



January 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-1792-NC — Medicare and Medicaid Programs: Announcement of Application from a Hospital Requesting Waiver for Organ Procurement Service Area

Dear Administrator Brooks-LaSure:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to the request for public comment issued by the Centers for Medicare and Medicaid Services (CMS) related to a donor hospital that has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated organ procurement organization (OPO).

ASN is committed to maximizing patient access to kidney transplantation, and to ensuring that access is equitable for all patients regardless of geography, race/ethnicity, socioeconomic status, or other factors. As you are aware, ASN has previously called for improvements in OPO performance and transparency in order to better serve the more than 90,000 patients on the kidney transplant waitlist.ⁱ Implementation of the 2020 OPO Conditions for Coverage Final Rule is one crucial step towards this goal. Together with other urgently-needed transplant-related changes to the kidney health system that ASN has enumerated on in previous correspondence with CMS, continued improvements to our nation's organ procurement process are essential to maximize equitable patients access to kidney transplantation, the optimal therapy for kidney failure^{ii, iii, iv}.

OPO performance varies substantially nationwide, yet OPO performance is a critically important factor influencing the availability of organs to patients (and to transplant programs at hospitals serving those patients) in a given geographic area. Research suggests that this variation is not due to regional differences in the causes of death or local demographics.^v Research also suggests that there is variation among OPO performance on organ donation consent rates by race/ethnicity, which may contribute to missed opportunities to increase the organ supply for patients and populations living in certain geographic areas.^{vi}

As CMS outlines in the Federal Register, pursuant to section 1138(a)(2)(A) of the Social Security Act, a hospital may request a waiver to work with an OPO other than the one designated by CMS, provided the Secretary determines that the waiver is expected to increase organ donations and will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO, along with other factors such as cost-effectiveness or improvements in quality that the Secretary may consider. ASN strongly urges

CMS to prioritize opportunities within the agency's authority that increase organ donation and equity in general and in particular with respect to access to kidney transplantation.

The most recently available CMS data (2020) indicate that the OPO currently serving the area in which the hospital requesting a waiver is located is designated as a "failing" OPO. The OPO the hospital requests a waiver to work is designated as a "passing" OPO.^{vii,viii} However, beyond this data, little information is publicly available regarding the specifics of the operations and performance of either OPO under consideration in the context of the hospital's waiver request. ASN has previously called upon CMS to make all OPO process data publicly available, which would enable transparency and research into differential OPO communications with donor hospitals, donor families and donor management strategies. This step would inform ongoing solutions through operational improvement and professionalization of the OPO workforce to a high level of clinical competency and evidence-based procurement practice, as well as iterative policymaking. ASN again urges CMS to increase the transparency of OPO performance by making OPO process data publicly available.

Typically, under current regulations, hospitals would only have the possibility of being served by another OPO every four years, as part of the OPO recertification process. The waiver presents an exception to this four-year cycle by establishing a pathway by which hospitals that believe that the patients under their care may be better served by another OPO, can request an earlier change—provided the Secretary determines that the change is expected to increase organ donation and will ensure equitable treatment of patients referred for transplants. Again, these are outcomes ASN believes the entire kidney health ecosystem should be working to achieve, and urges CMS take steps to do so wherever possible under existing statutory authority, including in the context of donor hospitals and OPOs.

Thank you for the opportunity to provide comment. ASN stands ready to assist CMS in any way possible to way in service of our shared goals of maximizing patient access to kidney transplantation and ensuring that access is equitable for all patients. To discuss these recommendations further, please feel free to contact Rachel Meyer, ASN Strategic Policy Advisor to the Executive Vice President, at rmeyer@asn-online.org or 505-720-2009 or David White, ASN Regulatory and Quality Officer, at dwhite@asn-online.org or (202) 640-4635.

Sincerely,



Michelle A. Josephson, MD, FASN
President

ⁱ <https://www.organdonor.gov/learn/organ-donation-statistics/detailed-description#fig1>

ⁱⁱ <https://www.asn-online.org/policy/webdocs/19.9.27OPORFIMetricsCommentLetterFinal.pdf>

ⁱⁱⁱ <https://www.asn-online.org/policy/webdocs/ASNTxRFIFinal2.1.22.pdf>

^{iv} [https://www.asn-online.org/policy/webdocs/ASNfinalMay23RFIOPTNContract_\(002\).pdf](https://www.asn-online.org/policy/webdocs/ASNfinalMay23RFIOPTNContract_(002).pdf)

^v <https://pubmed.ncbi.nlm.nih.gov/26031323/>

^{vi} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3557536/>

^{vii} <https://opodata.org/state/NC>

^{viii} <https://qcor.cms.gov/main.jsp>