

May 14, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid 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 Transplantation (AST), I am writing to express the Society's concerns regarding the proposed policy changes issued on February 12, 2024, entitled "Research Data Request and Access Policy Changes." AST, which represents more than 5,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care, is the largest organization in the field of transplantation. Our members and the transplant recipients and donors they care for would be adversely affected if this change is adopted as proposed.

The data affected by this proposal are essential for research and analyses that advance our field and improve patient care. Perhaps even more importantly, CMS data are used to inform and propose innovation and changes to policy and practice, and to assess the effectiveness of those changes in improving access to and outcomes following organ transplantation.

In recent years, various agencies within the Department of Health and Human Services (DHHS), including the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA), have focused their efforts on encouraging the transplant community to increase access and equity within transplantation. Finding innovative ways to achieve those noble goals relies upon our members' ability to have ready access to the data necessary to formulate, implement, and evaluate programs, services, and patient outcomes. This proposal, in making data access considerably more difficult, works in opposition to goals of DHHS and others by impeding the very efforts that stand to help make achievement of those goals possible. In addition, the proposed changes could limit data access to only those investigators at the largest research centers with the greatest resources, thereby further limiting innovation and equity.

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The availability of CMS data has long been a powerful tool in our arsenal, in part due to the high concentration of Medicare recipients among the transplant (and potential transplant) population. We have dramatically increased the number of transplants over recent decades, giving more patients the gift of life and better honoring the organ donors and their families who so generously make transplants possible. Transplantation is a success story because of partnerships among government agencies, hospitals, physicians, patients, and donors. CMS has always been a committed partner in that effort, and for that reason, we are confident that the proposed policy change was not intended to slow or impede this essential work. We urge CMS to consider the unintended impact of the proposed changes on the field of transplantation at a time when we are all working together to continue to help more patients.

Undoubtedly, data security and the privacy of patient information must be paramount. We support your commitment to those principles; however, we believe that there are many measures available to fully safeguard patient privacy that do not impede research to the degree that this proposal would. We encourage CMS to table this proposal and instead convene a panel inclusive of transplant research scientists and policymakers to formulate a plan that reflects our shared mission to increase access and equity in transplantation. AST would be pleased to nominate representatives from our community to work with you to develop policies that meet your goals while ensuring our vital work continues with minimal hindrance.

AST appreciates the opportunity to provide comments on the proposed policy changes. Please do not hesitate to reach out to Bill Applegate at bapplegate@polsinelli.com with any questions or if AST may further assist in your efforts.

Thank you, as always, for your partnership.

Sincerely,

A handwritten signature in cursive script that reads "Josh Levitsky".

Josh Levitsky, MD
President
American Society of Transplantation

Cc: Dr. Suma Nair, Associate Administrator, Health Systems Bureau, Health Resources and Services Administration (via email)