



Charles N. Kahn III
President and CEO

February 3, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3409-NC,
P.O. Box 8010,
Baltimore, MD 21244-8010

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 Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. The FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding its request for information (RFI) on *Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities* published in the Federal Register (86 *Fed. Reg.* 68,594) on December 3, 2021.

Through this RFI, CMS poses numerous questions on potential changes to the requirements that transplant programs, organ procurement organizations (OPOs), and end-stage renal disease (ESRD) facilities must meet in order to participate in the Medicare and Medicaid programs. The agency indicates that feedback received will be used to help inform potential changes that would create system-wide improvements and ultimately, improved organ donation,

organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services. Although changes have been made to existing CMS regulations focused on the transplantation ecosystem with the goals of improving patient health, safety, and outcomes in transplant programs, OPOs, and ESRD facilities, there is recognition that additional system-wide improvements may be needed. CMS is also interested in identifying and addressing disparities and inequities across organ donation, transplantation, and dialysis.

The FAH welcomes the opportunity to respond to this broad, yet complex RFI. We have long supported efforts to decreasing barriers and increasing access to organ donation, specifically live kidney donation – as there is significant room for improvement in this area. FAH members operate large, live, and deceased donor programs and support CMS’ goals to improve the organ transplantation ecosystem and mitigate the decline in organ donations.

Solicitation of Public Comments – Transplant Program Conditions of Participation

There are key aspects of organ transplantation that can be improved. CMS therefore is soliciting feedback on how it can meaningfully measure transplant outcomes, as well as incentivize and ensure performance quality in organ transplantation.

The FAH appreciates CMS’ recognition that more work is necessary to improve the transplantation ecosystem and this is especially important due to the ongoing COVID-19 public health emergency (PHE). The reduction of live organ donations resulting from the PHE exacerbates the existing nationwide shortage of organ transplants. Many transplant centers continue to perform life-saving organ transplants during the pandemic, but the outbreak has posed unique challenges for both organ procurement and transplantation.

Some centers initially paused transplants temporarily during PHE, yet some were not able to re-start efficiently and return to optimal or pre-pandemic levels, due to patients changing their minds about undergoing a transplant or lack of safety precautions available or in place for a center to minimize risk of transmission of COVID-19 to a recipient patient. This has led to patients going on dialysis, which further decreases their access to transplantation because unfortunately it is common practice for patients to be referred for dialysis, but not timely referred to the organ transplantation waitlist.

The FAH strongly supports CMS’ interest in measuring and incentivizing transplant programs. However, there is a need for greater transparency that assists in CMS identifying and supporting effective transplant centers that are patient-centered, as well as have high, quality outcomes. Patients should have access, as well as adequate information and education, about programs that demonstrate a higher level of expertise in transplantation.

The FAH recommends that CMS consider the following principles, as it seeks to implement additional policy changes to the organ transplant program:

- Increase access to living donor transplants
- Incentivize early referral to transplantation (pre-dialysis) and reduce variability in referral patterns

- Develop measure concepts that show the experience and volume of organ transplants completed at a transplant center, with an exception for pediatric programs which typically have lower volume and therefore may not be indicative of expertise
- Prioritize patient health and safety measures for living donors
- Certify programs that meet agreeable benchmarks and thresholds; and
- Expand current two-year follow up of living donors to five-to-ten years.

We encourage CMS to thoughtfully consider policy changes that bolster accountability, improvement, transparency, and increased access to care for organ transplant centers, but also includes payment adjustments and certification decisions based on health outcomes.

Kidney Health and End-Stage Renal Disease Facilities

CMS is interested in learning how to support and promote transplantation prior to the need for dialysis (preemptive transplantation), while also improving long-term outcomes and quality of life for transplant recipients. The FAH recommends patients have earlier access to a kidney transplant, when appropriate, prior to going on dialysis. Unfortunately, it is common for patients to be monitored for kidney disease for years but referred to the transplant list only after the patient begins dialysis – yet, in many cases a patient could have been transplanted prior to dialysis.

CMS should also review the number of individuals on a dialysis unit’s transplant waiting list and ensure they are appropriately and timely referred for transplants from living and deceased donors, when warranted. The common practice of referring patients to a transplant center only when kidney function reaches ten percent should be addressed. These are not timely referrals and reduces patient access to a transplant. Patients generally are eligible to be added to a transplant list once kidney function reaches an estimated glomerular filtration rate of 20 ml/min/1.73m², yet less than forty percent are actually referred at that point.

The number of patients awaiting kidney transplantation has steadily increased over time. The gap between organ supply and demand continues to widen despite initiatives to expand the use of nonstandard or “marginal” deceased-donor organs. The FAH supports the use of organs from living donors as one strategy to address the increased need for transplants, particularly for minority populations, who have higher rates of kidney disease. Live donor transplant is significantly less in African American and Hispanic populations and need specialized focus and expertise due to historically receiving disparaged cared.

Recipients of organs from living donors experience significant graft and patient survival advantages over those who receive deceased-donor grafts. In addition, living-donor transplants may be performed with minimal delay, which permits transplantation prior to dialysis or transplantation early in a recipient’s course of kidney failure.¹ The FAH recommends offsetting

¹ Hart A, Smith JM, Skeans MA, et al. OPTN/SRTR 2016 Annual Data Report: Kidney. Am J Transplant 2018; 18 Suppl 1:18.

live donor expenses, as well as ensuring availability of more resources to encourage the expansion of organ donors.

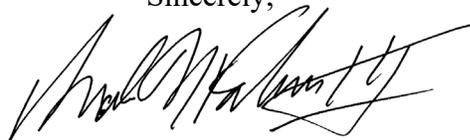
Organ Procurement Organizations – Assessment & Recertification & Competition

The FAH supports the oversight of organ transplantation by the Organ Procurement and Transplantation Network (OPTN), which is operated under contract with the Department of Health & Human Services (HHS) by the United Network for Organ Sharing (UNOS). Additionally, we support the requirement that organ procurement organizations demonstrate improved outcomes relative to increased deceased donor availability.

However, we believe the same principle should apply to live donor transplants. The OPTN policies define the minimum requirements for the evaluation and selection of living kidney donors in the United States but stop short of denying certification to transplant centers that fail to perform an established minimum number of live transplants.² We believe setting a benchmark to bring all transplant programs up to a greater number of transplants is necessary to increase the health and safety protections for donors, but this process should occur with an on ramp for programs that initially do not meet these minimums and should not unnecessarily terminate programs prematurely. (Further, as discussed above, a minimum number requirement should recognize that pediatric transplant programs typically have lower volumes that are not necessarily an indicator of expertise.) Doing so will ensure all transplant programs respond more effectively to securing access to transplants and prevent patients from being forced into dialysis.

The FAH appreciates CMS’ continued leadership and dedication toward implementing system-wide improvements to organ donation and organ transplantation. If you have any questions, please contact me at 202-624-1534, or any member of my staff at 202-624-1500.

Sincerely,



² Organ Procurement and Transplantation Network: Policies. <http://optn.transplant.hrsa.gov/governance/policies/> (Accessed on January 26, 2022).