## United States Senate WASHINGTON, DC 20510

May 2, 2019

The Honorable Gene Dodaro Comptroller General of the United States 441 G Street, NW Washington, D.C. 20548

Dear Mr. Dodaro,

Organ transplantation is a life-saving procedure for many Americans. However, the need for organ donors is much greater than the number of people who actually donate. Every day in the United States, more than 20 people die waiting for an organ and more than 113,000 adults and children await life-saving organ transplants.

The National Organ Transplant Act of 1984 called for a unified transplant network and established the Organ Procurement and Transplantation Network (OPTN), overseen by the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services (HHS). Since 1986, HRSA, through OPTN, has contracted with the United Network for Organ Sharing (UNOS), a private and not-for-profit organization, to operate the OPTN, which includes managing the processes by which deceased donor organs are procured and allocated. Through UNOS, organ donors are matched to waiting recipients.

Significant concerns have been raised about OPTN's recent decision to change its liver allocation policy. Specifically, that the changes to policy disregarded expert opinion, both from their own internal Liver and Intestine Committee and from outside transplant hospitals. This calls into question the processes OPTN used to develop its new policy.

Further, OPTN is considering changes to distribution policies for other organs and we are concerned a flawed process, like the liver allocation process, may bias these other organ distribution policies. In light of these concerns, we are requesting that the Government Accountability Office determine whether HRSA is exercising adequate oversight of changes made by OPTN, and to what extent the process used by OPTN took into account the opinions of experts in the areas of organ transplantation. Specifically, we are interested in answers to the following questions:

- 1. How did OPTN's policy for distributing organs for transplantation change and what was the rationale for the change?
- 2. What processes and data do HRSA and OPTN use to review and make changes to current organ allocation policies and practices, and in particular, what specific modeling was

completed and provided to the UNOS Board and to HRSA of the specific liver allocation policy adopted by the Board and being implemented on May 1, 2019?

- 3. How does the OPTN agree on the modeling and how frequently is the information included in the model updated?
- 4. How do HHS and OPTN oversee the processes used to review current organ allocation policies and practices and ensure that they take into account clinical expertise and public comments from organizations involved in organ procurement and distribution?
- 5. How has the change in lung allocation impacted costs for acquiring, processing, and transplanting lungs, and have those costs impacted Medicare and Medicaid expenses for lung transplant patients?

a. Did OPTN and HRSA consider the results from the reformed lung allocation policy prior to implementing this policy?

Thank you for your attention to this request.

Sincerely,

Jerry Moran