



April 30, 2024

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

*Submitted Electronically*

Dear Administrator Brooks-LaSure,

On behalf of the American Society of Transplant Surgeons (ASTS) and our patients, I am writing in response to the proposed policy changes issued on February 12, 2024, entitled “Research Data Request and Access Policy Changes.” ASTS is concerned that the proposal to limit access to CMS data critical for improving access and equity in health care and facilitating shared decision-making for patients with end-stage organ disease will limit advances in care for these often historically disadvantaged patients. ASTS is a medical specialty society representing approximately 2,000 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

The data affected by the proposal are not only used for scientific research intended for dissemination among academic audiences. Rather, these data are routinely used to monitor outcomes, processes of care, access, equity in care delivery, and the effects of policy changes. These data are vital for the development of decision-tools for patients and clinicians. Absence of broad access to these data will limit our understanding of the effects of practices of care and our ability to base decision-making on direct empirical evidence. These data have been instrumental in informing policy reforms overseen by the Health Resources and Services Administration (HRSA), identifying significant disparities in health care delivery, and are used by the Food and Drug Administration (FDA) to evaluate the efficacy and safety of medications. As such, other departments within the Health and Human Services Department are also dependent on timely access to these data in their collaborations with the transplant community.

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We believe that a crucial aspect of access to CMS data is to make them available to a diverse set of stakeholders. In order to facilitate timely understanding of outcomes and processes of care among CMS beneficiaries, it is critically important that investigators with varied opinions and research perspectives are able to conduct and validate findings from CMS data. A cornerstone of research practice is to allow for replication of study findings, validate research findings in unique subsets of the populations of interest and attenuate any inherent biases that investigators may have regarding interpretation of findings. A model of limited access to CMS data consistent with the current policy proposal will dramatically narrow the pool of available investigators that can access these data and will limit the scope of research and the validity and robustness of findings based on these data.

The proposed policy change will also dramatically limit the research tools available for investigators. Researchers commonly combine data sources using a diverse set of programming and statistical software and are able to access data quickly to address time sensitive questions affecting transplant candidates and recipients. Significant impediments to the processes used to access data in a timely manner and limit the functionality of these data will hamper the ability to use the sophisticated analytical tools essential to data interpretation.

One of the important benefits of access to health care data is the ability to provide accountability and transparency. Limiting access to these data will significantly impede the ability to broadly evaluate best practices among providers, identify cost-effectiveness of care, and characterize important systemic changes that may inform policy and the polity. This policy proposal would stifle the timeliness and efficacy of research that would enable this critically important accountability in health care.

We acknowledge that data privacy and security are vitally important. We share your commitment to the protection of patient privacy. We disagree that the draconian limitations to data access in this proposal are necessary for such data protection. We are convinced that alternative mechanisms of data protection exist that preserve access and transparency while maintaining data security.

Organ transplantation saves lives every day in part because of our partnership with CMS in analyzing CMS data and using those analyses to inform policy and improve care. Our understanding of effective clinical interventions, the development and impact of healthcare policies, and the ability to inform patients and referring caregivers about best practices and treatment options is highly dependent on analysis of CMS data. CMS data are unique in their ability to help us understand and care for organ failure patients. CMS data is also integrated with other databases such as the United States Renal Data System (USRDS), all-payer databases, and other claims data that critically important in the holistic evaluation of transplant populations. Loss of broad access to these data will inhibit innovation and transparency of processes of care and outcomes for current and future transplant candidates and recipients and ultimately will harm patients.



ASTS appreciates the opportunity to comment on this proposed policy changes. If you have any questions, please do not hesitate to contact ASTS Associate Director, Advocacy, Emily Besser, MA, CAE at [Emily.Besser@asts.org](mailto:Emily.Besser@asts.org).

Sincerely,

Elizabeth A. Pomfret, MD, PhD  
President, American Society of Transplant Surgeons