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MEMORANDUM

To: Senate Finance Committee Staff
Allyson Horstman
Shade Streeter
Robert Walsh

Date: March 16, 2026

Subject: The Organ Transplant System Improvement Act - Discussion Draft

Summary

Thank you for the opportunity to comment on the Discussion Draft of “The Organ Transplant System Improvement Act.” As a researcher and expert on deceased donor care and the use and outcomes of centralized donor management, I support proposed efforts to regulate and monitor donor care units to ensure that processes and outcomes deliver promised value and mitigate potential risks to system stakeholders.

In the United States, care of potential organ donors after brain death resembles care of living patients, but with crucial differences; because these patients are legally dead, some patient care protections (such as hospital bed licensure and clinical staff credentialing) do not apply. Therefore, deceased donor care delivery exists in a poorly understood and highly variable healthcare system at risk of unethical practices and poor outcomes. Until we have rigorously established that known differences between care delivered to deceased organ donors and living patients are both necessary and superior, regulatory and reimbursement structures designed to ensure safe care of living patients should also apply to deceased potential organ donors.

This memo includes suggestions regarding the statutory text that will address some system shortcomings by

- 1) Refining the definition of an organ recovery center (ORC),
- 2) Expanding the group of facilities to which an ORC designation would apply, and
- 3) Enumerating the standards they should meet in service of this goal.

Background

I am a physician anesthesiologist, intensivist, and health services researcher who has worked in two hospitals – University Hospital San Antonio (Texas) and the Hospital of the University of Pennsylvania (Philadelphia) – that operate hospital-based organ recovery centers in partnership with regional organ procurement organizations (OPOs). Based on these experiences, I founded

the DONOR group – a consortium of donation-focused intensivists who lead these centers in 17 US acute-care hospitals – in 2021.^{1,2} Therefore, I have firsthand knowledge of hospital-based ORC operations – specifically the challenges clinicians face in leading and working in these centers to serve donors, families, and transplant recipients.

My research examines how centralizing deceased organ donor care affects the delivery of organ donor care, donation, and transplantation outcomes in the United States. I have received competitive research funding from AHRQ/PCORI and the NIH NHLBI for these efforts, which aim to identify opportunities to best leverage these units to improve donor management nationwide. One of the fundamental findings of my research is that donor care units vary widely in organizational structures, leadership, and clinical decision-making processes.^{1,2} These differences lead to highly varied priorities, including clinical services provided (for example, whether those services are shared with living patients), the proportions of regional donors transferred from acute-care hospitals, and individual center outcomes.³ While ORCs have been endorsed by a National Academies report,⁴ the number and types of organs recovered and transplanted from donors in these centers also vary.⁵ Furthermore, these outcomes are not universally superior to donation outcomes in regional hospitals, suggesting opportunities for system-wide improvement through standardization and data collection.

Our understanding of these centers and the best practices needed to provide promised value remains nascent because available information is captured by individual organizations for internal use without standardized collection or reporting. However, I believe that these challenges are surmountable using the tools available to the Senate Finance Committee. More specifically, because no DCU operates without direct investment and participation by organ procurement organizations, existing regulatory standards may be modified to address their use. In some cases, DCUs are owned and operated entirely by organ procurement organizations. In others, OPOs partner with one or more acute-care hospitals in their donation service area, with whom contract to provide space and clinical services. As a result, CMS jurisdiction over OPOs, acute-care hospitals, and ambulatory surgical facilities necessarily applies to all donor care units. I have reviewed and commented on the draft legislation, with my comments summarized here by section:

Section 103. Requiring clear protocol standards in organ donation recovery proceedings

Because deceased organ donation remains a rare event at most hospitals, and because organ donation processes and technologies are evolving rapidly, the content and quality of protocols for donor management vary among hospitals and donation regions. Our work has found, for example, that OPO protocols used to guide anesthetic care delivery during organ recovery from deceased organ donors after brain death are frequently outdated and inadequate to guide contemporary management⁶ – which may be particularly crucial when this work is not carried out by physician anesthesiologists or anesthesia care teams. More generally, protocolization is not a panacea; protocols are limited by the available evidence, require concerted implementation, updating, and adherence efforts. Despite these limitations, there is evidence

¹ Vail EA et al. Best Practices for Intensivists Planning and Opening Hospital-Based Deceased Organ Donor Care Units: Part 1. *CHEST Crit Care* 2025 Mar; 3(1):1100110. [https://www.chestcc.org/article/S2949-7884\(24\)00064-9/fulltext](https://www.chestcc.org/article/S2949-7884(24)00064-9/fulltext)

² Vail EA et al. Best Practices for Hospital-Based Donor Care Unit Operations: Part 2. *CHEST Crit Care* 2025 Jun; 3(2):100144. [https://www.chestcc.org/article/S2949-7884\(25\)00017-6/fulltext](https://www.chestcc.org/article/S2949-7884(25)00017-6/fulltext)

³ Vail EA et al. Characterizing proximity and transfers of deceased organ donors to donor care units in the United States. *Am J Transplant* 2024 Jun;24(6):983-992.

⁴ National Academies of Science, Engineering, and Medicine. Realizing the Promise of Equity in the Organ Transplantation System. Washington, DC: National Academies Press, 2022. <https://doi.org/10.17226/26364>

⁵ Vail EA et al. Lung Donation and Transplant Recipient Outcomes at Independent vs Hospital-Based Donor Care Units. *JAMA Netw Open* 2024 Jun 3;7(6):e2417107.

⁶ Vail EA et al. Anesthetic Management of Organ Recovery Procedures: Opportunities to Increase Clinician Engagement and Disseminate Evidence-based Practice. *J Neurosurg Anesth* 2024 ; 36(2) : 174-176

that protocol adherence is better in ORCs.⁷ Anecdotally, high-volume donor centers offer opportunities for intensivists and other clinician experts (including transplant physicians and surgeons) to develop and refine evidence-based protocols that incorporate critical safety measures (such as donation pause initiatives recently proposed by HRSA⁸ and protocols for reevaluating brain death when misdiagnosis is suspected).

Therefore, I recommend that in the statutory text, you require:

- 1) The HHS Secretary to establish an expert process to inform a set of national standards
- 2) Hospitals and organ procurement organizations to adhere to these standards
- 3) Reporting of major protocol violations – including adverse events that occur during clinical donor management and organ recovery – by hospitals and organ procurement organizations to HHS.

Section 104. Organ Recovery Centers and 105. Regulations regarding Organ Recovery Centers

1. The term 'organ recovery center' may not be acceptable to all system stakeholders. For example, the LifeLink of Georgia ORC at Piedmont Hospital (Atlanta, GA) recently changed its name to a 'Donor Care Unit' (DCU) on the recommendation of donor family council members. This is also the term preferred by most DONOR group members.
2. The proposed legislation appears to exclude most operating ORCs – which are co-located within acute-care hospitals. In hospital-based ORCs, donor management and recovery responsibilities are shared in varying ways among hospitals, clinicians and staff (acting as contractors), and OPOs. Because hospital-based DCUs now represent most US DCUs,¹ and because not all hospital-based DCUs apply the same standards of care to patients and deceased donors (e.g., by using hospital beds not licensed by state agencies), they should also be subject to donor management-specific oversight efforts.

Therefore, I recommend changing the term to 'Donor Care Unit' or 'Donor Care Center' (more comprehensively including both ICU and OR space) and adopting a more inclusive definition of an ORC, such as 'any facility that accepts transfers of potential organ donors after brain death or potential DCD patients' from acute-care hospitals for the purpose of donation-specific evaluation, management, and organ recovery.'

3. Policymakers need data and tools to understand donor centralization. In addition to mandating donor care unit inspections, please consider the following DCU requirements, proposed to facilitate performance benchmarking and outcomes research:
 - a. Complete an annual operations and outcomes survey and site visit, with center locations, operations, and outcomes made publicly available.

At present, there is no registration or certification process for DCUs. Therefore, system stakeholders do not have ready access to important information about DCU operations and outcomes. For example, the DCU list provided (attachment) was compiled through direct OPO communication and review of publicly available materials (e.g., press releases) and is therefore limited. The data collection and reporting process for DCUs

⁷ Chang SH et al. Lung Focused Resuscitation at a Specialized Donor Care Facility Improves Lung Procurement Rates. *Ann Thorac Surg* 2018 May; 105(5): 1531-1536.

⁸ HRSA Directive for OPTN Donation after Circulatory Death Policy Development . 2025. Available at: <https://www.hrsa.gov/optn/policies-bylaws/public-comment/hrsa-directive-optn-donation-after-circulatory-death-policy-development>

could mirror that already used by SRTR to generate and publish OPO and transplant program-specific reports and datasets for use by researchers and policymakers.

- b. Convene a consensus conference to establish donor care unit best practices and performance measures important to stakeholders; the DONOR group has published a proposed preliminary list¹
 - c. Classify DCU operations into one of four types, all of which are currently in use in the US:
 - i. Independent (separate from hospital facilities, typically co-located with OPO offices)
 - ii. Hospital-based (co-located with and sharing some or all resources with an acute-care hospital)
 - iii. Operating room only (accepting transfer of potential donors direct to operating rooms for organ recovery only)
 - iv. Hospital transfer arrangement (accepts transfer of potential donors to spaces entirely shared with living patients on an ad hoc basis, without specific intensivist leadership)
 - d. Report when individual donors are transferred to ORCs using existing registry programs (e.g., OPTN Donor Net). Limited information about donor transfers has been included in the deceased donor registry files since 2017, but recording remains optional, and data are incomplete (for example, the DCU name is entered by organ donation coordinators as a free-text field, requiring manual classification for comparison between centers).
4. Safe operations. Participate in a mandatory donor safety surveillance system (that includes recording and auditing of adverse events during donor transfer, clinical management, and organ recovery). This is particularly important because of work demonstrating higher rates of cardiac arrest after brain death among organ donors transferred to donor care units.⁹ CMS standards should apply – moving a donor to another location does not obviate their need for high-quality care or waiving of standards applicable to acute-care hospitals.
 5. Reimbursement. Require DCU-specific cost reporting. Adoption of donor care units has rapidly outpaced the strength of published outcomes evidence; operational and cost efficiency appear to be major drivers. However, cost savings are self-reported¹⁰ and cannot be ascertained from the current format of CMS cost reports. ORC-specific costs, including construction, equipment overhead, staffing, and operations, should be separately delineated.

Thank you for the opportunity to submit these comments.

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⁹ Vail EA et al. Deceased Organ Donor Management and Organ Distribution From Organ Procurement Organization-Based Recovery Facilities Versus Acute-Care Hospitals. *Prog Transplant* 2023 Dec; 33(4): 283-292

¹⁰ Gauthier JM et al. Economic evaluation of the specialized donor care facility for thoracic organ donor management. *J Thorac Dis* 2020;10:5709-5717.

Enclosures:

List of donor care units operating in the United States as of January 22, 2026 – compiled with Rocio Lopez Moscoso, PhD (University of Colorado)

- 1) List of DONOR group member content experts
- 2) Slide deck summarizing contemporary US donor care unit use, outcomes, and knowledge gaps

Views expressed by the researchers are their own and do not necessarily represent those of the University of Pennsylvania Health System (Penn Medicine) or the University of Pennsylvania.