

Organize appreciates the opportunity to comment on important questions raised by the Centers for Medicare and Medicaid Services on ways to improve the nation's organ donation system. Organize is a non-profit patient advocacy group that promotes evidence-based policy solutions to increase patient access to organ transplant nationally. For 2015 and 2016, Organize served as the Innovator in Residence in the Office of the Secretary of the Department of Health and Human Services (HHS).

During this time, with philanthropic support from the Laura and John Arnold Foundation and in research partnership with The University of Pennsylvania and the Bridgespan Group, we undertook research and published an objective framework by which to evaluate the effectiveness of the organ donation system, particularly pertaining to Organ Procurement Organizations (OPOs), which operate as unchecked regional monopolies with no systemic pressures for performance improvement.

Organize supports, without modification, the performance metrics proposed in the NPRM:

- “Donation rate,” measured as the number of actual deceased donors as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation; and
- “Organ transplantation rate,” measured as the number of organs procured within the DSA and transplanted as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation.

For too long, OPOs have operated with no accountability, allowed to self-interpret and self-report their own performance standards, and effectively operating under a set of gameable and unenforceable metrics. This has allowed underperforming OPOs to retain lucrative government contracts indefinitely, and has allowed middling OPOs to operate without urgency to improve in a space where the cost of underperformance is life and death. As a result, patients have been saddled with a system which fails to recover as many as 28,000 lifesaving organs for transplant every year.<sup>1</sup>

Additionally, Organize supports, also without modification, the performance standard proposed in the NPRM, which requires OPOs to maintain performance that is not statistically significantly different from the top 25 percent of OPOs in order to maintain their certifications. Given that OPOs only recover roughly 35% of potential donors<sup>2</sup>, it is clear that the field of government contractors is failing across the board, and patients deserve a minimum acceptable standard which reflects that.

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<sup>1</sup> <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf>

<sup>2</sup> <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf>

Organize also applauds CMS for setting a standard anchored in a relative measure rather than an absolute measure, given that macro changes in public health may increase or decrease the eligible donor pool in any year, even if OPO performance does not change.

For instance, while OPOs tout an improvement of 46% nine years<sup>3</sup>, peer-reviewed research shows that this is “almost wholly attributable to the drug [opioid] epidemic, and reflects the byproduct of a national tragedy, rather than an improved system to be celebrated.”<sup>4</sup> If OPOs were held only against an absolute performance standard, however, this circumstantial improvement in the absolute number of donors recovered could potentially allow a poor-performing OPO to retain its contract.

It is also vitally important that CMS take meaningful action against OPOs deemed out of compliance. Historically, interventions as simple as targeted management changes have proven transformative.

For example, the Washington OPO replaced its CEO in 2010 and increased donation by 66% over 5 years, outpacing the national average improvement of 14%; OPOs in Oklahoma, Arizona, and Nevada each replaced CEOs in 2012, and within 5 years had improved recovery rates by 100%, 98%, and 73%, respectively, far outpacing the average OPO improvement of 26% over that same period, which itself was largely due to the opioid epidemic<sup>5</sup>; and, most recently, the San Francisco OPO changed its CEO in 2019 and increased donation rates by 29% in one year, suggesting that significant improvements can be affected immediately, even in geographies in which donation rates have been chronically low for decades.

Beyond simply driving targeted management turnover, CMS can also outright decertify an underperforming OPO, with its designated service area assigned to neighboring OPO(s), and/or force that OPO to consolidate with other OPOs. CMS should not hesitate to consider either of these interventions.

While OPOs arguments for the status quo have often been rooted in the argument that change could lead to disruption in service — and, by extension, a short-term decrease in donation rates — during such a period of transition, empirical evidence shows the opposite. Although flaws in the current OPO metrics (in place since 2006) have prevented OPO decertifications<sup>6</sup>, there is still precedent for OPO consolidation from prior to 2006 in cases ranging from 1996 - 2004.

The last five times OPOs were consolidated — before the current regulations came into place — were in Georgia (1997), Washington State (1997), Florida (2004), Virginia (2000), and California (1999), which saw 5-year increases in donation rates of 46%, 40%, 33%, 26%, and 16% respectively, each outpacing the national average OPO improvement over that same

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<sup>3</sup> <https://www.aopo.org/2019-marks-another-record-year-for-organ-donation/>

<sup>4</sup> <https://onlinelibrary.wiley.com/doi/abs/10.1111/ctr.13755>

<sup>5</sup> <https://onlinelibrary.wiley.com/doi/abs/10.1111/ctr.13755>

<sup>6</sup> [https://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](https://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)

period.<sup>7</sup> Additionally, in 3 of the 5 cases organ recovery increased even in the same year (Georgia by 22%; Virginia by 17%; and Florida by 2%).

Historical results also likely understate how effective this intervention will be going forward since they happened due to individual OPO decisions, rather than CMS proactively identifying underperforming OPOs and consolidating those DSAs into markedly higher performing ones.

The alternative intervention would almost necessarily be some form of allowing an OPO to retain its contract while imposing upon them some sort of corrective action plan or systems improvement agreement (SIA), and there is no empirical evidence to suggest that SIAs are effective. One high-profile example is the OPO-based in New York City, LiveOn New York, which has been on successive corrective plans since at least 2013 and has continually failed to improve its performance<sup>8</sup>, including being considered non-compliant under the current NPRM.

Additionally, interventions for failing OPOs must also be considered from a systems-level perspective rather than in a vacuum. If underperforming OPOs are allowed to maintain contracts, then middling OPOs feel no credible risk of decertification; regardless of the impact of an OPO's decertification within its own service area (which, per above, historical evidence suggests will drive increases in donation), CMS must strongly enforce OPO decertifications and/or consolidations or else other OPOs will not feel urgency to meet compliance standards.

As such, the OPO argument that decertification will lead to a decrease in donation rates seems to be exactly wrong; not only is it countered by historical evidence suggesting that OPO consolidations bring short-term benefits to their DSAs, but it is very likely that donation rates will stagnate - if not even decrease - across the country if an underperforming OPO is *not* decertified. In a chronically underperforming system, patients should fear a perpetuation of the status quo, not a disruption of it.

Finally, it is important that these changes be brought to bear as quickly as possible. With 1,000 Americans dying or being removed from the organ waiting list each month for being too sick to transplant, we applaud any action that quickly changes what is possible for thousands of our country's most vulnerable patients.

Greg Segal  
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<sup>7</sup> <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>

<sup>8</sup> [https://www.washingtonpost.com/national/despote-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](https://www.washingtonpost.com/national/despote-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)