The Honorable Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave S.W.
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave S.W.
Washington, DC 2021

Dear Secretary Azar and Administrator Verma,

Thank you for your leadership on organ donation issues. As you are well aware, this is an area of great importance to the nearly 115,000 Americans currently on the waiting list for a lifesaving transplant, and one in dire need of reform. As such, I was heartened to see OPO metrics reform included in the President's Executive Order on Advancing American Kidney Health.[1]

As the President cited, recent research supported by Arnold Ventures has found that accountability measures for Organ Procurement Organizations (OPOs) could help the U.S. organ donation system recover as many as 28,000 additional organs for transplant every year.[2]

This is an issue I studied deeply during my tenure as Chief Technology Officer at HHS. As your Administration now has fewer than ninety days to propose a new OPO metric which is "reliable, transparent and enforceable," I hope my experience can be instructive as you consider how to engage with various stakeholders to inform your policy decisions.

In particular, I would like to bring your attention to a response to the Executive Order from the Association of Organ Procurement Organizations (AOPO). This response contains many misleading statistics, which I feel are important to correct so that you may operate on the best available information. What follows are the AOPO claims and fact checks of those claims.

---

[1] https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/

[2] https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf

AOPO claim: The last eight years have seen successive records for organ donation.

Fact check: While this is technically true, it is also enormously misleading; according to researchers at UNOS, Brigham and Women's Hospital, Eurotransplant International Foundation, and University of Utah Health, the recent increase in donations, and therefore transplants, are due to the opioid epidemic rather than improvements in OPO performance. According to Mandeep R. Mehra, MD, medical director of the Heart and Vascular Center at Brigham and Women's Hospital and first author on the study: "We were surprised to learn that almost all of the increased transplant activity in the United States within the last five years is a result of the drug overdose crisis".[3]

AOPO claim: Patient deaths on the waitlist are at an 18-year low according to the OPTN data.

Fact check: Over that same 18-year period from 2000 - 2018, while deaths on the waiting list have decreased by roughly 1,000 there has been a precipitous rise in patients codified as "too sick to transplant" of roughly 4,700. Such patients inevitably die after waitlist removal. The waitlist 'mortality' metric used by the Scientific Registry of Transplant Recipients (SRTR) combines those who die or are removed because they become 'too sick to transplant,' therefore the combination of these two waitlist removal reasons is the true definition of waitlist mortality.[4]

Because of the change in list management practices, the decline in reported deaths is illusory, and the organ shortage continues to present a critical risk to organ failure patients.

AOPO claim: OPO data reporting requirements are dictated by regulatory bodies and validated during regular audits. Oversight and accountability are provided through Centers for Medicare & Medicaid Services (CMS), the Health Resources and Services Administration (HRSA) of the U.S. Department of Health & Human Services, and the Organ Procurement and Transplantation Network (OPTN).

Fact check: While AOPO lists the various bodies who have some form of oversight over OPOs, what is at issue, by virtue of the President's Executive Order, is OPO performance metrics — for which only CMS has the responsibility to ultimately hold OPOs accountable. Although AOPO asserts here that OPOs are subject to regular audits, in a 2013 letter to the Office of Management and Budget, they argued: "[OPO] data are unaudited and self-reported, [and] there is no provision for even random audits of the data submitted by OPOs to assess the accuracy of the data reporting."[5]

---

[3] https://healthcare.utah.edu/publicaffairs/news/2018/05/nejm-opioid.php

[4] See also: https://www.srtr.org/media/1100/hart-a_predict-outcomes-on-liver-tx-wait-list-in-us_large-region-varia-in-organ-avail_2016-transplantation.pdf

[5] https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf

Here it is worth noting the role of the OPTN. With regard to OPO performance related to organ recovery, the OPTN is tasked by the Final Rule 1221.10 to "design appropriate plans and procedures… a peer review process, and data systems, for the purpose of… conducting ongoing and periodic reviews and evaluations of each member OPO... for compliance with these rules and OPTN policies."

Despite this language, the OPTN exerts minimal oversight of OPOs, and has been characterized in media reporting as a "reluctant enforcer" with "collegiality...built into [its] very structure"[6]. As a consequence, OPO underperformance continues unaddressed and unremediated for extended periods of time while the waiting list patients in those areas are left to suffer.[7]

Regardless of any OPTN role, the ultimate responsibility for ensuring OPO accountability rests with CMS. As was noted in a recent *Washington Post* report about UNOS's failure to provide meaningful oversight over the Miami OPO after it failed to report a near-fatal infection in a uterus it recovered for transplant, "safety standards are enforced by UNOS, [but]... only the federal Centers for Medicare and Medicaid Services (CMS) can shut down an organ procurement group."[8]

AOPO claim: There is a complex and highly regulated system for organ donations in the U.S. that ensures the integrity, safety and transparency of the donation and the procurement process, as well as accountability for OPOs.

Fact check: This is an issue of data quality, not data availability. While OPOs may be subject to data reporting requirements, the data they reported are — as recently characterized by DJ Patil, the former United States Chief Data Scientist — "functionally useless."[9]

This problem was recently highlighted in the *New York Times* by an OPO whistleblower who said: "I used to work at an OPO and we reported false numbers to make it appear we were doing better than we were... The research shows a lack of oversight, inefficiency, and a culture of dishonesty."[10]

This whistleblower's statement corroborates official policy statements from OPOs. In a 2013 joint letter from the New York City OPO and AOPO to Office of Management and Budget, they explicitly acknowledge compromising failures of the OPO reporting system.

---

[6] https://www.latimes.com/archives/la-xpm-2006-oct-22-me-transplant22-story.html

[7] 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?utm_term=.e502479a1253

[8] https://www.washingtonpost.com/national/health-science/behind-the-failure-of-the-first-us-uterine-transplant/2019/02/13/6345f018-07c0-11e9-85b6-41c0fe0c5b8f_story.html?utm_term=.e1c732574d3c

[9] https://twitter.com/dpatil/status/1148867331180785664

[10] https://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html

The New York City OPO argued: “The data that OPOs submit to CMS in connection with the outcome measures is self-reported and unaudited. Not surprisingly, errors have been found in the data on which CMS has relied as the basis for judging OPO performance. Clearly, this type of ‘evidence’ fails to meet any reasonable definition of ‘empirical.’" AOPO validates this claim, arguing that “All [OPO] data are self-reported and unverified… [and the] accuracy and consistency of data cannot be assured.”[11]

AOPO claim: Ongoing performance monitoring by the OPTN is reinforced by on site surveys every three years. CMS makes similar on-site audits, monitoring their own separate regulatory requirements which includes data validation and review of donor records.

Fact check: In 2016, The Bridgespan Group conducted interviews with more than 40 stakeholders from the organ donation industry, resulting in the report which the President cited in his remarks at the signing of the Executive Order. Among the stakeholders that Bridgespan interviewed were executives across nine OPOs; a representative sampling of quotes from their interviews include:

- “CMS is not engaged. They evaluate OPOs every 3-4 years, and the evaluation is a joke.”
- “The [OPO] system is in-bred and out of regulatory control.”
- “The OPO strategy is to confuse people with data – always have data available to tell your board or CMS that you’re doing good: yield … increase in hearts, DCD rates… ‘As long as I’ve got something, I’m good.’"
- “Everyone [in the OPO community] is looking at eligible deaths as a bad denominator.”
- “[I] would hypothesize that the leader is the primary driver. Frankly, some of the [veteran leaders] have lost the vision and are milking the cow.”

Thank you for all you are doing to help more patients access life-saving transplants. Reform of OPOs who have a critical responsibility in the nation’s deceased donation system is a critical first step in bringing transparency and accountability to a space in need of both.

Sincerely,

Bryan Sivak
Former Chief Technology Officer
Department of Health and Human Services

[11] https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf