

March 4, 2021

The Honorable Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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 Administrator Richter:

As leaders in the national donation and transplant system, we thank you for providing the public an additional opportunity for comment on CMS's final rule on Organ Procurement Organization (OPO) Medicare conditions for coverage (CMS-3380-F2). We are speaking with a unified voice because we are united in the shared mission of our national system to save the most lives possible through organ donation and transplant. We appreciate the efforts by CMS to focus the community on continuous improvement and respect the outcome of the federal Rule Making Process.

The recently-issued CMS rule included regulatory changes for only OPOs to bear full responsibility for increasing access to transplantation, and in doing so created unintentional and unnecessary imbalances within our complex and interdependent organ donation and transplant ecosystem. This system was created to be collaborative and has become the best in the world thanks to the strength of that collaboration. Further system improvements can be achieved by maintaining the collaborative spirit, and with the help and support of a new Administration committed to building on the successes of the transplantation effort.

In asking for your support, we believe we should make it clear that all the signatories acknowledge two facts: 1) all participants in the system – donor hospitals, transplant centers, OPOs, clinicians and surgeons, researchers and scientists in the field, governmental agencies (including both CMS and HRSA) and, most importantly, organ donors (living donors and family of deceased donors) and transplant candidates and recipients – are dedicated to saving American lives; and 2) most who work within the system desire and are committed to a collaborative system modification. We believe there is ample opportunity to advance our shared vision, in the following ways:

1. **Improve the entire system, not just one part:** Our system is undoubtedly capable of increasing the number of organs available for transplant and is already on track to exceed the benchmarks sought by the previous Administration. However, to achieve these targets, in addition to re-designing OPOs regulations, we must also make other system changes necessary to increase the identification and referral for donation, remove many of the disincentives for donation, and increase the transplantation of organs at risk of discard. The system can, and should, increase clinically appropriate utilization of such organs. These organs are suitable for transplantation for carefully selected potential recipients but which currently are not transplanted as the result of a number of features of the current system that disincentivize utilization of these organs.

We recommend that the Administration support transplant community efforts to revise transplant center metrics to remove current disincentives to transplant organs at risk of discard, and that work with the community to jointly develop and to implement a plan for increasing utilization of more high-risk organs, as do European countries.^{1,2}

2. **Involve all stakeholders in the system design:** As colleagues across the system, we routinely work together to improve it from the inside. Similarly, government intervention should include perspectives from the patients, donor families, and professionals that do this lifesaving work every day.

We recommend the Administration establish the Organ Donation & Transplant Innovation Task Force and ensure it includes representatives of CMS, HRSA, the FDA, the OPTN, the SRTR, representation from the American Society of Transplantation, and the American Society of Transplant Surgeons, and from the transplant donor and recipient communities to continue work on these critical issues in collaboration.

3. **Eliminate barriers and align incentives:** While organizations such as ours are continuously improving our own work, we would benefit significantly from government intervention that eliminates barriers to collaboration across groups, with the aim of continuous improvement.

We recommend additional favorable adjustments to payment models for transplants utilizing organs at risk of discard, streamlining the OPO merger and decertification processes, increasing hospital incentives for donor identification, removing family disincentives that hinder donation, and improving coordination between agency partners. These are just a few of the solutions that can be put into effect immediately.

4. **Capitalize and expand the available framework for improving the system collaboratively:** The original intent in Congress' establishment of the Organ Procurement and Transplantation Network (OPTN) was to enhance system change via collaborative improvement. Further strengthening of the system through utilization of currently available resources can be achieved for the benefit of our patients. One of the best examples of achieving progress through collaboration has been the increases in donation following the Organ Donation Breakthrough Collaborative³ that brought together 95 transplant and non-transplant hospitals and all OPOs to share effective practices.

We recommend the administration facilitate strengthening the collaborative spirit of the current system, through expanding access to projects such Collaborative Innovation and Improvement Network (COIIN)⁴ and the recommendations of the OPTN Systems Performance Committee.⁵

5. **Ensure system performance and quality with a detailed implementation plan:** We all agree that OPOs must demonstrate their ability to best serve patients. We agree that consistently underperforming OPOs should engage in a process that starts with detailed improvement plans prior to consideration for decertification.

¹ Chandraker, Anil, et al. "Time for Reform in Transplant Program-Specific Reporting: AST/ASTS Transplant Metrics Taskforce." Wiley Online Library, John Wiley & Sons, Ltd, 23 May 2019, <http://onlinelibrary.wiley.com/doi/10.1111/ajt.15394>.

² *Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards*. 22 October 2018. <https://www.kidney.org/news/report-national-kidney-foundation-consensus-conference-to-decrease-kidney-discards>

³ Institute for Healthcare Improvement. *Improvement Stories: Organ Donation Breakthrough Collaborative*. <http://www.ihl.org/resources/Pages/ImprovementStories/OrganDonationBreakthroughCollaborative.aspx>. Retrieved 12 Feb. 2021.

⁴ The OPTN Collaborative Innovation and Improvement Network. <https://optn.transplant.hrsa.gov/resources/coiin/>. Retrieved 12 Feb. 2021.

⁵ 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/>

We recommend that the OPO Conditions for Certification CfC Final Rule incorporate a highly detailed process improvement plan for underperforming OPOs. In addition, a transition plan should be developed for decertified OPOs to ensure that organ recovery can continue without disruption or patient harm and that other initiatives underway to maximize the system still move forward.

A partnership among the key stakeholders in the system is key to ensuring we not only meet but exceed the reform goals. Recent estimates demonstrate that by working more closely together as outlined above, partners in organ donation and transplantation can perform **10,000 more transplants**⁶ than to the 41,000 projected in the OPO CfC Final Rule, an important step on the road toward providing a transplant to everyone who needs it. As proud representatives of this life-saving system, we are eager and ready to work with the Biden administration to achieve this goal and save more lives.

Sincerely,



David Mulligan, MD
President, United Network for Organ Sharing



Marwan Abouljoud, MD
President, American Society of Transplant Surgeons



Richard Formica, MD
President, American Society of Transplantation

⁶ Hamory, B., Javanmardian, M., Shellenbarger, D. *Increasing Deceased Donor Organ Donation & Transplantation: Opportunities for Improvement 2021-2026*. February 2021. [https://www.oliverwyman.com/content/dam/oliverwyman/v2/publications/2021/feb/Organ%20donation_Feb9%20\(003\).pdf](https://www.oliverwyman.com/content/dam/oliverwyman/v2/publications/2021/feb/Organ%20donation_Feb9%20(003).pdf).