Maintain its earlier correct judgment disallowing zero donors, which do not result in organs transplanted/lives saved and which could undermine the integrity of the rule by creating a gameable loophole; and

² Press Release, Bipartisan, Bicameral Members of Congress Commend Federal Efforts to Reform Organ Donation System, Urge Acceleration of Rule’s Impact (July 20, 2021), <https://www.finance.senate.gov/chairmans-news/bipartisan-bicameral-members-of-congress-commend-federal-efforts-to-reform-organ-donation-system-urge-acceleration-of-rules-impact->.

³ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77898 (published Dec. 02, 2020) (42 C.F.R. Part 486) (CMS-3380-F), <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to->.

⁴ Press Release, Bipartisan, Bicameral Members of Congress Commend Federal Efforts to Reform Organ Donation System, Urge Acceleration of Rule’s Impact (July 20, 2021), <https://www.finance.senate.gov/chairmans-news/bipartisan-bicameral-members-of-congress-commend-federal-efforts-to-reform-organ-donation-system-urge-acceleration-of-rules-impact->.

⁵ Press Release, Bipartisan, Bicameral Members of Congress Commend Federal Efforts to Reform Organ Donation System, Urge Acceleration of Rule’s Impact (July 20, 2021), <https://www.finance.senate.gov/chairmans-news/bipartisan-bicameral-members-of-congress-commend-federal-efforts-to-reform-organ-donation-system-urge-acceleration-of-rules-impact->.

⁶ Press Release, Bipartisan, Bicameral Members of Congress Commend Federal Efforts to Reform Organ Donation System, Urge Acceleration of Rule’s Impact (July 20, 2021), <https://www.finance.senate.gov/chairmans-news/bipartisan-bicameral-members-of-congress-commend-federal-efforts-to-reform-organ-donation-system-urge-acceleration-of-rules-impact->.

- Remove the loophole in the 2020 regulations that enabled OPOs to count pancreata for research in the metrics. 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. We urge CMS to include the procurement of pancreata islet cells for transplant rather than the much broader inclusion of all pancreata for research.

CMS should also require OPOs to submit process data and make it publicly available on its website. Currently, this data is not available to CMS, Congress, or to the public. This reduces transparency and allows for continued underperformance, failures, and missed opportunities for improvement. At least seven OPOs have already committed to sharing their process data with the Massachusetts Institute of Technology, which will de-identify the data and make it publicly available.⁷

CMS should also require robust, independent oversight by each OPO governing board and medical advisory boards consistent with best practices for non-profit governance. Members of these boards should follow professional guidelines that require them to attest to serve the public interest and oversee OPO leadership, policies, and procedures. Members should also disclose any conflicts of interest, including any direct or indirect financial arrangements relating to organ donation or transplantation, and make these attestations available to CMS. To help accomplish this, we ask that CMS:

- Review the membership of the governing boards to ensure all stakeholders are adequately represented, including transplant centers, donor hospitals in their assigned service area, and patient and donor families.

As CMS begins to implement and enforce the new OPO performance metrics, CMS should also establish a competitive and efficient process for replacing decertified, underperforming OPOs to facilitate continuity and improvements in the operation of the U.S. organ procurement and transplant system. Evidence suggests that mergers following decertification of underperforming OPOs could result in increased efficiency, increased procurement of transplantable organs, and reduced overall cost incurred by CMS.⁸ We ask that CMS consider the following:

- Prepare adequate guidance and systems to facilitate the transition of a decertified OPO's donation service areas with minimal disruption;
- Publish independent guidance and best practices to manage the decertification and merger process; and⁹
- Establish a process for continued review of merged OPO donation service areas to ensure there is not a decrease in performance outcomes.

⁷ Press Release, FAS Announces Organ Procurement Organization Innovation Cohort (May 4, 2021), <https://fas.org/press-release/fas-announces-organ-procurement-organization-innovation-cohort/>

⁸ Paul Rosenberg et al., *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations*, THE BRIDGESPAN GROUP (Nov. 19, 2020), <https://www.bridgespan.org/insights/library/public-health/transforming-organ-donation-in-america>.

⁹ *Id.*

Lastly, we urge CMS to prioritize the review and implementation of input received through its RFI. Once finalized, we ask CMS to produce a summary of the RFI input to our staff and provide a briefing on the steps CMS determines are necessary to realize the full potential of the U.S. transplant system, based on its research to date and input from the RFI.

We look forward to collaborating with HHS, CMS, and HRSA as we work to ensure that the U.S. organ procurement and transplantation system performs to its highest potential. Please contact Melissa Dickerson with Chairman Wyden's staff, DeLisa Ragsdale and Caitlin Soto with Senator Grassley's staff or Beth Nelson with Senator Young's staff if you have any questions.

Sincerely,



Ron Wyden
Chairman
Committee on Finance



Chuck E. Grassley
Member
Committee on Finance



Todd Young
Member
Committee on Finance



Benjamin L. Cardin
Member
Committee on Finance



Jerry Moran
United States Senator