



February 21, 2020

The Honorable Alex M. Azar, II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Seema Verma  
Administrator, Centers for  
Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**ATTN: CMS-3380-P: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization**

Dear Secretary Azar and Administrator Verma,

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the proposed rule for Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization. ASN's more than 22,000 members are leading the fight to prevent, treat, and cure kidney diseases and advocating for the highest quality care for the 37,000,000 Americans and more than 850,000,000 people worldwide affected by kidney disease. In keeping with ASN's mission, we applaud the Trump Administration for creating an ambitious agenda for kidney health through the Executive Order on Advancing American Kidney Health, aspects of which are addressed in this proposed rule. ASN strongly supports these goals and stands ready to work in collaboration with the administration, Congress, and other stakeholders to achieve success.

The President's Executive Order specifically calls on the Secretary of Health and Human Services to "propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance."

With 115,000 Americans waiting for an organ, ASN supports the proposed rule to establish both transparent, uniform metrics to help assess the performance of each of the 58 OPOs and clear procedures for evaluating those organizations including processes for improvement and re-certification. ASN believes that reforming the current system of OPO performance oversight is necessary to enable the Advancing American Kidney Health goal of doubling the number of kidneys available for transplant by 2030 as well as to approach the proposed target transplant rate described in the ESRD Treatment Choices proposed model and the four tracks of the voluntary model.

ASN provides comments on the following specific issues impacted by the proposed rule and re-affirms its support of policies the society commented on in its September 27, 2019, comment letter to CMS on the CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1717-P). ASN supports the following:

- Using the inclusionary Cause, Age, and Location Consistent (CALC) metric described in the Proposed Rule, as opposed to the proposed denominator that uses exclusionary diagnosis
- Avoiding penalties for “zero organ donors”
- Opposing risk adjustment based on race and ethnicity
- Creating a system that transparently evaluates OPO performance with clear pathways to addressing improvement and consequences for not improving
- Reporting outcome measures of organ transplant rates by type of organ
- Taking future steps in other proposed rules to address waitlist criteria, less than ideal organs and patients, and payment issues for less than ideal patients

#### **Cause, Age, and Location Consistent (CALC) Donation Measure:**

ASN supports using the inclusionary CALC metric described in the Proposed Rule, as opposed to the proposed denominator that uses exclusionary diagnosis. Although CMS has shown that the net result in terms of among-OPO comparisons is similar, the CALC metric has superior face validity, because it restricts the denominator to inpatient deaths from causes that are consistent with donation, rather than the exclusionary measure which includes causes of death that never lead to donation. A metric, such as CALC, derived in an inclusive manner using a broad range of diagnostic codes to report the mechanisms of death, offers a much closer parallel with the potential donor supply in an area. Recent research demonstrates that adding a filter for exclusionary diagnoses, such as malignancy or sepsis, does not change the relative performance of different OPOs due to the comparatively uniform rate at which these conditions are reported as coincident to CALC mechanisms of death.

As lead author David Goldberg, MD, and his colleagues accurately summarize, “compared to the current metric that relies on eligible deaths, the benefits of our proposed donation metric are that it:

1. Does not rely on self-reported data
2. Utilizes a uniform process of estimating the donation potential within each donor service area
3. Includes potential DCD donors that are excluded from the eligible death definition, and
4. Provides a reliable year-to-year measure of OPO performance to track changes in performance.”<sup>1</sup>

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<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pubmed/31199562>

The researchers also write “[T]hese conclusions should provide CMS, and the transplant community, with comfort that the proposed CMS metric using CDC inpatient death data as a tool to compare OPO is not compromised by its lack of inclusion of ventilation or other comorbidity data.”<sup>2</sup> Additionally, ASN believes that if CMS has the ability to create efficiencies of data reporting between CMS and the CDC, an expedited timeline for the release of WONDER data for this purpose would be optimal – and supports efforts to do so.

### **Donation rate numerator (or Definition of donor)**

Also, ASN encourages CMS to avoid penalizing OPOs under the scenarios when extensive efforts are made to procure organs for transplant, but ultimately no organs are placed for transplant (so called “zero organ donors”). The following scenario could occur and credit for the attempt would be denied if only donors from whom organs are transplanted are considered donors:

- A deceased (brain-dead or donation after cardiac death) donor is identified that matches a locally available potential recipient
- There is preliminary determination of medical suitability, and preliminary offer acceptance by a transplant center
- The donor is taken to the operating room, but during organ procurement the transplant surgeon unexpectedly finds an unacceptable situation (such as unsuspected intra-abdominal cancer)
- Surgeon appropriately cancels use of the organs for transplant

The requirement for effort and expense to reach this stage is unlikely to lead to “gaming” to obtain credit for donation. Further, more aggressive pursuit of higher risk and older donors will likely lead to more identification of medical contraindications at later stages. Aggressive pursuit of organ donors will always be accompanied by some medically appropriate non-utilization.

Ultimately, ASN supports holding OPOs accountable and supports intervening with any OPO that does not perform adequately – while ensuring that the Department minimizes any potential disruptions in procurement and patient access if an OPO is decertified. ASN also supports the proposal that the outcome measures assessment occur at least every year and be based on data from the most recent 12 months of data along with an up to three-year period for improvement. OPOs in need of improvement relative to the performance threshold should be provided the opportunity to take actions for improvement and should also identify the actions that they will undertake to improve their outcome measures in their QAPI program. CMS should prevent a lapse in any service area that would leave a gap in the collection and provision of organs thereby limiting access to transplantation. The society believes that the current four-year cycle is too long a period for an OPO to be allowed to under-perform.

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<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=goldberg+doby>

## **Risk Adjustment:**

ASN supports CMS' decision to not risk adjust based on race and does not support additional risk adjustment based on race – and appreciates the agency's request for comment on this issue.

To say that examining the role of race in America can be a multi-faceted challenge is clearly an understatement. Janice F. Whaley, MPH, CTBS, CPTC Chief Executive Officer of Donor Network West addressed the issue of race and ethnicity in organ donation in the OPO's comment letter to CMS in September 2019 on its proposed rule on "Organ Procurement Organizations Conditions for Coverage: Proposed Revision of the Definition of Expected Donation Rate".

"As past-President of Association for Multicultural Affairs in Transplant (AMAT) and deeply steeped in minority and ethnic concerns during my nearly 30-year career in donation and transplantation, I would like to offer a word about donation and communities of color. Increased focus has been given recently to minority authorization rates and a perceived burden of producing good results in these measures based on the racial and ethnic composition of the OPO service area. This increased attention has been a positive development because it allows for a full-throated discussion about race, ethnicity and the nexus of organ donation. The view of race and ethnicity needs to evolve in our community much the same as it has for our nation across various assets and services. Minorities donate. Further, in some parts of the country, minorities donate at the same rate as do Caucasians. Thus, it can be done and when the DSA functions as a true community, it is done."

ASN welcomes both a "full-throated discussion about race, ethnicity and the nexus of organ donation" and an equally rigorous engagement on this issue by all OPOs. ASN believes all OPOs must address the issues facing all members of the communities they serve and, therefore, opposes risk adjustment based on race in organ donation.

## **Success Threshold and Expected Donation Rate/ Decertification:**

CMS proposes "[T]herefore, our proposed definition of success will be based on how OPOs perform on the outcome measures of donation rate and organ transplantation rate compared with the top 25 percent of donation and transplantation rates for OPOs." The agency requested comment on this issue.

ASN supports redefining the definition of success and basing that success on how OPOs perform on the outcome measures of donation rate and organ transplantation rate compared with a top percent of donation and transplantation rates for all OPOs. However, concerns have been raised that setting the threshold as CMS has proposed will set the bar too high and could lead to a "decertification cliff" with a majority of OPOs being deemed as underperforming.

Currently, CMS conducts recertification inspections of OPOs for compliance with requirements and performance standards every four years as a condition of Medicare and Medicaid participation and payment. In addition to those periodic recertification inspections, the rule proposes a review of OPO performance every 12 months to provide more frequent feedback to all OPOs. If an OPO's outcome measures — its donation and transplantation rates — fall statistically significantly below the top 25 percent of OPOs (as defined by a given OPO's upper limit of the one-sided 95 percent confidence interval falling lower than the threshold rate), CMS would require that OPO to revise its quality assurance and performance improvement (QAPI) program in order to improve. ASN requests further information from CMS on the process by which OPO underperformance would be remediated after the new metrics go into effect and whether the top 25 percent rate is static or reoccurring.

In particular, the society requests clarity on the process for re-certifying and de-certifying on an annual basis and at the conclusion of the four-year cycle. In light of some confusion, some ASN members have expressed concern that, as written, at the end of the four-year cycle a large, en masse decertification of OPOs could potentially occur. Some ASN members are also concerned that an OPO could perform well for the first three years, but not in year four, and be at risk of being de-certified without the opportunity to improve.

One thought in discussion is whether CMS should stagger the end of the four-year deadline so that not all 58 OPOs are on the same deadline – for example, 1/3, 1/3, 1/3 as the elections for the United States Senate are structured to ensure that as some OPOs are potentially decertified, other higher-functioning OPOs are in existence to maintain the supply of procured organs as well as bid for the contracts of any OPOs that have failed to improve their performance during their four-year window.

If OPOs immediately and drastically improve performance across the board, and CMS is faced with a dramatically tightened band of performance between OPOs, that will be detectable in the data and will be a welcome outcome, potentially saving thousands more patients from death. ASN would welcome a scenario in which OPOs are rapidly and consistently improving to the point that it is challenging to identify underperformance with objective data.

Overall, however, stakeholders' fear of change should be weighed against the very real fear, lived and expressed by the patients ASN members serve, that their lives will end before they can access a transplant because OPOs are underperforming. These patients might not receive a transplant because the system has not asked every OPO to meet an objective, verifiable standard of performance with an evidence-based standard of practice.

## **Organ Transplantation Rates by Type of Organ:**

ASN supports reporting outcome measures of organ transplant rates by type of organ. The criteria qualifying for a transplant not only differ based on transplant center, but also on the type of organ. A given donor may provide some organs suitable for transplant but not others, for reasons including the manner of death but may also be impacted by care preserving organ perfusion, oxygenation and function.

In reporting these data, ASN suggest that CMS consider how to distinguish the rate of organs transplanted versus those that were expected to be transplanted by organ type as well. This ratio would likely differ based on type of procurement, such as thoracic and abdominal organ procurement; donor management factors prior to procurement as these can affect usability and transplant success; and other factors.

In addition to the parameters of this proposed rule, ASN encourages CMS to consider future steps to address constraints and the unintended consequences associated with them in the metrics for transplant centers/programs.

## **Waitlist Criteria:**

While this issue is outside the scope of the proposed rule, ASN calls for a national dialogue regarding the evidence for, and appropriateness of, a consolidated set of waitlist criteria that are applied in transplant centers across the country. The variation in transplant candidacy criteria may be the result of legitimate practice differences: for example, some transplant centers may have expertise in transplanting highly sensitized patients, while others may not have the expertise to transplant such patients. Regardless of the cause of variable waitlist criteria, navigating these inconsistencies is a challenge for patients who must understand, first, that they have options, and, second, what those options are, in order to find their way to the transplant center most likely to accept them.

ASN recognizes that the decision to accept a patient as a candidate for transplant is complex and multifactorial, but the system must ensure that waitlist and living donor candidacy criteria utilized are as inclusive and patient-centered as possible, giving all patients a chance to pursue a transplant if they so choose. We reiterate that maintaining a level of flexibility and transparency in waitlist criteria that reflects the highly complex process of accepting a patient for transplant is imperative. CMS should consider additional steps such as the creation of a patient-centered internet portal to provide access and easier comparison of waitlist criteria across centers.

## **Less than Ideal Exemptions:**

Also outside of the scope of this proposed rule but critical to the national goal to transplant more patients via a patient-centered process, transplant centers must be evaluated on a different set of criteria that enable them to accept less than ideal patients and less than ideal kidneys than they do at present, while also being accountable for

other factors that patients value, such as the hope that accompanies being placed on the waitlist.<sup>3</sup> This would both increase patient access to transplant while improving the overall patient-centricity of the transplant system.

Achieving success with this approach would require collaboration between OPOs, donor hospitals, and transplant centers, and would also support the goal of using all available organs instead of the current climate in which many patients who could do well with a kidney transplant but are not *truly ideal* candidates are not given the chance to receive a transplant (and similarly, many organs that are not ideal are passed on and/or discarded). The disconnect between patient survival rates on dialysis and the survival rates that transplant centers are asked to achieve is significant.

### **Payments for Less than Ideal Patients:**

ASN also observes that, while the care of less than ideal organ recipients or less than ideal organs is more resource intensive, CMS does not adequately reimburse for the more costly, higher healthcare utilization that results (Axelrod/Lentine Am J Transpl 2017 PMID: 27565133). Again, this is outside of the scope of the proposed rule, but ASN wishes to flag this issue. The society strongly recommends that CMS explore higher payments for these less than ideal kidneys and patients, who are more resource-intensive to care for but who are also likely to benefit from a deceased-donor kidney transplant versus continuing with dialysis. This change would create greater harmony between the objectives OPOs are asked to achieve and the objectives transplant centers are asked to achieve—with the primary beneficiaries of this change being patients with a higher likelihood of getting a kidney.

Today, the compensation for kidney transplantation is a global fee that covers three months of care. However, individuals who receive organs that are of less than ideal quality (or are a less than ideal patient), take more resources such as a longer length of stay and more inpatient complications, as well as more intensive care in the outpatient post-transplant care setting. As highlighted in the Report of the National Kidney Foundation Consensus Conference to Decrease Kidney Discards, deceased donor kidney transplant in patients with Estimated Post Transplant Survival (EPTS) scores of 85-100 (indicating a shorter expected survival) was associated with \$5,257 more in costs but only \$2,475 of additional Medicare payments. These candidates are typically offered organs from less than ideal (e.g. higher Kidney Donor Profile Index (KDPI) score) donor, and the challenges of using these less than ideal kidneys (such as delayed graft function and associated expenses) further compounds expected losses.

Having a payment system that accounts for additional care in less than ideal organs and less than ideal patients would provide programs with the ability to optimize outcomes. Alternatively, CMS could develop a set of positive incentives for listing less than ideal patients (or transplanting less than ideal patients) and transplanting less than ideal organs, instead of a punitive system.

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<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6314030/>

ASN applauds CMS' efforts to structure the regulatory environment in such a way that an OPO which could have fulfilled their duty to maximize organ donation is accountable for all outcomes to their work, including when the OPO makes discretionary decisions not to approach, not to evaluate at the donor hospital, or not to recover organs, just as we expect to be held accountable for how those organs are accepted—or not—for transplant.

Again, ASN appreciates the opportunity to provide these comments and suggestions to further improve the proposed rule. If there are any questions or CMS would like to discuss the contents of this comment letter, please contact David White, ASN Regulatory and Quality Officer, at (202) 640-4635 or [dwhite@asn-online.org](mailto:dwhite@asn-online.org).

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Anupam Agarwal", with a long horizontal line extending to the right.

Anupam Agarwal, MD, FASN  
President