June 28, 2021

Dear Administrator Brooks-LaSure,

The undersigned organizations – representing the nation's foremost transplant centers, transplant providers, transplant recipients and potential recipients, donors and donor families, and medical and hospital associations – write to express our concerns that portions of the 2022 Inpatient Prospective Payment System Proposed Rule ("Proposed Rule") have a significant potential to reduce organ availability and access to transplantation. **We request that CMS complete a thorough analysis of the Proposed Rule's potential impact on patient access to transplantation before determining whether these proposals should be finalized.**

Proposed Rule Contradicts Shared Focus on Increasing Access to Transplantation

We are puzzled that these proposals have been put forward at a time when CMS has clearly acknowledged that transplantation is generally the best and most cost-effective treatment option for those with ESRD and is undertaking numerous initiatives focused on increasing the availability of kidney transplantation. While we understand that CMS' stated intention is to reimburse only for organs procured for Medicare patients, this proposal appears to have been put forward without consideration of its potential impact not only on the availability of deceased donor kidneys but on the availability of all other deceased donor organs as well.

Proposed Rule Eliminates Successful Incentives for Transplant Centers to Procure Deceased Donor Organs, Rushes Changes

CMS estimates that these changes would result in substantial Medicare payment reductions for organ acquisition costs. The most significant proposed change would eliminate a longstanding feature of the payment system under which organs that are procured at a Transplant Center hospital and transplanted at another Transplant Center are "counted" as Medicare organs for the purpose of determining Medicare's portion of organ acquisition costs. This feature of the cost accounting system functions as a strong incentive for Transplant Center hospitals to establish effective programs for the identification of potential deceased organ donors and engage in other organ acquisition-related activities. The incentive has worked: Transplant Centers constitute only 4% of Medicare certified hospitals but retrieve 36% of deceased donor organs, and organ donation has been increasing over the last few years.

The precipitous elimination of this feature of the payment system – scheduled to begin as early as October 2021 for some Centers – has the potential to significantly reduce the deceased donor organs available for transplantation, reduce access to transplantation, and increase the number of patients who die while waiting for a transplant. In addition, the Proposed Rule would appear to impose an unreasonable burden on Donor Transplant Centers, which would be required to obtain from Recipient Transplant Centers information regarding the Recipient Centers' non-Medicare third party payer contracts (to confirm Medicare as Secondary Payer liability) and to track recipients' Medicare eligibility determinations, many of which are made retroactively. It is our understanding that some portion of these increased administrative costs would be passed on to the Medicare Program.

Proposed Rule Fails to Consider the Potential Medicare Costs of Reduced Access to Kidney Transplantation

The Proposed Rule does not take into account the potential impact on Medicare costs of the potential reduction in access to kidney transplantation and the concomitant increase in Medicare spending for dialysis. Other provisions of the Proposed Rule that bear further scrutiny would preclude Medicare payment for organs transplanted under a research protocol, eliminate Medicare payment for living donor follow up visits, and preclude Medicare payment for transportation of donor organs.

For these reasons, we strongly urge CMS not to move forward with the proposed transplant-related proposals in the IPPS Proposed Rule prior to completion of a comprehensive study of the potential impact of the transplant-related proposals in the IPPS Proposed Rule on patient access to transplantation and to work closely with stakeholders in conducting this evaluation. We stand ready to work with you to ensure that any changes to transplantation do not have a deleterious impact on patient care and access to this often life-saving procedure.

American Association of Kidney Patients (AAKP)

American College of Surgeons

American Medical Association

American Society for Histocompatibility and Immunogenetics (ASHI)

American Society of Transplant Surgeons (ASTS)

American Society of Transplantation

Banner University Medical Centers (Tucson/Phoenix)

Beth Israel Deaconess Medical Center

Boston Medical Center

Children's Hospital Association

Children's of Alabama

ChristianaCare

Crozer Medical Center Kidney Transplant Program

Dell Children's Medical Center

Donor Network West

Duke University Hospital

Einstein HealthCare Network

Eye Bank Association of America

Global Liver Institute

Houston Methodist Hospital

Jefferson Health

Lahey Hospital & Medical Center

Lankenau Medical Center

Lehigh Valley Health Network-Transplant (PALV)

Living Kidney Donors Network

Lucile Packard Children’s Hospital/Stanford Children’s Health

Maine Medical Center

Massachusetts General Hospital

NATCO

NYU Langone Health

Ochsner Health

Organ Donation & Transplantation Alliance ("The Alliance")

Penn Medicine

PennState Health Milton S. Hershey Medical Center

Renal Physicians Association

The Children's Hospital of Philadelphia

The University of Texas Health Science Center at San Antonio

Transplant Recipients International Organization (TRIO) - Manhattan Chapter

Transplant Support Organization

TRIO: Transplant Recipients International Organization

TRIO-Oklahoma

TSO of Staten Island New York

UNC Health

United Network for Organ Sharing

University Health

University of California San Francisco Medical Center

UW Health