OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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The Honorable Norris W. Cochran
Acting Secretary
U.S. Department of Health & Human Services
200 Independence Avenue S.W.
Washington, DC 20201

RE: [CMS-3380-F2] Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date

Dear Acting Secretary Cochran,

The Organ Procurement Transplantation Network (OPTN) is pleased to submit additional comments in response to the final Organ Procurement Organization ("OPO") performance measures rule. The OPTN is the nation's organ donation and transplantation network and is made up of over 350 clinical, professional, patient and donor volunteers. The OPTN has carefully reviewed the final rule as published on December 2, 2020. The OPTN's support for the goals of the final rule is unwavering, as a better understanding of "donor potential" would be beneficial for assessing OPO performance and continuing improvement of the system to serve patients in need of transplantation. We remain concerned that the approach adopted by CMS is methodologically flawed and lacking in evidence. Further, it does not sufficiently address implementation nor does it take into account the realities of the private nonprofit sector. The OPTN encourages deeper engagement of the community in the development of innovative, holistic approaches to system accountability and improvement.

Our recommendations are as follows:

- **Set the performance "bar" on a four-year cycle.** The system's current success is due in part to a longstanding focus on collaborative improvement. A hypercompetitive environment with annual re-benchmarking will not serve the goals of collective improvement. Significant variability year-to-year is inherent in our system, and donation and transplant rates may vary based on variables outside of the control of OPOs and transplant programs alike. Setting a performance bar every four years will allow for stable progression towards an identified goal while ensuring clear accountability of an OPO's performance over time.

- **Improve coordination between CMS, HRSA and the OPTN**: Regular information exchange between the entities with overlapping jurisdiction over the national donation and transplantation system is key to identifying gaps in performance. The interdependence of these entities in ensuring aligned incentives and oversight is key to moving the system forward in a coordinated manner.

- **Develop a plan for management of service areas of decertified OPOs, and limit the number of OPOs that are decertified or DSAs up for competition in one year.** The final rule makes several assumptions about the operations of the system in the midst of decertification and does not offer guidance about how donation may be facilitated in the event an OPO (or multiple OPOs) cannot maintain staffing levels in the year prior to decertification. Guidance is necessary because, among other practical considerations, OPOs are unlikely to compete for or work towards a "friendly merger" for fear of being unable to conduct a turnaround in less than a year and risk decertification themselves. A performance threshold at the 25th percentile is unprecedentedly high, and could require surviving OPOs to absorb and turnaround more than one decertified OPO simultaneously while maintaining high performance in their existing service area. CMS can address these issues by ensuring a manageable number of transitions occur simultaneously, prioritizing the low performing OPOs facing decertification and either eliminating, as a regulatory component, or deferring any competition for tier 2 OPOs until later certification cycles occurring after the system has developed clear processes to appropriately manage service area transitions.

- **Leverage existing data sharing innovations to obtain data critical to understanding "donor potential."** Reports of existing voluntary data sharing agreements between OPOs and donor hospitals (currently in place in New England, the South, and Midwest) have yielded patient-level hospital inpatient death data, which is provided to the OPO through a simple electronic process. Further, the OPTN is working to identify effective deceased donor referral practices[1] nationwide and plans to propose new standards to the Office of the National Coordinator for Health Information Technology (ONC). Improving the accuracy and timeliness of the data that can be utilized to hold OPOs accountable presents a real, system-wide opportunity. The data set in the final CMS rule does not offer that improvement. In addition to being insufficiently accurate and timely, CDC death data is, simply put, generally unable to clinically identify a donor and does not offer improvements upon the current audited data available. Further, underlying conditions inconsistent with organ donation are not captured on death records. Critically, the presence or absence of a ventilator at the time of death is not captured; non-ventilated deaths have no potential for organ donation. We encourage CMS to review the solutions already in place in the system.

- **Remove external disincentives to transplanting organs from older donors and donations after cardiac death.** OPOs recover over 5,000 kidneys each year that are not transplanted. While both HHS[2] and the donation and transplant community have a longstanding commitment[3,4] to increasing the number of transplants, in part by expanding the use of these organs, existing payment models provide powerful disincentives. HHS' own collaborative efforts in 2012 espoused a "push-pull" solution of more donors *and* higher utilization by

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[1] *OPTN has embarked upon a demonstration project involving effective potential deceased donor referral practices.* (2020 November 18). Retrieved 10 February 2021 from https://optn.transplant.hrsa.gov/news/optn-has-embarked-upon-a-demonstration-project-involving-effective-potential-deceased-donor-referral-practices/.

[2] Institute for Healthcare Improvement. *Improvement Stories: Organ Donation Breakthrough Collaborative.* http://www.ihi.org/resources/Pages/ImprovementStories/OrganDonationBreakthroughCollaborative.aspx. Retrieved 12 Feb. 2021.

[3] The OPTN Collaborative Innovation and Improvement Network. https://optn.transplant.hrsa.gov/resources/coiin/. Retrieved 12 Feb. 2021.

[4] Neil, H., Overacre, B., Rabold M., Haynes CR. *OPTN Systems Performance Committee Report to the OPTN Board,* 10 June 2019. https://optn.transplant.hrsa.gov/members/committees/ad-hoc-systems-performance-committee/

transplant centers. Review of these and other factors is needed to ensure that the organs recovered by OPOs are actually accepted and utilized by transplant programs for the benefit of patients waiting. Without this alignment, holding OPOs accountable for transplantation under the CMS OPO metrics will not produce the desired result of actually transplanting more patients.

- **Enable OPOs to merge and share services.** In today's environment, OPOs that wish to merge face a costly, multi-year process. Offering a more streamlined process for reviewing and approving a change in ownership for currently-certified OPOs may yield many of the results desired in the rule. CMS should ensure that OPOs are not disincentivized from merging with a newly-merged service area of a formerly lower-performing OPO following implementation of the new regulation.

Today, our system stands as the highest performing in the world, garnering an eighth consecutive year of growth even in the midst of a worldwide pandemic.[5,6] It performs three times the deceased donor transplants as all other countries' living and deceased donor transplants combined.[7] The OPTN and its members are continually seeking methods for continuing incremental growth through a commitment to collaborative improvement. A review of the evidence offered in the proposed rule raises some concerns regarding the lack of empirical evidence for conclusions such as competition as a tool to drive performance improvement in a nonprofit network model and circular references, often from the same source of funding. Your collaboration with the patients, families and professionals that are dedicated to this work is key to driving improvement.

We welcome the opportunity to discuss further with you.

Sincerely,

David Mulligan, MD, FACS
President, OPTN Board of Directors

Attachments

[5] *Annual record trend continues for deceased organ donation, deceased donor transplants*. (14 January 2021). Retrieved February 10, 2021, from https://www.prnewswire.com/news-releases/annual-record-trend-continues-for-deceased-organ-donation-deceased-donor-transplants-301208387.html#

[6] Stewart D, Zehner A, Klassen D, Rosendale J. *The drug overdose epidemic does not explain all of the rise in deceased donation*. Clin Transplant. 2020 May;34(5):e13858. doi: 10.1111/ctr.13858. Epub 2020 Apr 10. PMID: 32275094.

[7] The Global Observatory on Donation and Transplantation. *Global Data.* Retrieved 19 Feb. 2021. http://www.transplant-observatory.org/summary/.