As physicians involved in the care and support of patients amidst the COVID-19 pandemic, we are writing to respond to this Request for Information on the urgency of accelerating organ procurement reforms to address pressing health equity issues and to save lives.

Each of us have treated patients grappling with the debilitating effects of organ failure, and the iniquitous ways that thousands of Americans are left to languish on the organ waiting list.

As physicians, it is horrifying to know that thousands of these patients each year could receive life saving transplants, however those precious opportunities are not currently available because of basic failures of accountability amongst organ procurement organizations (OPOs).

OPOs serve a critical function in American healthcare. We note, however, that:

- The majority of OPOs are failing tier 1 objective performance standards according to the Centers for Medicare and Medicaid Services (CMS);
- CMS has quantified those failures as costing thousands of lives each year;
- These failures disproportionately harm patients of color, who are more likely to need an organ transplant and yet less likely to receive one; and,
- No OPO known to be failing will be replaced by a higher-performing OPO until 2026, by which time 60,000 patients are projected to have died waiting for transplants.

We also note that COVID-19 damages organs and that the demand for organ transplants is estimated to increase dramatically, and, as bipartisan Congressional leaders have highlighted, increases the urgency of OPO reform. As Senators and House Representatives jointly wrote in July 2021: “The COVID-19 pandemic is exacerbating the need for organs now and creating an urgent health equity issue, as communities of color are disproportionately impacted by the failures of the current organ donation system and the effects of COVID-19.”

Given these facts, we ask that the Centers for Medicare and Medicaid Services (CMS) use this open rulemaking on OPO performance and equity to deliver on the Executive Order On Advancing Racial Equity and the Executive Order on Ensuring an Equitable Pandemic Response and Recovery with the following common-sense and patient-centered policies:

- All parts of the country should be served by high-performing OPOs as soon as possible, accelerating the date as called for by bipartisan Congressional leaders so that failing OPOs are replaced by higher performers before 2026.
- To be considered high-performing, OPOs must have a data-driven track record in equitable organ procurement across their designated service area.

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1 CNBC highlighted the prediction that “The next epidemic will be chronic kidney disease in the U.S. among those who recovered from the coronavirus.”

2 As noted at the bipartisan House Committee oversight hearing, several OPO executives have echoed the call for acceleration of accountability in patients’ interest.

3 As noted by CMS data published in Axios, there is a 10-fold variability in OPO recovery of Black donors across the country.
To have evidence of equitable service, CMS should make all OPO process data publicly available.\(^4\)

In determining which OPO will be awarded a designated service area, the relevant factors for patients should be (1) proven track record in recovered/transplanted organs; and (2) evidence of equitable service as seen in key process data such as response rates and times (e.g., no difference in response rates or times between potential donors of different ethnicities).\(^5\)

In enforcing the OPO final rule, CMS should continue to ensure that this lifesaving metric is not subject to manipulation that hides poor OPO performance by:

- Only counting transplanted organs within OPO performance (not organs procured, then thrown away, so-called “zero donors”); and,
- Rejecting OPO calls to lower standards of service for minority patient populations via a “race-based adjustment”, which [Congresswoman Ayanna Pressley](https://www.congress.gov/members/profile/ayanna-p.-pressley-116th-congress) characterized as a “racist request”, and which [past NAACP President Ben Jealous](https://www.naacp.org/) argued would “codify inequity into the health care system”.

Combining the points above, what matters to patients is receiving a call that a lifesaving organ is available. Incumbency of any individual OPO is not a patient-centered issue. CMS has already been clear: the status quo is killing patients. As physicians we share a sense of urgency that this fixable and deadly problem be addressed immediately.

As patient advocate and kidney recipient [Alonzo Mourning](https://www.washingtonpost.com/news/act-rx/wp/2019/08/02/this-should-be-easy/): “patients can’t wait; and the government shouldn’t either.”

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\(^4\) This follows international best practice (see [England](https://www.gov.uk/government/publications/guidelines-for-the-procurement-of-organ-and-tissue) and [Australia](https://www.redcross.org.au/medical-assistance/organ-donation-and-transplantation/organ-donation)), as well as the model of seven pro-reform OPOs who are working with the [Federation of American Scientists](https://www.fas.org/), to make all of their process available via the [Massachusetts Institute of Technology](https://www.mit.edu).

\(^5\) This follows a point made by pro-reform OPO Chief Executives in [Morning Consult](https://www.morningconsult.com): “HHS’s new proposal signals something potentially game-changing for patients: allowing the highest performing OPOs to replace those who have proven themselves incapable of serving their communities. To the extent that an OPO is not able to rise to the challenge of a high standard, the focus of our attention and energy must be on better serving patients on the national waitlist, not on protecting specific OPOs.”
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