NATIONAL KIDNEY FOUNDATION®

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September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services (CMS)
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

Re: File Code CMS-1772-P— Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the CY 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System (ASC). We specifically would like to offer our perspective on the organ acquisition elements regarding (1) research organs and (2) the costs of hospital services for potential deceased organ donors.

Counting Research Organs to Calculate Medicare's Share of Organ Acquisition Costs

NKF strongly advocates for increasing the utilization of kidneys recovered for transplant, yet we are also aware that genuine medical contraindications may preclude a kidney transplant from taking place. In this case, we fully support using non-transplantable organs for research. We are deeply concerned with the steadily rising number of procured kidneys that go unused. 20% of recovered kidneys have gone untransplanted[1] for over a decade. In 2018, 3755 recovered kidneys were not transplanted;[2] in 2019, the number increased by 19% to 4460 untransplanted kidneys.[2]

Individuals who indicate their wish to become an organ donor, and donor families who make the selfless choice to donate their loved one's organs, often do so with the hope of helping others receive the gift of life through transplantation. Even with sophisticated advances in medical technology, there are still circumstances when organ viability may not be ascertained until the recovered kidney is visualized in

[1] Out of an abundance of respect for organ donors and their families, we advocate for replacing the term "discard" with "non-utilization" or "untransplanted" as recommended by the Scientific Registry of Transplant Recipients (SRTR) 2022 Consensus Conference.

[2] Israni AK, Zaun D, Rosendale JD, Schaffhausen C, McKinney W, Snyder JJ. OPTN/SRTR 2019 Annual Data Report: Deceased Organ Donors. *Am J Transplant*. 2021;21(S2):567-604. doi:10.1111/ajt.16491

the operating room during procurement. When recovered kidneys are medically unsuitable for transplantation, utilizing them for clinical research maximizes their potential for advancing care for current and future kidney patients while still fulfilling the hopes of organ donors and their families.

Our recommendation to CMS is to engage the organ donation and transplant community, along with researcher companies who need access to non-transplantable organs to advance transplant innovation, to ensure policy decisions do not create unintended consequences that could disincentivize clinical research, innovation, or access to transplantation for end-stage renal disease (ESRD) patients who seek kidney transplantation as a treatment modality for their kidney failure. Extended ischemia, poor organ function, and anatomical abnormalities are a few contributing factors that lead to the non-transplantation of recovered kidneys, along with comorbidities such as diabetes, hypertension, and obesity.[3] The number of people on the kidney transplant waitlist far outpaces the available organ supply for transplant. The ability to investigate and study allograft outcomes amongst varying kidney profiles is a critical component of improving the future of transplantation. Organ procurement organizations (OPO) make valiant efforts to ensure every procured kidney is transplanted; however, when an organ is found to be ill-suited for transplantation, its use for research should be facilitated. Thus, we advocate for payment policies that create financially judicious access to research organs.

Costs of Certain Services Furnished to Potential Deceased Donors

NKF applauds CMS for recognizing the need to amend § 413.418(a) to include hospital services needed to determine organ viability before the declaration of death for potential organ donors when death is imminent, such as donation after cardiac death (DCD), in organ acquisition costs. As CMS is aware, not doing so could compromise the organ donation process and possibly interfere with honoring one's wish to donate organs for transplant. We also appreciate CMS viewing this matter through a health equity lens and realizing this practice could impede organ donation for those of lower socioeconomic status. Lastly, we undoubtedly believe that donor families, nor the donor's insurance company, should not incur any costs related to donating organs. As the kidney transplant waitlist continues to grow, NKF supports CMS in its endeavors to continue expanding access to organ donation and transplantation.

We also note that the greater transplant system poorly understands the costs of procuring kidneys. When gathering feedback from experts and researchers on this topic, we found that the mechanism by which OPOs: 1) allocate costs for kidneys, 2) set prices for research kidneys, 3) describe effort for research kidney procurement, and 4) describe potential financial "disincentives" for DCD procurement varied greatly between OPOs. We strongly urge CMS to consider requiring the public reporting of OPO cost reports for all organs and prices for organs made available for research. Unlike hospitals and other healthcare organizations, OPOs are not required by CMS to provide cost and price data that allow advocates, researchers, and the public to examine and compare OPO quality and cost of care.

[3] Mohan S, Chiles MC, Patzer RE, et al. Factors leading to the discard of deceased donor kidneys in the United States. *Kidney Int*. 2018;94(1):187-198. doi:10.1016/j.kint.2018.02.016

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We believe that the opacity of pricing and cost allocation practices by OPOs inhibits the ability of patient advocacy groups to take fully informed positions regarding possible reimbursement and cost allocation changes. With more information, and increased transparency, patients and advocates can ascertain which policy changes are more beneficial to patient care and outcomes.

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The National Kidney Foundation appreciates the opportunity to comment on the organ acquisition payment policy proposals. The shortage of organs for transplantation is a public health crisis, and we support any effort to honor organ donors and donor families by maximizing the utilization of donated organs. NKF would be glad to collaborate to support CMS' efforts in this space. Please contact Morgan Reid, Director of Transplant Policy and Strategy, at Morgan.Reid@kidney.org with questions or comments.

Kind Regards,

Kevin Longino
CEO and Transplant Patient

Paul Palevsky, MD
President