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February 1, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-3409-NC
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities, CMS-3409-NC

Dear Administrator Brooks-LaSure:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the request for information entitled “Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities,” 86 *Fed. Reg.* 68594 (December 3, 2021), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools and teaching hospitals and the millions of individuals employed across academic medicine, including more than 186,000 full-time faculty members, 94,000 medical students, 145,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC appreciates CMS’s willingness to engage stakeholders in the transplant community through this request for information (RFI), which addresses commenters’ concerns and recommendations submitted during the fiscal year 2022 Inpatient Prospective Payment System rulemaking. The RFI represents a first step in understanding the Agency’s direction in improving transplantation equity and dialysis care, increasing available organs, and facilitating these objectives across agencies. (p. 68596). In this letter the AAMC provides comments reflecting our discussions with AAMC-member transplant programs and practicing nephrologists on several topics addressed in the RFI to improve equity and promote efficiency within the transplant

system. More than 75% of AAMC members report offering transplant services for at least one type of organ in 2020.¹

Transplant hospitals are acutely aware of the shortage of available organs and attempt to transplant all usable organs, including suboptimal organs. Research to optimize all organs for transplantation has allowed organs once considered suboptimal and which would otherwise have been discarded to now be used for transplant. For example, programs now transplant Hepatitis C-positive organs and treat the patient post-transplant with a Hepatitis C drug that eradicates the virus from the organ.

CMS is also concerned about what it perceives to be a high organ discard rate. The reasons an organ may be refused are varied and align with accepted clinical rationales that are reported to the Organ Procurement and Transplantation Network (OPTN).² For example, at the time of offer, a patient may be sick, and physically unable to receive a transplant or the organ matching data is not available or results indicate that transplantation is contraindicated. On the other hand, there are instances where a patient is informed of an organ and the patient declines the offer. So, although an organ may not be suitable for one patient, it may be suitable for another. OPTN data shows that the median organ is offered seven times before being transplanted.³ Reporting that an organ is refused without providing the context of clinical decision-making and the needs of the patient at the time an organ is offered can distort the number of discarded organs.

TRANSPLANT RECIPIENT PATIENT RIGHTS

CMS notes that the patient and living donor rights⁴ do not currently require a transplant program or surgeon to notify a patient on the transplant waitlist that an organ has been offered to them. CMS suggests that increasing transparency between transplant programs and patients on the waitlist could prove beneficial in more patients accepting organs for transplant, pointing to studies showing that less than 16% of deceased donor kidneys are accepted without being declined at least once. To this end, the RFI requests comments on how transplant programs can facilitate greater communication and transparency with patients on the waitlist without causing undue delay or anxiety. (p. 68597).

¹ AAMC Analysis of American Hospital Association (AHA) Annual Survey Database, FY 2020. Hospital counts reflect total number of hospitals in the database and excludes federal hospitals, long-term care hospitals, and specialty hospitals. Reflects AAMC membership as of January 2022.

² OPTN, "Notice of Changes to OPTN Data Collection: Update to Refusal Codes" (2021). Available at: https://optn.transplant.hrsa.gov/media/4695/update_to_refusal_codes_june_2021_policy_notice.pdf.

³ OPTN Center Data: California. Available at: <https://optn.transplant.hrsa.gov/data/view-data-reports/center-data/#>; CJASN, "Outcomes of Deceased Donor Kidney Offers to Patients at the Top of the Waiting List" (2017), 12 (8) 1311-1320. Available at: <https://cjasn.asnjournals.org/content/12/8/1311>

⁴ 42 C.F.R. § 482.102. Available at: <https://www.law.cornell.edu/cfr/text/42/482.102>.

Existing Transparency Requirements Balance Patients' and Transplant Programs' Needs

The AAMC shares CMS's goal of providing appropriate information on available organs to potential transplant recipients. However, transplant programs believe that the current requirements provide a significant amount of information to patients that enable them to make informed decisions regarding their transplant options. The existing Conditions of Participation (CoPs)⁵ ensure that the patient is informed about the evaluation process, surgical procedure, potential risks, and alternative treatment options, as well as national and program-specific outcomes, and donor risk factors that include the complexity of the process and range of potential outcomes. Further, transplant programs provide patients with information, education, and support before, during, and after transplantation. Programs also seek patients' consent for them to be considered for suboptimal organs. Patients are also encouraged to take advantage of other public and non-profit organizations offering informational resources to support patients throughout the process.⁶

In current practice, transplant programs already notify patients that an organ was offered but was not a suitable match. This information, however, is generally not provided to the patient at the time the organ is offered as these offers occur at all hours. When this happens, it allows organs to be released to other patients on the waitlist. The entire organ offer process could be substantially slowed to the detriment of other waitlisted patients and the system as a whole if additional requirements are implemented.

The patient to whom the organ was offered but could not be used because it was not a suitable match, may already be experiencing a sense of loss knowing that there are more patients needing transplants than there are available organs. This uncertainty can cause sadness and anxiety knowing that an organ may never become available. Adding a requirement to inform patients that an organ is available but unsuitable for them at the time of offer would likely increase anxiety, disappointment, and despair for patient and their families. We do not believe that informing a patient of each organ is prudent. The existing transplant program CoPs delicately balance patients' and families' needs with the transplant team's need to make complex and timely clinical decisions in recipients' best interests on a case-by-case basis.

Additional Requirements May Cause Delays in Transplantation

Additional requirements to notify potential recipients of each organ offered could also create delays in organ allocation since transplant programs must operate within limited decision-making windows. According to United Network for Organ Sharing (UNOS) data, the maximum time each organ can be preserved after being excised varies,⁷ but certain types of organs have windows of less than 6 hours to transport and transplant. Additional requirements to notify a patient of each organ offer could result in increased rates of unused or discarded organs, which

⁵ *Id.*

⁶ UNOS Transplant Living. Available at: <https://transplantliving.org/>; Kidney Foundation Family and Patient Resources. Available at: <https://www.kidney.org/patients/resources>.

⁷ OPTN: How Organ Allocation Works. Available at: <https://optn.transplant.hrsa.gov/patients/about-transplantation/how-organ-allocation-works/>.

the Agency seeks to lower. For example, in California there were 21 transplant centers that performed approximately 4,700 transplants in 2021 – averaging 223 transplants per center. Requiring transplant programs to inform patients of each offer would slow the organ procurement and transplant process dramatically.

IMPROVING BOTH THE DONATION AND DISCARDED ORGAN RATES

The RFI seeks comment on generally improving both the donation and discarded organ rates. CMS notes that in 2018 approximately 13% of organs recovered from deceased donors were discarded, and that transplant programs “must play an important role in reducing the organ discard rate” through utilizing “marginal” organs. CMS cites that many organs deemed “marginal” are later transplanted successfully into patients or are discarded despite having “similar or better quality characteristics to organs that are successfully transplanted elsewhere.” To this end, CMS seeks feedback on potential changes to transplant programs and their CoPs to achieve this goal. (p. 68596-68597).

Transplant Centers Currently Use All Suitable Organs Whenever Possible

AAMC members consistently stated that a transplant team’s intent is to transplant an organ unless that organ is not suitable for the patient. The AAMC agrees that increasing the use of marginal organs will increase the supply of available organs, but we believe that the Agency’s assertion does not fully account for the complex, clinical decision-making associated with each transplant decision as noted earlier. Many organs that are not transplanted have acceptable rationales for not being used.⁸ OPTN data on refusal codes supports transplant programs’ belief that the majority of organ refusals are due to factors outside the program’s control: donor age or organ size, quality of the organ, failure to meet an organ’s minimum acceptance criteria, and logistical issues such as transportation, inclement weather or inability to travel for procurement.⁹ Although minimum acceptance criteria are institution-specific standards that programs use to define the clinical characteristics of organs they will accept for transplant, even these criteria are overseen, approved, and must be reported to the OPTN.¹⁰

Finally, transplant programs noted that requirements exist that penalize transplant programs for adverse transplant outcomes, while requirements for other facilities, such as Organ Procurement Organizations (OPOs), may incentivize the recovery of as many organs as possible, regardless of quality. These incentives may conflict with one another, as all recovered organs are not suitable for transplant. The AAMC recommends modifying or removing similar reporting requirements to minimize conflict.

⁸ OPTN, “Notice of Changes to OPTN Data Collection: Update to Refusal Codes” (2021). Available at: https://optn.transplant.hrsa.gov/media/4695/update_to_refusal_codes_june_2021_policy_notice.pdf.

⁹ CJASN, “Outcomes of Deceased Donor Kidney Offers to Patients at the Top of the Waiting List” (2017). Available at: <https://cjasn.asnjournals.org/content/12/8/1311>.

¹⁰ OPTN Policy 5.1. Available at: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

Invest in Research and Technologies That Improve Transplant Outcomes

Transplant programs feel that technological innovation in transplantation has expanded the ability to transplant suboptimal organs, but more could be done to improve the discarded organ rate and the number of transplanted organs. AAMC-member transplant programs reported that their OPTN-reported transplant rates continue to rise, and that the advent of several major innovations in transplant capabilities have increased the number of organs available for transplantation. Among these recent innovations is the ability for transplant programs to transplant Hepatitis-C infected kidneys into non-infected recipients,¹¹ increasing the number of kidneys available each year. Further, the use of ex vivo machine perfusion has expanded the donor pool, increased the range of donor hospitals, and offers extra time to determine an organ's health and performance before a transplant.¹² The AAMC recommends CMS consider policies that incentivize development and use of new and burgeoning innovations in the transplant field that can safely and reliably expand the donor pool and preserve the viability of organs.

IMPROVING DONATION RATES AND TRANSPLANT EQUITY THROUGH EARLY INTERVENTION AND EDUCATION

The RFI requests feedback on the use of early intervention and education to improve equity in organ transplantation, increase the number of donated organs, and improve the rate of discarded organs. Additionally, feedback on how to establish trust with underserved communities about organ donation to improve equity across these areas is requested. (p. 68597-68599). The Agency also seeks feedback on kidney health and ways to provide education and outreach to patients about behaviors that affect the progression of Chronic Kidney Disease (CKD), promote health literacy for high-risk individuals in the prevention of CKD, and educate primary care providers to improve timely referrals to nephrologists. (p. 68599). CMS also requests information on patient barriers to home dialysis. (p. 68599).

Improve Education to Decrease the Prevalence of CKD in High-Risk Populations and Address Misinformation about Transplantation

Education and early intervention can decrease the prevalence of CKD for at-risk patients. Practicing nephrologists noted that they commonly see CKD patients for the first time when the patient is experiencing acute kidney failure that often necessitates dialysis. Since these patients tend to have worse mortality outcomes compared to patients who receive earlier interventions, it is imperative that patients are timely referred to nephrologists before acute kidney failure.

¹¹ CJASN, "Multicenter Study to Transplant Hepatitis C–Infected Kidneys (MYTHIC): An Open-Label Study of Combined Glecaprevir and Pibrentasvir to Treat Recipients of Transplanted Kidneys from Deceased Donors with Hepatitis C Virus Infection" (2020). Available at: <https://jasn.asnjournals.org/content/31/11/2678>; Transplant Infectious Disease. "Hepatitis C-positive donor to negative recipient kidney transplantation: A real-world experience." Available at: <https://pubmed.ncbi.nlm.nih.gov/33259125/>.

¹² Current Opinion in Organ Transplantation, "Ex-vivo machine perfusion for kidney preservation." (2018). Available at: <https://pubmed.ncbi.nlm.nih.gov/29697462/>; Johns Hopkins Medicine, "Ex Vivo Perfusion." Available at: <https://www.hopkinsmedicine.org/transplant/programs/Ex-Vivo-Perfusion.html>.

Primary care providers should be encouraged to refer patients at-risk for CKD to nephrologists when the patient first begins to exhibit renal insufficiency. These referrals should not be subject to prior authorization by commercial insurance or Medicare, including Medicare Advantage plans.

Additionally, outreach efforts to communities at risk for higher prevalence of CKD about the signs and symptoms of CKD, the risk factors for CKD and the need to seek evaluation and treatment when first feeling ill will help to stem further progression of the disease and thereby decrease the need for dialysis and organ transplantation. AAMC-member transplant programs suggested exploring initiatives that promote primary care services, annual checkups, nutrition, and lifestyle programs to decrease the prevalence of CKD and other diseases that put patients at risk for end stage renal disease (ESRD) that requires a transplant.

AAMC-member transplant programs confirm that misinformation regarding transplantation remains a barrier to organ donation. Programs believe that prevention and early intervention are critical areas for improvement in health literacy and understanding transplant and treatment options. These efforts can work to clarify misconceptions related to transplantation and organ donation and establish trust between at-risk populations and the medical communities.

Address Barriers to Utilization of Home Dialysis in Some Communities

CMS notes that patients have several available home dialysis modalities to treat ESRD, including home hemodialysis and peritoneal dialysis. However, CMS suggests that White patients disproportionately receive home hemodialysis compared to Black patients, who receive comparatively more in-center hemodialysis. (p. 68600). CMS seeks feedback on overcoming barriers to ensure that patients understand all available treatment options.

Under the ESRD Treatment Choices (ETC) Model, providers are required to inform beneficiaries with ESRD they may choose to receive dialysis in their home, giving them flexibility to adjust the hours and frequency of their treatment.¹³ Additionally, CMS requires that ESRD facilities inform patients of all available dialysis treatment modalities, including home hemodialysis.¹⁴

However, home hemodialysis requires space for equipment, access to clean water, and increased electricity use that may be disproportionately difficult to afford or access in certain communities, creating equity issues.¹⁵ These barriers may account for some of the discrepancy in use of home hemodialysis. Insurance coverage may also influence patient choices if certain home dialysis costs are greater in comparison to in-center dialysis. Ultimately, ensuring that patients can afford in-home hemodialysis, through insurance coverage or other means, may improve use of home hemodialysis in certain populations that currently have shied away from this option.

¹³ End Stage Renal Disease Treatment Choices (ETC) Model. <https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model>

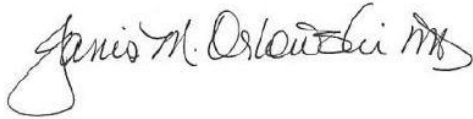
¹⁴ 42 CFR § 494.70. Available at: <https://www.law.cornell.edu/cfr/text/42/494.70>.

¹⁵ Nephrology Dialysis Transplantation, "Patient and caregiver values, beliefs and experiences when considering home dialysis as a treatment option: a semi-structured interview study." (2016). Available at: <https://academic.oup.com/ndt/article/31/1/133/2460107>.

CONCLUSION

Thank you for the opportunity to comment on this RFI. As a practicing nephrologist I understand the challenges faced by my patients who require dialysis and who are on the transplant waitlist. I applaud CMS for hearing the concerns of the transplant community. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic medical community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at mmullaney@aamc.org and Andrew Amari at aamari@aamc.org.

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski M.D." with a stylized flourish at the end.

Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

cc: Ivy Baer