

United States Senate

WASHINGTON, DC 20510

July 8, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue S.W.
Washington, DC 20201

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

Dear Administrator Verma and Secretary Azar:

We write today regarding the Department of Health and Human Services' (HHS) oversight of organ procurement organizations (OPOs). Recent reports suggest that OPOs, which are tasked with acquiring and distributing organs for donation, are systemically underperforming, resulting in long wait lists and thousands of deaths each year. In light of these reports, and the Administration's recent decision to place rulemaking regarding OPO metrics on the Unified Agenda, we request additional information on the steps HHS is taking to update OPO performance metrics.

Today, more than 100,000 Americans are on a wait-list for an organ transplant.¹ Transplants can be life-saving, yet critical shortages in organs available for donation force some patients to wait months—and even years—for the organs they need. As a result, roughly 22 people a day die while waiting for organs.²

Organ donations in America are facilitated by a network of 58 OPOs, each of which serves designated regions across the country. OPOs are “responsible for identifying potential organ donors,” “for obtaining as many organs as possible from those donors,” and “for ensuring that the organs they obtain are properly preserved and quickly delivered to a suitable recipient awaiting transplantation.”³ OPOs are certified by the Centers for Medicare and Medicaid Services (CMS), which reviews each organization every four years to assess its compliance with federal performance standards.⁴

CMS has made it clear that “OPO performance is a critical element of the organ transplantation system in the United States” and has stated that “an OPO that is efficient in

¹ American Transplant Foundation, “Facts: Did you Know?” <https://www.americantransplantfoundation.org/about-transplant/facts-and-myths/>.

² Donate Life America, “Organ, Eye and Tissue Donation Statistics,” <https://www.donatelife.net/statistics/>.

³ Department of Health and Human Services, Centers for Medicare & Medicaid Services, “42 CFR Parts 413, 441, et al. Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule,” <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/Downloads/cms3064f.pdf>.

⁴ Id.

procuring organs and delivering them to recipients will save more lives than an ineffective OPO.”⁵ Recent studies, however, suggest that OPOs are failing to procure and deliver organs in an efficient and effective manner.

An analysis of OPO performance conducted by the University of Pennsylvania, for example, found that nearly 28,000 organs per year are not procured “due to breakdowns in the current [OPO] system.”⁶ CMS has the authority to decertify underperforming OPOs, but the agency has not decertified a single OPO in 20 years, despite evidence of mismanagement and underperformance.⁷ Furthermore, reports suggest that existing self-reported data on OPO performance, is deeply flawed—hindering the government’s ability to conduct accurate and effective oversight.⁸

OPOs that function efficiently and effectively save lives and are essential to public health—and this Spring, the Administration placed on the Unified Agenda a rule that would “propose changes to the standards used to evaluate OPOs and ensure proper data on available organs and transplants is collected.”⁹ To help us better understand the Department’s plans to update OPO performance metrics, we request a staff-level briefing on the agency’s work to improve the organ procurement network no later than July 22, 2019. We appreciate your attention to this matter.

Sincerely,


Elizabeth Warren
United States Senator


Richard Blumenthal
United States Senator

⁵ Id.

⁶ The Bridgespan Group, “Reforming Organ Donation in America: Saving \$25,000 Lives per Year and \$13 Billion in Taxpayer Funds over Five Years,” January 2019, <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf>.

⁷ Washington Post, “Despite low performance, organ collection group gets new federal contract,” Kimberly Kindy and Lenny Bernstein, February 4, 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?utm_term=.5725d0561bf6.

⁸ The Bridgespan Group, “Reforming Organ Donation in America: Saving \$25,000 Lives per Year and \$13 Billion in Taxpayer Funds over Five Years,” January 2019, <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf>.

⁹ Office of Management and Budget, Office of Information and Regulatory Affairs, “Organ Procurement Organizations (OPOs) (CMS-3380-P),” Spring 2019, <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=0938-AU02>.