

September 13, 2023

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, DC 20201

The Honorable Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Organ Transplantation Modernization Efforts, Avoiding Unintended Consequences & Implementation of the Securing the U.S. Organ Procurement and Transplantation Network

Via e-mail: <u>xavier.becerra@hhs.gov</u>

carole.johnson@hrsa.gov

Dear Secretary Becerra and Administrator Johnson:

On behalf of the American Society of Transplantation (AST), representing more than 4,900 of the nation's multidisciplinary medical professionals engaged in the field of solid organ transplantation, we applaud your steadfast leadership and ongoing efforts to strengthen the health of our country and improve efforts to make the gift of life a reality for the more than 100,000 Americans currently awaiting a lifesaving donor organ. As you know, AST is proud of its long-term partnership with HHS and looks forward to continuing to work closely as the Department moves forward in advancing organ transplant modernization efforts. We bring expertise from across the donation and transplantation ecosystem, with members engaged in every aspect of transplant patient care and research in this field. Despite the diversity of our expertise, our primary focus is optimizing the gift of life to take the best possible care of the patients we serve every day.

I am writing to request the opportunity for our workgroup to meet with you for candid knowledge sharing and brainstorming as you undertake the process of redesigning a system that will better serve our diverse and complex patient population's needs. We have identified seven key areas that we believe warrant discussion:

- Equitable access to organ transplantation
- Organ transportation and related logistics
- Data transparency, integrity, and integration
- Coordination across or within regulatory agencies and contractors
- Stability and resiliency of the transplant system
- Minimizing redundancy or duplicity within the system (streamlining for efficiency)
- Governance and process for transplant professional community involvement in rulemaking and oversight

As expressed in the past, AST supports the need for change within the current system to serve our patients and donor families to the best of our ability. The Society remains engaged and eager to work with HHS and HRSA as the Department continues to evaluate, develop, award, and oversee grants, contracts and cooperative agreements essential to the transplantation system in the United States. As the largest society of transplant professionals in the US comprising a majority of stakeholder groups, we are developing a workgroup comprised of representatives from all organ groups, and Organ Procurement Organizations that we believe are critical to this discussion. We would greatly appreciate the opportunity to have you collaborate with us in this workgroup. We would welcome representation from your teams as you see appropriate. Further, we would appreciate opportunities to meet with your offices intermittently throughout this process as both a resource to you and to discuss these six areas.

The AST believes we are at a very exciting, challenging, and pivotal time for transplantation in the US. Our Society's members work every day in organ transplant hospitals, clinics, laboratories, operating rooms, and offices on behalf of our patients with life-threatening end-stage organ failure. We stand ready to lend our expertise and perspective as you formulate the new structure that will ultimately govern the survival and quality of life for our patients.

Please do not hesitate to contact me directly or the AST Director of Government Relations, Bill Applegate at bapplegate@polsinelli.com.

Sincerely,

Josh Levitsky, MD, MS, FAST

Josh Levitsby

President