



October 9, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Secretary:

As Organ Procurement Organization (OPO) leaders, we are grateful for your time and attention to the issue of organ donation. We want to make sure you have the best information available to empower the U.S. Department of Health and Human Services (HHS) to advocate for what will best serve transplant candidates and donor families - including and especially by publishing CMS's new proposed regulation.

OPOs are government contractors that hold the only access to organ donation for our communities. This is both an honor and a responsibility that we must continually earn; we are not entitled to retain a government contract unless we prove a high level of service to our community. Currently, the government's ability to objectively assess OPO performance is hindered by self-reported data¹ and a lack of transparency into our practice², which has allowed underperforming OPOs to avoid consequence. This can, and should, be remediated by CMS's new proposed OPO metric.

We understand Congressional offices have been relaying their constituent OPO's opposition to this new proposed rule, so we want to convey we support the rule—and are animated by what is possible for patients.

We do not believe any community will be left without organ donation services if OPOs are decertified for underperformance. CMS explicitly stated as much in the proposed rule: *"Our goal is to ensure continuous coverage of an OPO service area in the event an OPO is decertified."*³ In practice, when an OPO is decertified, what will happen is the OPO will be subsumed by a higher performing OPO, a practice rooted in decades of historical precedence. In fact, there were originally 128 OPOs, and after decades of consolidations—none of which were "disruptive"—there are now 58 OPOs. We trust that CMS can build on these lessons and industry best practices to ensure any transitions are smooth and patients are served by high performing OPOs.

Secondly, we understand there is some question as to whether the CMS proposed rule is "arbitrary." We don't believe so. We, instead, want to focus on whether the projected OPO improvement targets published in the NPRM are achievable and in our experience of working within the OPO community for 30 years or more, we believe unequivocally that they are. Several of us have personally led OPOs through performance improvement projects that

1 Cannon, RM, Jones, CM, Davis, EG, Franklin, GA, Gupta, M, Shah, MB. Patterns of geographic variability in mortality and eligible deaths between organ procurement organizations. *Am J Transplant*. 2019; 19: 2756- 2763. <https://doi.org/10.1111/ajt.15390>

2 Doby, B. L., Boyarsky, B. J., Gentry, S. and Segev, D. L. Improving OPO Performance Through National Data Availability. *Am J Transplant* 2019. doi:10.1111/ajt.15508

3 "OPOs Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization," Centers for Medicare & Medicaid Services, 2019.



have rapidly increased our OPO's performance, and we believe - with proper leadership - that such improvements are possible throughout the country.

Finally, we believe there are opportunities to work with HHS to create technology tools enabling hospitals to provide immediate, electronic notification of potential donors to OPOs⁴. We believe this could transform the organ donation process and meet HHS' objectives to substantially increase organ availability. We are ready to work with you in this regard.

If OPOs spent their time and resources, right now, rapidly improving their practice and increasing organ donors, we believe that many—if not all—of our colleagues would not face decertification. To the extent that an OPO is not able to rise to the challenge of a high CMS standard, the focus of our attention and energy must be on better serving patients on the national waitlist, not on protecting specific OPOs.

If we accept that such improvements are possible—and we understand that such improvements are lifesaving—realizing these gains is not simply a policy question, but a social imperative.

High performance standards in donation medical care are not arbitrary. Improved OPO performance is attainable, as shown by many of our organizations. Any weakening of CMS's proposed standard will—definitionally—result in lives lost, which is directly antithetical to our mission. Thank you for this opportunity, and we look forward to rising to meet the new, higher standards. Patients deserve nothing less.

Sincerely,

DocuSigned by:

Diane Brockmeier

EF14262F21B14C1...

Diane Brockmeier
President & CEO
Mid-America Transplant
St. Louis, Missouri

DocuSigned by:

Ginny McBride

2B2CA80894D9496...

Ginny McBride
Executive Director
OurLegacy
Orlando, Florida