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The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Topher Spiro
Acting Director for Health
Office of Management and Budget
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Washington, DC 20503

Dr. Marcella Nunez-Smith,
Chair of the COVID Equity Task Force
The White House
1650 Pennsylvania Ave NW
Washington DC 20502

Secretary Becerra, Acting Director Spiro, and Dr. Nunez-Smith:

I am writing as a retired officer of the US Public Health Service with thirty-seven years of active service, former Deputy Surgeon General, and former Acting Surgeon General of the United States.

More importantly, I write as an individual citizen, who has personal knowledge and experience with the organ donation and transplantation system, as a donor family member, twice over. I lost my wife, Donna Lee Jones Moritsugu, in 1984, to an auto crash. She became an organ and tissue donor. Four years later, a car struck and killed my younger daughter, Vikki Lianne Moritsugu. She too became an organ and tissue donor. And because of my wife and my daughter, many individuals received their organs and tissues, and a renewed lease on life for themselves, and for their families, loved ones, and society. I have been a fervent advocate for organ donation and transplantation, and have served on the Board of our local Organ Procurement Organization (OPO) for twenty-five years. I have seen and experienced the work and the impact of OPOs, from the outside, and from the inside.

With this background, I write you in full support of the Center for Medicare and Medicaid Services (CMS) rule issued on November 20, 2020: Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F.¹

I care passionately about these reforms because the biggest beneficiaries will be waiting list patients, organ recipients and donor families - all disproportionately people of color - which makes this rule a pro-patient and health equity reform. To understand why, it is important to understand the failings and shortcomings of the status quo.

The organ donation system is run by 57 government contractors called organ procurement organizations. But despite the incredibly important role OPOs play - the stakes are quite literally life and death - there are currently no objective measures in place to evaluate an OPO's performance, nor are there effective regulatory guardrails and metrics to ensure adequate management of those OPOs.

Indeed, the current OPO measures are self-interpreted and self-reported, rendering them not only unreliable, but legally unenforceable.² As a result, and despite what the Senate Finance Committee recently characterized as "OPOs... severely underperforming for decades,"³ no OPO has ever lost its government contract.⁴

It also must be underscored that poor performance from an OPO means that donor families are poorly served. Often, misallocation of OPO resources means OPOs do not respond to all donation cases, or do not properly train and support their frontline staff.⁵ The impact of this, unsurprisingly, falls disproportionately on families of color.

For example, a peer-reviewed study shows that "[t]he odds that a family of a White patient was approached for donation were nearly twice those for a family of an African American."⁶ And as Ben Jealous, past president of the NAACP, so powerfully wrote, "Black families are treated with far less compassion...The obvious corollary to Black Lives Matter is that Black deaths need to matter, too."⁷

¹ Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F, Centers for Medicare and Medicaid Services, <https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf>

² Kimberly Kindy, et al. *Despite low performance, organ collection group gets new federal contract*, The Washington Post, Feb. 2019, 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

³ Grassley, Wyden Subpoena the United Network for Organ Sharing as part of Continued Investigation into U.S. Organ Transplant System <https://www.finance.senate.gov/404?notfound=chairmans-news/grassley-wyden-subpoena-the-united-network-for-organ-sharing-as-part-of-continued-investigation-into-us-organ-transplant-system>

⁴ Laura and John Arnold, "A simple bureaucratic organ donation fix will save thousands of lives", STAT, July 2019, <https://www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/>

⁵ Kimberly Kindy, "Underperforming in New York: Nonprofit struggles to recover transplantable organs", the Washington Post, Dec. 2018, https://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html

⁶ Guadagnoli et. al, "The influence of race on approaching families for organ donation and their decision to donate." American Journal of Public Health, February 1999, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1508526/?page=1>

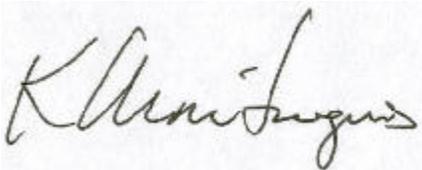
⁷ New Organ Donation Rule Is A Win For Black Patients And Health Equity, Health Affairs, <https://www.healthaffairs.org/doi/10.1377/hblog20201211.229975/full/>

The November 2020 OPO Final Rule will mark a major step in addressing these inequities. As one HHS official noted, “The most successful OPOs are high-performing because they are effective at serving the constituents within the geographic areas they serve. Conversely, if an OPO is deemed failing, this is highly likely to correlate with that OPO’s poor performance in communities of color.”⁸

More simply, by holding OPOs accountable through the swift and strong implementation and enforcement of the OPO Final Rule, HHS will create the proper incentives for OPOs to allocate taxpayer resources intelligently and effectively in service of donor families and in the spirit of inclusivity. The system has failed patients for forty years; the failure of government to address the underlying problem of OPO accountability would allow it to persist indefinitely.

The implementation of the OPO Final Rule will go far to improve the OPO part of the organ donation and transplantation system, resulting in more donors identified, approached, and consenting to donation, and concomitantly, in more individuals benefitting from increased organ recovery and availability, and increased transplantation. As a matter of health equity, patient outcomes, accountability and good, data-driven regulation,⁹ I urge the Biden-Harris Administration to implement the OPO Final Rule as quickly and as expeditiously as possible.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kenneth P. Moritsugu". The signature is written in a cursive style and is positioned above the typed name.

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⁸ The Costly Effects of an Outdated Organ Donation System: Inequity in Organ Donation, Bloom, <https://bloomworks.digital/organdonationreform/Inequity/>

⁹ The Costly Effects of an Outdated Organ Donation System: Foreword, Bloom, <https://bloomworks.digital/organdonationreform>