March 31, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS 3409-P [RIN 0938-AV65]

Dear Administrator Oz:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the nearly 22,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for your leadership on, and commitment to, kidney health. Dedicated to maximizing access to kidney transplantation for every American who could benefit, ASN appreciates the opportunity to comment on "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage."

ASN was supportive of the 2020 final rule that introduced more objective measurement and greater accountability for Organ Procurement Organizations (OPOs). At the time, the society also recognized that aspects of the final rule would need to be updated over time.[i,ii] Overall, ASN believes this proposed rule is an important step in that direction. ASN commends the OPO community on its overall gains in procurement since the new system was finalized in 2020. The recent increase in transplants was made possible by their efforts and improved performance as a community. While the system will continue to need refinement over time, this advancement speaks to the effectiveness of increased accountability in driving performance improvement.[iii]

Overall, ASN:

- Celebrates the OPO community's growth in organ procurement over the last several years, efforts that have saved thousands of lives.
- Commends CMS for issuing a proposed rule that moves towards greater clarity on OPO evaluation, re-certification, de-certification, and transitions, as this clarity is essential to ensure that patients, families, and communities have predictable, continuous, high-quality organ recovery operations.
- Applauds CMS for developing processes for potentially certifying new OPOs and soliciting input from stakeholders.
- Supports developing new definitions, though notes that these efforts will likely have a more profound effect on organ supply (and, ultimately, patient access to transplant) if they are instituted together with more holistic changes across the system to align incentives for multiple stakeholders.
- Agrees with CMS' proposal to label donor service areas (DSAs) by performance tier, as opposed to labeling OPOs by performance tier.

Clarifying pancreata used for islet cell research

ASN is aware that since the final rule was promulgated in 2020 there has been a substantial increase in the number of pancreata recovered for research purposes, and related concerns from both the administration and the community that this growth may not be consistent with the intent of increasing access to transplantation or advancing research.[iv,v,vi] CMS proposes that a pancreas that is used for islet cell research (but not transplanted to a patient) would count towards the donation rate outcome measure, but would not be included in the transplantation rate outcome measure, whereas a pancreatic islet allotransplant to a patient on the OPTN waiting list would be included in both the transplantation rate outcome measure and the donation rate outcome measure. ASN believes this is a reasonable clarification.

However, the society encourages CMS to closely monitor changes in procurement and use of pancreata for research and transplantation following this change to identify any unintended consequences. ASN also encourages CMS to engage with leaders in the field of pancreas research and transplantation, such as those whose research is cited in the proposed rule, to attain their impression of the effect of these changes in close to real-time.

Creating a new definition for adverse events

CMS notes a concern that the current definition of "adverse events" may be interpreted as an exhaustive list, not a list of examples, potentially contributing to under-reporting of “an untoward, undesirable”, a “usually unanticipated event that causes death or serious injury or the risk thereof.” Protecting patient safety is an integral component of maintaining public trust in the transplant system. This must include identifying adverse events as adverse events to trigger an analysis of what occurred and prevent the situation from happening again. Therefore, ASN supports CMS’s proposal to remove the specific list from the current definition of “adverse events,” and instead shift to a revised list of examples in OPO Quality Assessment Performance Improvement (QAPI) requirements. This shift appropriately encourages OPOs to think broadly about what might constitute an event that should prompt QAPI activities and potentially have a more expansive focus on ensuring patient safety.

Creating a new definition for medically complex organs and medically complex donors

For some of the nearly 100,000 people on the kidney transplant waitlist, even marginal organs could confer a better quality of life and longer life (as well as cost savings to the system) as compared to dialysis.[vii,viii] (Research also suggests that many patients who would benefit from kidney transplantation as compared to dialysis do not even attain waitlisting status, and the need is larger than the waitlist alone would suggest. Increasingly, patients who might benefit from a transplant are also removed from the waitlist. [ix,x,xi, xii, xiii, xiv]) In this context, procuring and using as many viable kidneys as possible, in alignment with patients’ individual risk-benefit preferences, is an important goal.

Organs from donors with less preferred characteristics may be perceived as less valuable for organ transplantation, based on factors such as the age, health, and DCD status of the donor. CMS notes that “declining to use these organs contributes to the chronic undersupply of transplantable organs, as well as potentially increasing mortality and decreasing quality of life for ESRD patients.” CMS cites a concern that OPOs may not be pursuing procurement from potential donors whose organs may be considered marginal.

ASN concurs that underutilization of marginal organs that would nonetheless confer survival and quality of life benefits to people with kidney failure as compared to dialysis is a substantial problem—but it is important to recognize that it is a problem with many contributing factors.[xv] The society encourages CMS to undertake a more holistic examination of the reasons these organs may be under-procured and under-utilized, which include misaligned incentives across numerous stakeholders and the absence of a systemic emphasis on elucidating patient preferences in organ offer decisions.

For example, transplant programs are held to tremendously high-performance standards, with most programs exceeding 90% on one year-graft and patient survival (key OPTN metrics). Because these success rates are close to maximized and even a small percentage change in outcomes that may not be clinically impactful can affect a program's status with OPTN, some programs may at times be conservative in organ offer acceptance.[xvi] Considering the high mortality rate of patients who remain on the waiting list as compared to patients who receive a kidney transplant, this approach may not optimally serve an individual patient, but may be viewed as necessary to serve the greater good of keeping a program "in good standing" with OPTN and open to perform transplants at all. In the context of this proposed rule, incentives for transplant centers to transplant the most optimal kidneys to maintain high performance standards are at odds with OPOs' incentives to procure and place as many kidneys as possible, including marginal kidneys.

Additionally, patient preferences may not be routinely accounted for in responses to organ offers made by OPOs. Health professionals receiving organ offers might not recognize that some patients would prefer accepting a lower-quality kidney if it allows them to come off dialysis sooner. Unfortunately, that preference is often not accounted for, which potentially contributes to the under-utilization of marginal kidneys. ASN has previously encouraged a national emphasis on, and a mechanism to, better account for patient preferences in organ offer decision-making and believes it may contribute to better alignment in the system and more appropriate organ utilization. (The society also notes that variation in expertise and volume between transplant centers means that some programs are capable and comfortable transplanting more complex organs and patients than others.)

Despite these pressures, transplant programs have made remarkable progress in the last decade in transplanting more complex kidneys and more complex recipients—organs and people who would never have been considered candidates in the past, such as HIV+, HCV+, and DCD donor kidneys.[xvii,xviii] This accomplishment on the part of both the OPOs who procured and placed the kidneys as well as the transplant programs that successfully transplanted them warrants acknowledgement and celebration.

With the goal of increasing focus on procuring and placing complex kidneys from complex donors, CMS proposes to define the term "medically complex organ," as an organ from a "medically complex donor," including those with a KDPI score of 50 or greater and from DCD donors, for OPO QAPI purposes. CMS proposes to include these organs and donors in OPOs' QAPI programs (such as efforts optimizing opportunities to recover and place these organs for transplant).

Having a definition of "medically complex donors" is reasonable, as is encouraging focus on placing them through QAPI, but ASN suggests a more detailed definition be developed than proposed in this rule. This step could be accomplished based on feedback and input from stakeholders with expertise in procurement and transplantation in this proposed rule, and/or in subsequent rulemaking. ASN notes that a KDPI score of 50, which CMMI proposes as the floor

for the definition of a medically complex organ would not generally be considered a medically complex organ. For example, current criteria for placement of a kidney through the existing accelerated placement pathway is a KDPI of 85. A lower threshold that more closely approaches a KDPI of 85, such as a KDPI of 70 (CMS' proposed alternative to 50), might be more suitable.

However, based on the complexity of factors that contribute to organ underutilization, ASN is unsure that revised definitions and greater emphasis on QAPI will meaningfully move the needle for patients on its own. If CMS continues to pursue this concept, the society suggests that it be undertaken as part of a system-wide effort to align incentives between OPOs and transplant centers and promote more patient-centric decision-making.

Creating a new definition for unsound medical practices

Recent feedback and events have prompted CMS to propose a definition in the OPO conditions for coverage for "unsound medical practices," which the conditions for coverage reference as grounds for immediate termination but do not presently define. CMS proposed that the term "unsound medical practices," would "refer to failures by OPOs that create an imminent threat to patient health and safety or pose a risk to patients or the public. These practices include, but are not limited to, failures in governance; patient or potential donor evaluation and management; and procurement, allocation, and transport practices and procedures."

ASN conceptually supports more concretely defining "unsound medical practices," that could result in immediate termination, but suggests that CMS more clearly delineate the difference between "adverse events" and "unsound medical practices." For example, the proposed rule *could* be interpreted to suggest that "adverse events", refer to so-called "never events," and "unsound medical practices," refer to systemic or ongoing policies or approaches (which could potentially give rise to adverse events), but ultimately it is unclear. Greater clarity and granularity are critical because these definitions result in two very different outcomes: "unsound medical practices" could result in immediate OPO termination whereas "adverse events" trigger an appropriate assessment and QAPI process.

Establishing details about OPO transitions

ASN supports ongoing accountability for OPOs and believes that having meaningful consequences for failure to meet a performance floor is important in a system with life-and-death stakes for the more than 100,000 Americans on the kidney transplant waitlist. Competition, with appropriate structure and transparency of process, could play an important role in creating meaningful consequences and ASN has previously encouraged CMS to address whether and how new OPOs may be designated. The society thinks it is reasonable to create a mechanism to potentially expand the pool of possible OPO contractors beyond the pool that were recertified between 2002 and 2005. ASN recognizes that there has been an evolving interpretation of the legalities around certification of new OPOs but conceptually supports it.

In this context, the society is pleased to see CMS start developing processes for potentially certifying new OPOs and soliciting input from stakeholders. ASN does not have deep expertise in OPO management and is therefore not in a position to opine in detail on OPO selection criteria but supports its development. The society recommends that however CMS finalizes these processes and criteria, a primacy should be placed on continued service to communities, donors, and donor families. This focus should include:

- Communicating, clearly and transparently, the standards by which competitors for a DSA will be judged for all stakeholders in the community, which will be important for building a sense of trust in the selection process and outcomes.
- Providing detailed expectations about the process and timeline for transition of responsibility from one OPO to another (whether that OPO is new or previously established)
- Defining a detailed data and information technology handoff plan
- Establishing a communication plan between the outgoing OPO, the incoming OPO, local donor hospitals, and the transplant centers within the DSA or that have historically interacted most often with the DSA

ASN is heartened to see in the proposed rule that the number of OPOs that may face decertification has decreased, based on CMS' estimate that no more than 10 OPOs would potentially expand to serve multiple DSAs following implementation of the December 2020 final rule's performance standards. Ideally, all OPOs could continue to improve their performance and provide continued, high-quality service to their communities and minimize the need for decertification altogether. The society encourages CMS, and the Department of Health and Human Services more broadly, to provide as much data, information, or incentives to OPOs in a timely fashion to enable their success during performance periods.

Labeling DSAs by tier status, not OPOs

CMS proposes to establish a new framework allowing a single OPO to be designated to serve multiple DSAs. CMS also proposed to designate an individual *DSA* by tier, as opposed to designating an OPO as a whole by tier. This change would allow an OPO to operate in a high-performing (Tier 1) DSA, middle-performing (Tier 2) DSA, and/or an underperforming DSA without being subject to decertification steps in each one. ASN supports labeling the performance of the DSA rather than the OPO as a whole, as it may decrease disincentives for high-performing OPOs to consider competing to provide service in a DSA with an outgoing underperforming (Tier 3) OPO. Not only is this approach fair to an OPO on its face, but it may also advance the goal of ensuring continued provision of procurement services to communities with an outgoing underperforming (Tier 3) OPO.

<u>Comment Solicitation and Discussion on Emerging Issues</u>

Potential conflict of interest issues

ASN supports the creation of a clear Conflict of Interest (COI) policy regarding OPOs. Their creation will help to address concerns that have arisen over recent years regarding relationships between OPOs and relevant organizations, such as hospitals and the broader healthcare system environment. Having a public COI policy is an important aspect of bolstering and maintaining public trust.

Automated electronic referrals from donor hospitals to OPOs

ASN is a proponent of instituting automated electronic referrals from donor hospitals to OPOs. Based on discussions with OPOs that have voluntarily established automated electronic referrals, the society understands that the practice has substantially increased efficiency for donor hospitals (such as ICU staff time), facilitated the swift sharing of relevant information needed to inform OPO decision-making, and supported an increase in organ recovery.[xix]

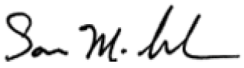
At the same time, ASN supports protecting the privacy and healthcare data security of all Americans, including those being evaluated as potential donors and those who go on to be organ donors. In the future, ASN believes that OPOs should be HIPAA-compliant entities. Especially as automated sharing of potential organ donors' information between donor hospitals and OPOs via electronic medical records happens more widely and the volume of data shared with OPOs grows, this change is all the more important. Ensuring data protection and privacy for potential organ donors is an important component of maintaining public trust in the organ donation system.

CMS reviews federal organ allocation rules and "clarifies expectations for regulatory and policy compliance necessary for maintaining public trust

ASN appreciates CMS' attention to organ allocation rules and the importance of adherence in terms of maintaining public trust. ASN has previously expressed concerns about the growth in allocation out of sequence and list-diving, and understands these practices as, in part, responses to changes to, and inefficiencies in, the matching system.[xx,xxi] The kidney allocation system has not kept pace with practice changes and transplant center or patient needs, somewhat compromising its credibility to make timely matches.[xxii, xxiii] This context may in part have given rise to concerns that the allocation system puts certain organs at risk of nonuse, driving some of the current trends in allocation out of sequence, and pointing to the need to redesign or revamp the allocation system.[xxiv, xxv] A formal process for allocating truly hard to place organs will be a critical component of a redesigned allocation system. ASN would be pleased to work with other stakeholders in the kidney and transplant community to advance this goal.

Again, thank you for the opportunity to provide comment. Please contact ASN Strategic Policy Advisor to the CEO Rachel Meyer at rmeyer@asn-online.org to discuss this letter in more detail with ASN.

Sincerely,



Samir M. Parikh, MD, FASN
President

---

[i] ASN comment letter. September 2019. https://www.asn-online.org/policy/webdocs/19.9.27OPORFIMetricsCommentLetterFinal.pdf
[ii] ASN comment letter. February 2020. https://www.asn-online.org/policy/webdocs/ASN_Comment_Final_Comment_Letter_CMS-3380-P.pdf
[iii] Bae H. et al. Organ Procurement Following the Centers for Medicare and Medicaid Services Performance Evaluations. November 19, 2025. JAMA Surgery.
[iv] Wyden, Grassley, Cardin, Young Raise Alarm Over Dramatic Increase in Pancreata Procurement. March 21, 2023. https://www.finance.senate.gov/chairmans-news/wyden-grassley-cardin-young-raise-alarm-over-dramatic-increase-in-pancreata-procurement-
[v] CMS Centers for Clinical Standards and Quality memorandum. August 2024. https://www.cms.gov/files/document/qso-24-19-opo.pdf

[vi] Goldberg DS et al. Procurement of Pancreatic Tissue for Research From Deceased Donors Before vs After the CMS Final Rule in 2020. September 2023. JAMA Network Open. doi:10.1001/jamanetworkopen.2023.32395

[vii] Sharma N et al. Marginal kidney transplantation: the road less traveled. February 2019. Curr Opin Organ Transplant. doi: 10.1097/MOT.0000000000000603

[viii] Axelrod, DA et al. An economic assessment of contemporary kidney transplant practice. January 2018. AJT.

[ix] Patzer RE et al. The ASCENT Intervention to Improve Access and Reduce Racial Inequalities in Kidney Waitlisting. February 2023. CJASN. oi: 10.2215/CJN.0000000000000071

[x] Patzer RE et al. A Randomized Trial to Reduce Disparities in Referral for Transplant Evaluation. JASN. March 2017. *DOI:* 10.1681/ASN.2016030320

[xi] Husain S et al. Disparities in Kidney Transplant Waitlisting Among Young Patients Without Medical Comorbidities JAMA Intern Med. doi:10.1001/jamainternmed.2023.5013

[xii] Schold JD et al. Association of Candidate Removals From the Kidney Transplant Waiting List and Center Performance Oversight. 2016. AJT. doi: 10.1111/ajt.13594

[xiii] Sokas CM et al. Evolving Metrics of Quality for Kidney Transplant Candidates: Transplant Center Variability in Delisting and 1-Year Mortality. J Am Coll Surg. June 2022. doi: 10.1097/XCS.0000000000000204.

[xiv] Schold JD, Huml AM, Poggio ED, Reese PP, Mohan S. A tool for decision-making in kidney transplant candidates with poor prognosis to receive deceased donor transplantation in the United States. Kidney Int. 2022 Sep;102(3):640-651. doi: 10.1016/j.kint.2022.05.025. Epub 2022 Jun 26. PMID: 35760150.

[xv] Bae H. et al. Organ Procurement Following the Centers for Medicare and Medicaid Services Performance Evaluations. November 19, 2025. JAMA Surgery.

[xvi] Poggio ED et al. Long-term kidney transplant graft survival—Making progress when most needed. August 2021. AJT.

[xvii] Durand CM et al. Safety of Kidney Transplantation from Donors with HIV. October 2024. NEJM. DOI: 10.1056/NEJMoa24037

[xviii] Huml, A et al. Kidney Transplantation and Candidate BMI: Viability is in the Eye of the Beholder. March 2022. AJKD. doi: 10.1053/j.ajkd.2021.04.005

xix Levan ML et al. Short Report: Evaluating the Effects of Automated Donor Referral Technology on Deceased Donor Referrals. Transplant Direct. July 2022 doi: 10.1097/TXD.0000000000001330.

[xx] ASN comment letter. September 2024. https://www.asn-online.org/policy/webdocs/24.9.24DraftContinuousDistribution.pdf

[xxi] Tucker EG, Yu ME, Adler JT, Cron DC, Sahni PV, Schold JD, Mohan S, Husain SA. Underrecognition of deceased donor kidney out-of-sequence allocation due to increasing use of free-text coding. Am J Transplant. 2025 Aug;25(8):1715-1722. doi: 10.1016/j.ajt.2025.04.002

[xxii] Masotti M, Wood NL, Hart A, Schaffhausen CR. The impact of increasing out-of-sequence allocation on kidney transplant patient outcomes. Am J Transplant. 2025 Nov 21:S1600-6135(25)03120-X. doi: 10.1016/j.ajt.2025.11.014.

[xxiii] Cron DC, Husain SA, Kuk AE, Mohan S, Adler JT. Increasing Incidence of Out-of-Sequence Allocation of Deceased Donor Kidneys. Kidney360. 2025 Jan 1;6(1):145-149. doi: 10.34067/KID.0000000640

[xxiv] Yu ME et al. Expedited Transplant Allocation Using a Paired Kidney Cohort. JAMA Netw Open. March 2026. doi: 10.1001/jamanetworkopen.2026.0257.

[xxv] Husain SA et al. Changes in Deceased Donor Kidney Recovery and Transplantation after Increased Regulatory Oversight of Allocation Out of Sequence. JAMA Network Open. March 2026. doi: 10.1001/jamanetworkopen.2026.0257.