March 31, 2026

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

RE: [CMS–3409–P]; RIN 0938–AU54; Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage for Organ Procurement Organizations (OPOs) ("OPO Proposed Rule")

Dear Administrator Oz:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on the Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage for Organ Procurement Organizations (OPOs) ("OPO Proposed Rule"). ASTS is a medical specialty society representing approximately 2,400 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS recognizes that many of the issues addressed in the OPO Proposed Rule are highly technical in nature and fall within the specialized expertise of CMS, OPOs, and the associations that represent them. However, the transplant system in the United States is highly complex, and the roles of transplant surgeons and physicians, transplant programs, OPOs, hemodialysis laboratories and other providers are highly interconnected. The system cannot function at all without the critical work of OPOs. It is in the spirit of ensuring our patients' continued access to transplantable organs that we venture to comment on the proposed revisions of the OPO Conditions for Coverage (CfC).

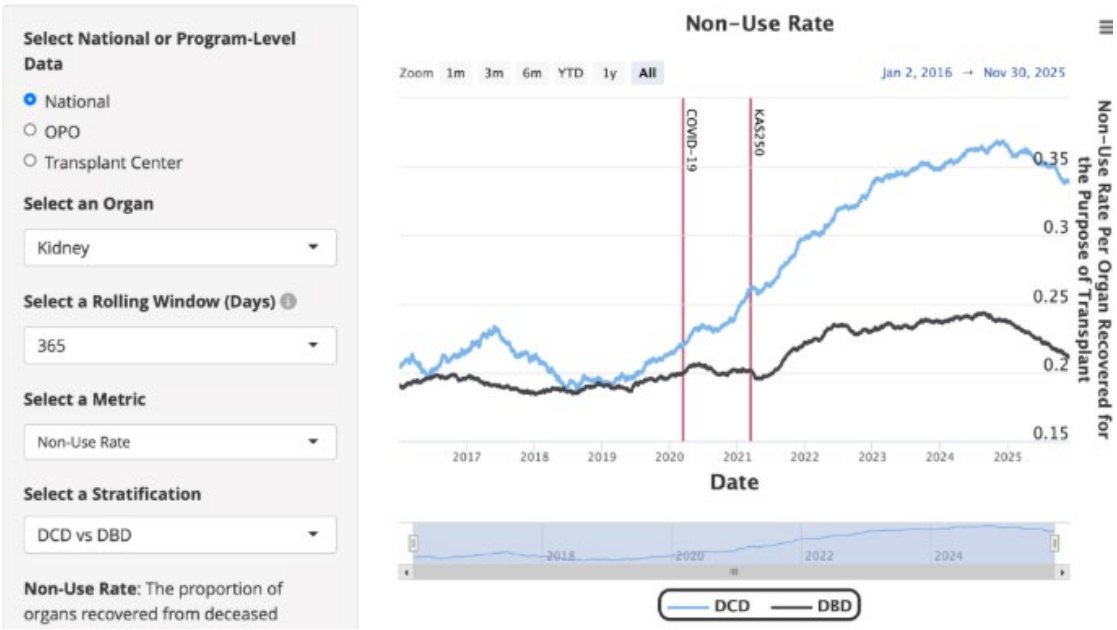
Preliminarily, we remain very concerned about issues that we have raised in the past and that are not addressed by the Proposed Rule. For example, and most importantly, the entire system reflects a continued lack of alignment between the incentives provided to OPOs and the incentives provided to transplant programs under current government programs: While the transplant program star ratings based on one year outcomes (under the auspices of the Scientific Registry of Transplant Recipients (SRTR), a HRSA contractor) strongly incentivize transplant programs to decline hard to place organs, the CMS outcomes measures incentivize OPOs to procure and attempt to place organs for transplantation aggressively. ASTS addressed this major problem when revisions to the OPO CfCs were initially proposed in November 2019 and in March 2021 (see Attachments A and B). We

urge CMS to review our recommendations for addressing this and other major substantive concerns about the new OPO standards as they consider necessary changes to the OPO CfCs, whether through the current or potential future rulemaking initiatives.

These comments are divided into three sections. The first sets forth our perspective on the impact of the new OPO standards to date—an impact that has been significant. Second, these comments address the proposed new requirements related to the qualifications of OPO clinical personnel involved in the procurement process. Finally, these comments provide our high-level perspective on the process to be used to implement the new standards, as set forth in the Proposed Rule, with a focus on the objectives that we believe should drive CMS' decisions regarding implementation of this process.

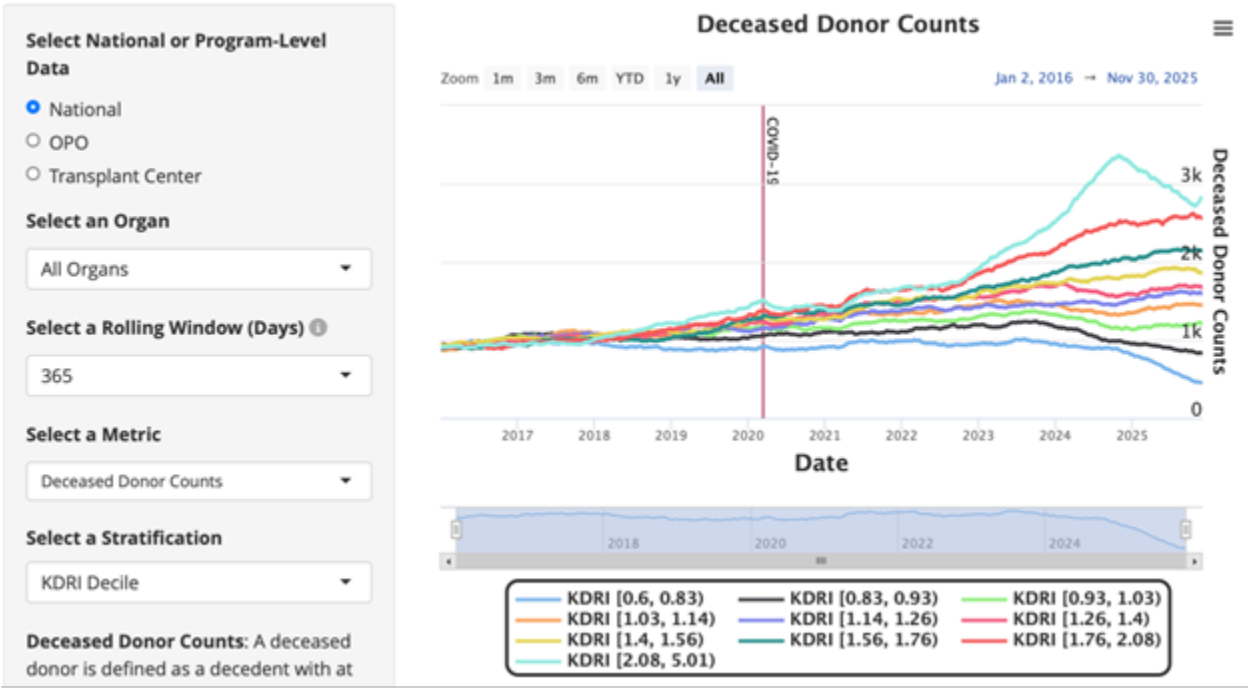
I. The Impact of the New OPO Outcomes Standards to Date

Since their adoption, the new OPO certification standards have had a significant impact on the availability of deceased donor organs. For example, the number of kidneys procured for transplantation grew from 23,689 at the end of December 2021 to 30,413 at the end of December 2025, an extraordinary 28% increase.
At the same time, there has also been a dramatic increase in non-use of kidneys procured for transplantation over the past several years, reaching a peak in 2024, the OPO assessment year.



Altogether, in 2024, approximately 9,266 to 9,275 kidneys recovered by OPOs were not transplanted. This number represents a significant increase in kidney non-use over the past five years, with many of these organs coming from older or medically complex donors. Of the total number of kidneys recovered but not transplanted in 2023 (the most recent data detailed breakdown publicly available), approximately 72% were declined by all transplant programs, strongly suggesting that the organs involved were unsuitable for transplantation for any waitlisted patient.[i]

A closer look confirms this conclusion: SRTR 2023 data indicates that a significant proportion of the increase in deceased donor organs procured by OPOs over the past several years were of low quality, based on donor age, diabetes/hypertension history, cause of death, and other characteristics relevant to the relative risk of organ failure, as measured using the Kidney Donor Risk Index (KDRI):



In the above chart, the turquoise line represents organs that have an estimated risk of failure that is two to five times that of the median and the red line represents organs that have an estimated risk of failure up to twice that of the median. Fundamentally, while OPOs are increasing the number of kidneys procured, the quality of a high proportion of these organs is extremely problematic, resulting in a substantial growth in the number of kidneys that are rejected by all programs. The problem was particularly severe (as might be anticipated) during 2024, the OPO assessment year.

Recommendation: *Based on the data available to date, it appears that assessing OPOs solely on one year of data is resulting in a significant increase in procurement of organs unsuitable for transplantation during that year, increasing the non-use rate substantially and placing extraordinary administrative pressure on transplant programs that may be inundated with organ offers for organs unsuitable for transplantation. For this reason, we urge CMS to consider expanding the assessment period used to evaluate OPO performance.*

Recommendation*: The Proposed Rule appears to suggest that OPOs have been remiss in failing to procure organs from "medically complex" donors, and, for that reason, the Proposed Rule includes a new QAPI requirement to encourage procurement and placement of organs from these donors. We encourage CMS to re-examine the assumptions underlying this new requirement, since that data suggests to us that, if anything, OPOs are already procuring organs from a significant number of high-risk donors, contributing to a significant increase in organ non-use.*

II. Proposed Human Resources Proposals

A. Proposed Licensure and Certification of Medical Director

The OPO Proposed Rule would revise § 486.326(d) (‘‘Medical Director”) to specify that an OPO’s medical director would be “*a”* physician licensed in at least one of the States or territories within one of the OPO’s service areas or as required by State or territory law or by the jurisdiction which the OPO is located. As CMS recognizes, state laws differ regarding whether, and under what circumstances, a physician who is not licensed by the state and who is located out of state may practice medicine in the state. In light of the OPO consolidation likely to result from implementation of the new standards, some OPOs may be subject to state practice of medicine restrictions in many states, some of which may effectively preclude an out of state medical director from providing services in one or more of the OPO’s DSAs. In light of the complexity of state law in this area, we urge CMS to explicitly authorize OPOs to retain different medical directors in different states, as required by state law, so long as all medical directors are required to comply with applicable Medicare certification requirements.

B. Licensure and Certification of Other Clinical Personnel

The OPO Proposed Rule would add a new standard (§ 486.326(e), Licensure), which would require that personnel performing clinical duties to be legally authorized (licensed, certified, or registered) to do so, in accordance with applicable Federal, State and local laws and would also require that such personnel function solely within their scope of State licensure or certification. While we strongly support the intent of this new requirement, we caution that, at least with respect to surgical removal of deceased donor organs, implementation may prove more complex than it might otherwise seem.

While the practice of surgery on living patients is universally considered the practice of medicine, state law is generally silent on whether surgical removal of organs from deceased donors constitutes the practice of medicine, and current Medicare certification requirements do not require that organs be procured exclusively by physicians, let alone surgeons with specialized training. Each OPO is authorized to establish its own qualifications or other standards for organ procurement personnel, and the qualifications or other standards required by OPOs vary widely. Those individuals who meet an OPOs qualifications requirements are included on a national registry (ACIN); however, this registry simply lists those individuals whose names are provided to it by OPOs and does not itself ensure compliance with licensure or other quality standards, such as tracking organ injuries. Regardless of what criteria are used by an OPO to ensure that an individual is qualified to procure organs, the individual’s name is included on the registry, and donor hospitals routinely authorize organ procurement by registered individuals. A survey conducted by ASTS in late 2024 and early 2025 indicates that some organs are recovered by Nurse Practitioners, Physicians Assistants, and Surgical Technicians (data was collected from 38 OPOs).[ii]

The ASTS Council has approved numerous standards documents for the procurement of organs:

- Procedural Standards for Deceased Donor Organ Recovery
- Surgical Standards for Surgeons Performing Normothermic Regional Perfusion (NRP)
- Surgical Standards for Surgeons Performing Deceased Donor Organ Procurements for Transplantation

The third document in particular outlines licensure, training, and experience standards for *surgeons* (including fellows) who procure deceased donor organs (Attachment C); however, these standards are not legally binding under state law nor are they binding on OPOs or applicable to non-physician clinical personnel who OPOs may

authorize to procure deceased donor organs. ASTS is currently developing a certificate of completion program for clinical personnel who procure organs and we are hopeful that OPOs will require those who procure organs for them to complete the course.

We also wish to call to CMS' attention a closely related issue. Over the past several years, there has been a growing trend for organs to be procured by surgeons and others employed by perfusion companies and by OPOs themselves, rather than by transplant program surgeons and fellows. While this practice may increase OPO efficiency, ASTS believes that it is critical that transplant program fellows continue to have the opportunity to procure organs for OPOs, both under supervision and independently (once proficiency has been demonstrated). Without this training opportunity, the pipeline of qualified procurement surgeons may be significantly and adversely affected. ASTS has proactively addressed this issue in standards listed above for NRP (Attachment D) and we urge CMS to also consider addressing this issue in future modifications of OPO regulations.

III. Establishing the Objectives of the OPO Certification Process

It is imperative that Medicare's OPO certification standards and process function in a manner that facilitates the consistent procurement of the maximum number of transplantable organs (consistent with ensuring the safety and respect of donors and potential donors), while guarding against instability, inefficiency and disruption in access. In this section of our comments, we identify the primary objectives that the OPO certification/recertification process should prioritize and outline our concept of what an ideal process might look like, from the perspective of patients, donors, and transplant providers. We leave to CMS the task of determining whether, and to what extent, the processes outlined in the OPO Proposed Rule fulfill these objectives and whether these objectives can be achieved through sub-regulatory guidance.

A. Objective: Predictable Timing

It is our understanding that the four-year OPO certification cycle ends on June 30, 2026, less than three months away. Yet, at this stage, CMS has not yet made public OPO performance data for 2024, the assessment year upon which recertification determinations will be made. While the OPO Proposed Rule includes a broad outline of the process CMS intends to use in implementing the new outcomes standards, many issues have yet to be addressed, and it is possible the rules will not have been finalized by the expiration of the current certification cycle. Most certainly, there will have been no time for CMS to make assessment year data available; to implement a competitive bidding process; and to determine the "winners" prior to the expiration of the current certification cycle. This situation has resulted in substantial unease not only for OPOs but for the entire transplant community. It seems possible, if not likely, that this problem may recur in future recertification cycles, since, based on the past two years of experience, public release of OPO performance data may be delayed by 18 months or more following the close of a calendar year. If this is the case, critical assessment year data and Tier classifications may be made public only a few months before the end of future four-year certification periods, resulting in significant public concern about which OPOs may be decertified or otherwise cease operation in the DSA, and when.

Recommendation: *ASTS recommends that CMS extend the certification of the current OPOs until December 31, 2026, and establish four-year certification cycles that begin on January 1. Assuming that assessment year data and Tier Rankings continue to be available on or before June1 of the last year of the certification cycle, this would allow a period of six months for the public and the OPO community to verify the data, for appeals to be filed (and potentially decided), and for CMS to complete the competitive bidding process for Tier 2 DSAs.*

Recommendation: *Regardless of whether CMS decides to extend certification of the current OPOs through December 31, 2026, as recommended above, we believe that the entire system would be best served if this data were required by regulation to be made available no later than six months prior to expiration of the OPO contracts. The early public availability of this data has the potential to minimize the potential disruption in organ procurement that may result from application of the new standards in several ways. For example, a transplant program in an area likely to be impacted by an OPO decertification or other transition may request CMS to assign it to a different OPO, a process that may take several months; an OPO likely to be de-certified can begin planning for the necessary transition; or transplant stakeholders in a Tier 3 DSA can begin efforts to organize a new OPO as a successor.*

B. Objective: Flexibility

Under the new outcome standards, anywhere between zero and over 50% of OPOs may be classified in Tier 3 DSAs (and therefore required to be de-certified) during any certification cycle. It is unclear—at least to us—whether there will be a sufficient number of high performing (Tier 1) OPOs willing to take over Tier 3 DSAs if a significant number of OPOs are classified into Tier 3 in any certification cycle. Moreover, it seems to us possible—if not likely—that, at some point, retention of an OPO (under a suitable plan of correction) may be the best practicable alternative for a Tier 3 DSA. For this reason, we strongly believe that the regulations should provide substantial flexibility to CMS to ensure unbroken access to organ procurement in Tier 3 DSAs (as noted in our March 2021 comments).

The need for such flexibility is not theoretical. Based on the 2025 CMS OPO Annual Public Aggregated Performance Report, 26 OPOs were classified in Tier 2 or Tier 3 (16 in Tier 2 and 10 in Tier 3), representing 47% of all OPOs. While 30 OPOs (54%) were classified as top-performing Tier 1 OPOs, only 10 OPOs consistently have consistently attained Tier 1 status over the past three years. If 2024 performance leaves these rankings relatively unchanged, it is possible, if not likely, that those Tier 1 OPOs in a position to expand will be more likely to bid for a Tier 2 DSA than to take on the challenge of improving the donation and transplant rates in a Tier 3 DSA, leaving CMS with no (or no acceptable) options for continued organ procurement in those DSAs.

The OPO Proposed Rule's provisions related to appeals are structured in a manner that may increase the likelihood that there will be no viable Tier 1 bidders to take over all of the Tier 3 DSAs. Specifically, under the OPO Proposed Rule, while OPOs serving Tier 3 DSAs have appeal rights, those in Tier 2 do not. Selection of an OPO for a Tier 3 DSA does not open until after the Tier 3 OPO's appeal rights are exhausted, and, by this time, the competitive process for the (likely more desirable) Tier 2 DSAs will already have occurred. It seems possible, if not likely that, by the time a Tier 3 DSA opens for competitive bidding, qualified Tier 1 OPOs interested in expanding will already have done so through the Tier 2 DSA competitive bidding process and may be unwilling or unable to further extend its resources to take on a Tier 3 DSA.

For these reasons, we urge CMS to consider modifying the regulations to authorize the retention of an OPO serving a Tier 3 DSA under specified circumstances, such as:

1. When no OPO serving a Tier 1 or Tier 2 DSA submits a bid to provide organ procurement in a Tier 3 DSA,
2. When a Tier 3 DSA OPO has substantially increased its donation and/or transplant rate during the four-year certification cycle,
3. When a Tier 3 DSA OPO's performance in the year following the assessment year improves significantly; or

4. When performance during the assessment year was aberrant due to a natural disaster or other unusual circumstance.

Such flexibility could be included in the regulations either through adoption of a mitigating circumstances process similar to that available to transplant programs that fail to meet outcomes requirements applicable to them, or by explicitly authorizing Tier 3 DSA OPOs to appeal decertification determinations based on improvements in performance, natural disasters, or other circumstances.

***Recommendation**: The OPO CfC should include a mitigating circumstances or other process authorizing waiver of outcomes requirements under specified circumstances, where waiver (accompanied by an appropriate plan of correction) is necessary to ensure continuity of organ procurement in Tier 3 DSAs.*

C. Objective: Stability

The stability of the organ procurement system is critical. In our view, the foundational objective of the new system is to ensure the continued procurement of organs throughout the country without interruption and with minimal disruption. We strongly urge CMS to focus on ensuring that OPO assessment and decertification processes are carefully constructed and implemented in a manner that facilitates seamless organ procurement as necessary changes are implemented.

We urge CMS to implement the new standards in a manner that reinforces the stability of the organ procurement system by considering the following actions:

i. Encouraging voluntary transitions when practicable:

We believe that voluntary transitions and changes in control are more likely to result in uninterrupted organ procurement and to ensure that the outgoing OPO retains sufficient staff to perform basic functions throughout the transition. We urge CMS to institute procedures under which a Tier 3 OPO may opt for a voluntary change in control (under conditions approved by CMS), rather than pursuing an appeal or having the DSA subject to competitive bidding. The regulations, as currently drafted, require at least six months' notice of a voluntary termination. We suggest that this requirement be waived in the case of an OPO that decides to terminate its certification voluntarily after it has been classified to a Tier 3 DSA for an assessment year.

ii. Utilizing solicitations of interest for Tier 3 DSAs:

Under the OPO Proposed Rule, competitive bidding for a Tier 3 DSA does not begin until after appeals have been exhausted. If, at that time, no other OPO is willing to take over the Tier 3 DSA, there is likely to be considerable uncertainty for potential donors and affected transplant providers. CMS may wish to consider issuing an early solicitation of interest for Tier 3 DSAs to guard against this result (see below).

iii. Facilitating expeditious transitions for Tier 3 DSAs:

Once a DSA is designated as Tier 3, we believe that key OPO staff are likely to seek employment elsewhere and performance is likely to deteriorate. For this reason, expeditious resolution of uncertainty is in the best interests of transplant patients and donors alike. Ideally, upon learning that its DSA is designated as Tier 3 based on preliminary data released by CMS six months or more prior to the expiration of a certification cycle (see discussion above), an OPO would have the following options:

(a) accept the selection of a successor OPO through the competitive process and begin to plan for the transition;
(b) request that CMS waive noncompliance with the outcome measures, with the understanding that waiver would be contingent on compliance with a comprehensive plan of correction;
(c) negotiate a voluntary change in control with another OPO or new entity, subject to CMS approval; or
(d) appeal the Tier 3 designation (presumably based on the argument that CMS erred in classifying the DSA as Tier 3).

If the Tier 3 DSA OPO were to request a voluntary change in control or request a waiver of outcomes requirements due to mitigating circumstances, CMS would have the option to issue a solicitation of interest to determine whether transplant patients and donors would be best served by selection of a successor OPO through the competitive process, through voluntary reorganization, or through a plan of correction. Providing OPOs these options would significantly reduce the likelihood of a protracted appeal potentially followed by an unsuccessful competitive process.

iv. Providing Tier 2 DSA OPOs an Opportunity to Appeal:

The OPO Proposed Rule does not provide Tier 2 DSA OPOs an opportunity to appeal if another OPO is chosen to take over their DSA in a competitive bidding process. We see no reason to deny the opportunity to appeal to Tier 2 DSA OPOs, while allowing an opportunity to appeal for worse-performing Tier 3 DSA OPOs. But more importantly, we believe that Tier 2 DSA OPOs should be given the opportunity to show that the best interests of donors and potential donors would be better served by retention of the Tier 2 DSA OPO than by a transition.

v. Minimizing volatility in Tier rankings:

We understand that, over the past several years, Tier Rankings have been volatile. Volatility increases uncertainty for patients and affected providers, and we urge CMS to take such steps as may be necessary to reduce volatility in Tier Rankings.

vi. Authorizing Delayed Assessment for all Successor OPOs:

When the OPO responsible for organ procurement in a DSA is changed—regardless of the reason—it is critical that the new OPO have sufficient time to become familiar with the social and demographic composition of the area, the transplant programs operated in the DSA, and the capabilities and communications practices of the area's donor hospitals. Under the OPO Proposed Rule, if an OPO takes over another OPO's DSA through competition or CMS assignment, the new OPO will be held accountable for its performance on outcome measures in the new area in the final assessment period of the following agreement cycle. Under the Proposed Rule, the same leniency does not apply if a new OPO takes over another OPO's DSA as a result of a change of control or ownership or service area. We believe that any new OPO—whether taking over as the result of a competitive process, CMS assignment, or voluntary change in control or DSA—should be given ample opportunity to meet OPO certification standards and should not be de-certified as the result of its performance during its first certification cycle. Otherwise, a DSA may be subjected to repetitive transitions within a short period, which would be inherently destabilizing for the entire system.

vii. Authorizing extensions of the transition periods, when needed:

Under the OPO Proposed Rule, there is a 90-day period authorized for the transition from an outgoing OPO to its successor. We support those provisions of the regulation that allow an OPO's certification to be extended if necessary to complete a transition and encourage CMS to utilize this authority liberally to ensure that transitions are completed in an orderly fashion that minimizes the impact on organ procurement in the DSA.

D. Objective: Transparency

Transparency is key to ensuring trust in the OPO certification system. In our view, transparency should be reflected in all stages of the process, from the release of assessment year data and Tier Rankings, through the appeals process.

We strongly urge CMS to continue to release all OPO performance data relevant to the certification process to the public, and to provide an opportunity to affected stakeholders to review and confirm CMS' calculations before Tier Rankings are finalized. In light of the importance of OPO Tier Rankings, sufficient information should be made public to enable replication of CMS calculations and identification of any potential data errors or discrepancies. We also believe that the system would be best served by full transparency in other aspects of the process as well. The OPO Proposed Rule does not appear to include any provision for CMS to provide a public notice when it finds that there is insufficient time to conduct a competition and selects a successor OPO without a competitive process (42 C.F.R. §486.308(a)(4)) or when it opens the competitive bidding process for a DSA. Rather, it appears that the OPO Proposed Rule only requires that CMS provide public notice "in the service area" of the date that a new OPO will be designated for the DSA (42 C.F.R. § 486.311(b)(2)). Likewise, in cases of urgent need, the OPO Proposed Rule requires CMS to provide prompt public notice "in the service area" of the date of de-certification and the date that a new OPO will be designated for the DSA. We encourage CMS to consider strengthening the public notice provisions in the OPO Proposed Rule to ensure that the transplant community is fully informed of developments at each stage of the process.

We are also concerned that no provision of the Proposed Rule would require CMS to issue a notice explaining its selections when a DSA is open for competition or when CMS selects a successor OPO without a competition. The criteria for selection in the case of an OPO selected by CMS without a competition (§ 486.308(a)(4)) and the criteria for selection as the result of a competition (§ 486.316(d)) are extremely general, and, at least in the case of the selection of the Nevada OPO to replace the Miami OPO, the reasons for CMS' final decision are not clear. It is our understanding that a major objective of the new standards is to enable OPOs to improve their performance, but without a public explanation of CMS' selections, OPOs are much less likely to understand which aspects of performance CMS considers key.

E. Objective: Regulatory Consistency (Definitions)

We applaud CMS' focus on clarifying the definitions of key terms in the OPO CfC. We believe that uncertainty among OPOs regarding CMS expectations is inherently destabilizing for the system as a whole. However, the proposed definitions are vague and, in some cases, inconsistent with definitions used by the OPTN or HRSA. We urge CMS to reconsider those provisions of the OPO Proposed Rule that would deviate from those used by the OPTN or by HRSA, since inconsistent regulatory definitions create confusion for the transplant community. The community would be best served if all three groups agreed on the definition of key terms.

i. Definition of Unsound Medical Practices

We urge CMS to tighten its definition of "Unsound Medical Practices." Unsound medical practices are referenced in § 486.312(b) as an example of circumstances in which CMS may decertify an OPO based on ''urgent need;'' however, there is no definition of ''unsound medical practices'' in the regulations. Under the OPO Proposed Rule, "unsound medical practices" would be defined as 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. ASTS respectfully suggests that CMS consider defining "unsound medical practices" to mean failures that create an imminent threat to patient health and safety, including but not limited to failures impacting donor and potential donor evaluation and management."[iii] In our view, while failures in governance, allocation and transport practices and procedures, if sufficiently frequent and egregious, may warrant decertification, these types of failures should not be characterized as "unsound medical practices" for regulatory purposes.

ii. Definition of "Donor"

We also believe that it would be extremely helpful for CMS and the Health Resources and Services Administration (HRSA) to both use the same definitions of key terms, since discrepancies in terminology have the potential to result in significant confusion in the community and in public discourse. For example, the OPO Proposed Rule and the OPTN definitions of "donor" differ significantly. While the OPTN defines a deceased donor as an individual from whom at least one vascularized organ is recovered for the purpose of transplantation after being declared dead, the CMS Proposed Rule includes those from whom only the pancreas is removed if the pancreata is used for research. We urge CMS to confer with HRSA and the OPTN to agree on a common definition of key terms. At the same time, we support CMS' efforts to close the "islet loophole" consistent with our 2019 comments on the new certification standards when they were initially proposed.

iii. "Adverse Event"

Along similar lines, under the OPO Proposed Rule, the examples of what constitutes an "adverse event"—transmission of disease from a donor to a beneficiary, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended beneficiary—would be removed from the definition of "adverse event" and a revised list of examples of "adverse events" would be included in the QAPI requirements at § 486.348(c). We note that the OPTN has historically adopted the CMS definition of the term "adverse event" and this definition serves as the basis for OPTN adverse event reporting requirements for OPOs. It is unclear to us whether, and to what extent, the changes proposed by CMS with respect definition of "adverse events" are intended to—or will—impact OPTN reporting requirements, but we urge CMS to address this issue proactively with HRSA and the OPTN before finalizing the proposed definitional changes.

iv. "Medically Complex Organs and Donors"

We also urge CMS to coordinate its definition of "Medically Complex Organs and Donors" with the OPTN's work, which is expected to define organs eligible for expedited placement (Allocation Out of Sequence Work Group). Disparate regulatory definitions of "medically complex organs and donors" (for CMS certification purposes) and organs eligible for expedited placement (for OPTN allocation purposes) is likely to create unnecessary confusion ;-

for both OPOs and transplant programs. The OPTN is currently working on the definitions, processes, and criteria to be used to facilitate expedited placement of organs, and we urge CMS to coordinate with HRSA to use common nomenclature.

We hope that these comments are helpful. If you have any comments or questions, please do not hesitate to contact Emily Besser, ASTS Director, Advocacy & Professional Practices, at Emily.Besser@ASTS.org.

Respectfully,

James. F. Markmann, MD, PhD

[i] Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2023 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2025. Accessed March 1, 2026. https://srtr.transplant.hrsa.gov/annualdatareports

[ii]

Q11: What percentage of the following are recovering organs in your OPO? Please estimate a percentage or put zero. Concerns were expressed about the validity of the data for questions 6, 10, 11, and 12. These questions were not clear about who the question pertained to with regard to OPO recovery staff, fellows, or outside transplant center surgeons. It could confound the data.		
Transplant Center Surgeon / Faculty level surgeons (i.e., have completed fellowship or training programs)	52.96% (Average)	
OPO hired MD/DO/foreign equivalent surgeons / Faculty level surgeons (i.e., have completed fellowship or training programs)	28.96% (Average)	
Industry hired MD/DO/foreign equivalent-level surgeon / Faculty level surgeons (i.e., have completed fellowship or training programs)	9.55% (Average)	
Transplant Fellows	18.03% (Average)	
Physician Assistants or Certified Nurse Practitioners	2.95% (Average)	
Surgical Technicians	8.04% (Average)	
Unsure	0	• Majority of all recoveries are completed by Transplant Center surgeons -Difficult to estimate and will vary by organ type

[iii] The term “patients”, which is included in the proposed definition, is generally understood to mean transplant candidates and recipients, whose evaluation and management falls outside the scope of OPO responsibility and authority.

ASTS
American Society of Transplant Surgeons

Attachment A

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ASTS.org

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February 20, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W. Room 314G
Washington, DC 20201

Re: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization; file code CMS-3380-P; RIN: 0938-AU02.

Dear Administrator Verma:

ASTS is pleased to have the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposal to modify the outcomes requirements for Organ Procurement Organizations (OPOs), as set forth in the December 23, 2019 *Federal Register* (OPO Proposed Rule). ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS strongly supports CMS' efforts to increase the availability of kidney transplantation and believes that modification of the Conditions for Coverage (CfCs) for OPOs can have a significant impact on increasing the number of kidneys available for transplantation. We support the Administration's goal of doubling the number of clinically appropriate kidney transplants by 2030 and believe that increasing the availability of kidneys for transplantation is critical to achieve this important objective. We applaud CMS for its focus on this aspect of the current transplantation ecosystem and hope that these comments will assist the agency in effectively improving OPO performance while maintaining organizational stability in organ recovery efforts.

We think that a system-wide, disease-based approach to transplant system metrics is the best way to measure transplantation benefit. Unfortunately, the US ESRD healthcare ecosystem is regulated in silos: dialysis facilities, nephrologists, Transplant Centers (TCs), and OPOs each are regulated separately. It is likely that a change in one system will produce unintended consequences in another. We strongly agree that increasing the rate of kidney transplantation should benefit those with ESRD and that performance metrics change is essential to spur and assess process improvements. We also appreciate that CMS has time constraints for changes imposed by Executive Order 13879. However, system change to double the number of kidney transplants by

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2030 will require performance metrics that recognize the interdependence of the various elements of ESRD/transplant care, including access to transplant care, the size and composition of the kidney waitlist, kidney availability/use and the maintenance of desired outcomes. Changes in composite transplant metrics will affect community providers and hospitals, dialysis units, TCs (plus others). Changing kidney availability and quality by modifying OPO metrics without anticipating the impact upon the other elements of the ESRD healthcare system can lead to unintended outcomes and underachievement of transplant goals. In short, we are concerned that unintended system consequences may follow from well-intended changes that address only one component of the complex transplant ecosystem.

For this reason, the ASTS/AST has established a Task Force on Transplant System Metrics to develop a comprehensive view of transplant metrics that incorporates the needs of people with ESRD, the provider, and regulatory communities that focus on the benefits of transplantation over other treatment options. While we agree that OPO metrics revision is necessary, the desired system change is unlikely without a more comprehensive approach: A broader system metrics change is necessary if transplant care is to be optimized.

We recognize, however, that system-wide metrics are difficult to design and implement and that it would not be prudent to delay modification of the OPO CfCs pending the development of a more comprehensive system. In that spirit and with the understanding that addressing this component of the system is necessary, but not sufficient, to maximize the benefit of transplantation, we are pleased to have the opportunity to share the following comments on the proposed OPO CfCs.

I. The Proposed OPO Outcomes Metrics

We agree that it is time to replace the current OPO metrics with metrics based on a potential donor "denominator" that is calculated based on a verifiable, objective methodology. Without this, it is impossible to evaluate efforts to improve OPO performance or to compare performance over time or across OPOs. Because the current metrics are subjective and self-reported, we agree that change is needed.

CMS is proposing to revise the outcome measures for re-certification at §486.318 to replace the existing outcome measures with two new outcome measures that would be used to assess an OPO's performance: "donation rate" and "organ transplantation rate" effective for CY 2022. Each of these is discussed separately below.

A. "Donation Rate"

Under the OPO Proposed Rule, the "donation rate" would be measured as the number of actual deceased donors as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation. This new metric differs in a number of key respects from the donation rate metric that it would replace. First, the numerator of the proposed metric is defined as the number of actual deceased donors in the DSA who had at least one organ transplanted based on data reported to the OPTN: CMS is proposing to change the current donation metric to require that, in order for the donor to "count," at least one donor organ must be transplanted, not just recovered. Second, the denominator of this metric (and for the organ transplantation rate metric described below) is calculated based on data obtained from the Center for Disease Controls' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of Death (MCOD).

Generally, ASTS supports these changes in both the numerator and denominator of the "donation rate" metric. We believe that counting only those donors who had at least one organ transplanted in the numerator of the measure (rather than counting all organs acquired) will dissuade OPOs for pursuing

potential donors whose organs are unlikely to be suitable for transplantation. This may reduce organ wastage and the unnecessary organ procurement expenses that drive up the standard acquisition costs (SACs) for organs.

We also agree with CMS's efforts to redefine the denominator of this measure to reflect a more objective and verifiable definition of potential donors. In conjunction with a prior CMS Request for Information (RFI) on the issue of OPO metrics, ASTS, in conjunction with the American Society of Transplantation (AST), submitted comments on the use of the MCOD to calculate potential donors. In that response, we noted that while we support the use of an objective and verifiable methodology to determine the universe of potential donors, the MCOD files have a number of shortcomings that should be addressed before they are used for assessing OPO performance. For example, it is our understanding that the MCOD uses state data on inpatient hospital deaths and that each state has different rules for the collection of this data. If state databases are not collecting data using uniform reporting rules, they may be unsuitable for use to compare OPO performance in different states. We recommended that CMS establish a working group that includes OPOs, the transplant community, CDC and others to refine the MCOD data files before they are used for the assessment of OPO performance and to consider whether there are other inpatient hospital death data sources available that might be more suitable for this purpose.

> ***Recommendation****:* W*e support the use of objective and verifiable inpatient mortality data files to determine potential donors. We urge CMS to form a Potential Donor Working Group that includes the CDC and representatives of the transplant and OPO communities to identify and address any shortcomings arising from the use of the MCOD data files to identify potential donors (including, but not limited to, variations in state mortality reporting practices) and to determine whether there is an alternative data source available.*

We also note that the OPO Proposed Rule would exclude from the definition of "potential donor" those with a cause of death that is an "absolute contraindication to organ donation." The OPO Proposed Rule requests comment on the ICD-10 diagnosis codes that should be used to exclude deaths from being counted as potential donor deaths. We agree that this list requires refinement: For example, bacterial sepsis is listed as an exclusion from donation, but at least some transplant surgeons may utilize these organs under certain circumstances. The list mentions skin cancers twice – once it specifies melanoma, while the second time it does not. Overall, the list is considerably narrower than that used in the transplant community to rule out potential donors, and using so narrow a list of exclusions has the potential to significantly overstate the number of potential donors, thereby distorting OPO performance measurement.

> ***Recommendation****: If CMS chooses to implement a methodology that excludes potential donors based on ICD-10 Diagnosis Code, we recommend that CMS charge the Potential Donor Working Group with the task of formulating the list, based on a consensus based approach that includes substantial transplant surgeon representation.*

Ideally, however, we recommend that CMS define "potential donors" based on the CALC method proposed by Goldberg et al, as described in the Regulatory Impact Statement discussion of "Alternatives Considered" by CMS. The primary difference between the CALC methodology and our proposed methodology is that the CALC method uses the ICD–10 codes to identify deaths that are consistent with donation (that is, inclusion criteria) whereas the OPO Proposed Rule would exclude ICD–10 codes that are an absolute contraindication to organ donation (that is, exclusion criteria). As CMS notes, while the two methods generally flag the same OPOs, when the two methods are applied to the 2017 data, the CALC results in a donor potential of 101,479 inpatient deaths, whereas CMS' proposed methodology results in 272,105 inpatient deaths—nearly three times as many.

We believe that modifying the definition of eligible donor as set forth in the Proposed Rule is likely to result in significant over-identification of potential donors: At least initially, the data set is likely to be relatively messy, and it is our understanding that errors in reporting the cause of death are not uncommon. We also understand that OPOs already experience relatively high call volume from donor hospitals notifying the OPOs of inpatient deaths of patients who are not suitable donors. Under these circumstances, we believe that it would be prudent to define eligible donors as narrowly as practicable, at least initially. This approach has the potential to focus donor hospital attention on ensuring accurate cause-of-death reporting for a manageable set of ICD-10 codes and to focus OPO attention on potential donors with diagnoses that meet specified criteria.

> ***Recommendation:*** *Because we believe that many of the patient deaths identified using CMS' proposed criteria are unlikely to be suitable donors, we believe that the CALC method is likely to result in a more accurate measurement of OPO performance and that it would be more appropriate to utilize the CALC method than that described in the OPO Proposed Rule to define the universe of potential donors.*

ASTS would also like to address the issue of risk adjustment in the definition of potential donors. ASTS is concerned about establishing risk-adjustments based on clinical characteristics, particularly as it pertains to racial disparities among potential organ donors. There are 58 OPOs in this country, with significant variation in population demographics between many of the OPOs. OPOs serve populations with varying racial/ethnic diversity. In the past, it has been suggested that minority populations have lower rates of donation compared to Caucasians, thus accounting for lower observed donation rates in areas that have more racially diverse populations. However, much of this data is not current, is incomplete, and is not representative of the current understanding of the interplay between health outcomes, healthcare delivery, and unconscious bias.

ASTS supports efforts to provide more research data relating to organ donation rates, OPO practice, and effectiveness of OPO practice. We believe this is an area that is underserved in both resources and research data; we have many questions as a community of providers that can be answered with OPO-specific process data that is already gathered by OPOs on a daily basis. More and better research will lead to structured, balanced, and culturally humble approach to donation amongst minority populations.

We believe that allowing for risk adjustments for race, demographic, and public health factors is a misguided proposition, doubly bad for the communities that such adjustments would attempt to 'correct' for and for the transplant system at large. In effect, adjustments based on historically poor results serve only to elevate stereotypes of poor minority donation to the level of doctrine while systematically excusing OPOs from fully engaging with these populations.

Not including such risk-adjustment models in performance goals will help stimulate the donation community to more optimally identify all potential donors and maximize donation. This belief is supported by arguments made to Congress in 2014 when there were proposed risk adjustments for race in Medicare's Value-Based Purchasing Programs, where it was stated that "…adjusting measures for social factors risks masking disparities in the quality of care provided…directly adjusting measures could excuse the delivery of worse care…adjusting the measures may have a negative impact on transparency." Consistent, thorough OPO-level data reporting at each step in the OPO process would allow researchers and TCs to be better partners to OPOs in identifying interventions that would support OPOs in their life-saving work. Resisting the inclusion of a race-based adjustment stimulates the transplant community to better collaborate with the OPO community, increase donation, and save more lives.

Recommendation: *ASTS does not endorse risk-adjustment models involving race, demographic, or public health factors.*

B. "Organ Transplantation Rate"

Under the OPO Proposed Rule, the "organ transplantation rate" would be measured as the number of organs procured within the DSA and transplanted as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation. The OPO Proposed Rule also provides clarification as to how the organs are counted for purposes of determining the organ transplantation rate and excludes organs procured for research but not transplanted, except for pancreata that are procured for islet cell transplantation or research (transplanted or not transplanted).

We have serious reservations about using organ transplantation rate as a measure of OPO performance at this time, and we urge CMS to delay finalizing this measure pending further consideration. As noted in the OPO Proposed Rule, some OPOs have objected to measuring OPO performance based on transplant rate because OPOs do not control TC acceptance practices, and, in general, we agree. Fundamentally, we believe that while transplant rate is an appropriate systems metric, it is not appropriate to hold OPOs solely responsible for the transplant rate associated with the organs it procures. In fact, area TC(s), nephrologists, dialysis facilities, and others all play a role in determining the transplant rate for organs procured by an OPO. OPOs do not have control over the TC(s) to whom an organ is initially offered, or whether an organ is offered to a TC with liberal or conservative acceptance practices: OPOs are required to offer organs in accordance with OPTN allocation policy based on the waitlist maintained by the OPTN. And while OPOs may have a role in placing organs that are not otherwise placed, by the time an organ has been considered and rejected in accordance with OPTN allocation policy, it is often difficult or impossible to place. While it is true that, as stated in the preamble to the OPO Proposed Rule, transplant surgeon involvement in OPO operations and OPO involvement with TCs have the potential to impact TC organ acceptance practices, OPOs ultimately have no control over whether or not a TC accepts an organ.

Unfortunately, TCs continue to have a strong regulatory disincentive to transplant imperfect organs. Imperfect organs may result in poorer outcomes, and, <u>while CMS has eliminated one year outcomes requirements as a condition of Medicare recertification for TCs, substantial change in TC organ acceptance practices is unlikely unless and until the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) similarly eliminate or substantially modify the use of one year outcomes measures in assessing TC performance</u>.

More specifically, the OPTN currently utilizes one year outcomes measures—measures that are significantly stricter than those recently rescinded by CMS—in determining TCs' continued eligibility for OPTN membership, and the SRTR utilizes one year outcomes measures in its "five star" TC ratings—ratings that are routinely used by private payers in determining which TCs may participate in their networks. Thus, unless and until the disincentive for TCs to accept imperfect organs is removed, TCs will continue to be reluctant to transplant imperfect organs. Therefore, OPTN and SRTR evaluation methodologies for TC evaluation create a substantial impediment to CMS efforts to increase the availability of transplantation and, unless and until these OPTN and SRTR methodologies are modified, any effort by CMS to hold OPOs responsible for Transplant Rates will inevitably place OPOs in conflict with TCs. The non-utilization of organs retrieved but not transplanted is a very multifactorial metric which includes both OPO retrieval of poor quality organs and TC "cherry picking." The ultimate way to address this is to link OPO and TC performance metrics, but this cannot be done until regulatory disincentives to transplant imperfect organs have been eliminated.

Recommendation: *ASTS strongly urges CMS to work with HRSA to eliminate the current disincentives for TCs to transplant imperfect organs—disincentives that are created by current OPTN membership evaluation and SRTR star ratings methodologies—prior to instituting any metrics that measure OPO performance based on transplant rate*. *With respect to kidney transplantation, we also urge CMS and HRSA to work together on metrics that compare the outcomes of transplantation to the outcomes of dialysis as a more appropriate metric of transplant benefit for the individual with ESRD. The desired measure of system success is not defined by ranking TCs; rather, it should be defined by the amount of benefit the people with disease gain from transplantation relative to alternative treatments for their organ failure (e.g., for ESRD, dialysis).*

While we have considerable reservations about making an OPO responsible for the transplant rate as described in the OPO Proposed Rule, we recognize that it may be imprudent to place substantial pressure on OPOs to increase organ donation rates without including some mechanism to ensure that the organs retrieved are transplantable. Otherwise, it is possible that at least some OPOs may retrieve organs that are clearly unsuitable for transplantation solely to meet the organ donation rate threshold (whether that threshold is relative and variable or static (see discussion below)). For this reason, if CMS decides to include a transplant rate metric in the OPO Final Rule, we urge CMS to modify the performance standard, such that the transplant rate metric focuses on improvement in an OPO's transplant rate, rather than comparing an OPO's transplant rate to that of other higher-performing OPOs. See discussion below.

C. Other Potential Measures

While we have serious reservations about the transplant rate metric, especially in light of the high transplant rate threshold described in the OPO Proposed Rule, we do not support a single metric system that would rely solely on the organ donor rate to assess OPO performance. We strongly agree that the current organ yield metric historically has dissuaded OPOs from pursuing single organ donors and we believe that it is appropriate to include a revised organ yield metric in the OPO Final Rule. Unlike the current yield measure however, the organ yield should not be assessed based on the number of organs recovered from each donor but the number of organs recovered from organ donors as a whole. Along these lines, the OPO Proposed Rule includes a clarification of how organs are to be counted for purposes of determining the organ yield. For example, table 1 in the OPO Proposed Rule indicates that pancreata procured for islet cell transplantation or research are to be counted as organs and that two organs are to be counted for recovery of both left and right organs; double/en block organs; and two organ segments.

Recommendation: *We recommend that CMS include in the Final Rule a revised organ yield outcomes requirement whose numerator is calculated based on the number of organs procured from actual deceased donors within the DSA. For the purposes of this measure, the term "actual deceased donors" would be defined to include only donors from whom at least one organ is transplanted*.

Second, we recommend that CMS consider including an improvement focused metric in the OPO Final Rule, so that OPOs that do not meet the ambitious standards for established OPO performance with respect to donation and/or transplant rates but that nonetheless make substantial progress do not face decertification. The uncertainty and potential disruption resulting from the decertification of an OPO has the potential to significantly and adversely impact our patients and potential patients in the affected DSA. For this reason, we urge CMS to consider the including in the Final Rule a mechanism to extend the certification of an OPO that does not meet donation rate, transplant rate, or yield metrics if the OPO is making substantial progress in making more transplantable organs available. Also see discussion below regarding mitigating factors.

Recommendation: *We recommend that CMS consider including in the OPO Final Rule a provision that facilitates continued certification of an OPO that is making substantial improvement in meeting donation, transplant rate, or yield outcomes requirements, and to work with the TC and the OPO communities in establishing the parameters for what constitutes substantial improvement.*

II. Threshold Requirements

The OPO Proposed Rule would establish a threshold donation rate and organ transplantation rate based on the lowest rate among the top 25 percent of donation rates and organ transplantation rates during the 12-month period prior to the time period that is being evaluated. For example, since the OPO Proposed Rule would go into effect for the 2022-2026 cycle and would consider only the fourth year of performance in determining whether an OPO would be eligible for recertification (calendar year ending December 2026), then the assessment would use data from January–December 2025 and would be based on the top 25 percent of donation rates and organ transplantation rates during the 12-month period from January to December 2024. By establishing a definition of success that is compared with the top performing OPOs, CMS hopes to increase the number of organs, particularly kidneys, to achieve the goal of doubling kidney transplantations by 2030.

We support the goal of doubling the number of transplants by 2030 and understand that establishing the definition of success based on top performers appears to be supported by the wide variation in OPO performance. At the same time, we believe that it is critical that the metrics used to evaluate performance be realistic and enforceable. Based on the data published in the OPO Proposed Rule, if the new metrics were applied based on 2017 data, assuming that the high performers remain at steady state, eight OPOs would be subject to de-certification in 2026 for failure to increase their donation and/or transplantation rates by more than 50 percent to meet the threshold rates, eighteen OPOs would be subject to de-certification for failure to increase their donation and/or transplantation rates by more than 25 percent to meet the threshold rates, and thirty-three OPOs may be subject to decertification for failure to increase their donation and/or transplantation rates by more than 10 percent to meet the threshold rates.

Under these circumstances, we are concerned that the adoption of the metrics set forth in the OPO Proposed Rule has the potential to result in the "flagging" of so many OPOs that it may prove impracticable for CMS to take effective and timely enforcement action without substantially disrupting organ procurement in the United States. While we recognize that some provisions of the OPO Proposed Rule—for example, provisions requiring annual assessment and continuous quality improvement—are intended to ensure that OPOs reach the goals established through the metrics, we believe that, if the goals are considered unreachable, this may dissuade underperforming OPOs from putting forth their best efforts.

For this reason, we urge CMS to consider modifying the organ donation and transplant rate thresholds described in the OPO Proposed Rule. In the "Alternatives Considered" section of the Regulatory Impact Statement, CMS solicits comments on whether it would be preferable to use an absolute threshold as a viable alternative to use as a relative performance metric. Specifically, the OPO Proposed Rule models using the geometric mean or the median donation rate and/or transplant rate, rather than using a variable performance rate that would change every year based on the performance of the top 25%.

We believe that using an absolute threshold in assessing OPO donation rate performance has a number of significant advantages over the use of a relative performance metric. We believe that most OPOs would benefit from a clear objective standard that would remain unchanged during the certification cycle and that having a clear donation rate goal would provide some assurance to key OPO personnel that they are not chasing a "moving target." Moreover, a variable performance metric is impracticable over the long term, since, at some point, OPOs may become "victims of their own success" by continuing to move the threshold

ever higher. While we acknowledge that establishing an absolute threshold has the potential to incentivize complacency once the threshold is reached, we note that establishing the threshold at either the geographic mean or at the median would leave substantial room for improvement for most OPOs. And establishing a fixed threshold of performance appears to be particularly well suited to minimize the current variation in OPO performance levels. Once OPOs are all functioning at an acceptable level, the threshold can be further increased, or a relative performance metric can be instituted at that time to further incentivize exemplary performance.

> ***Recommendation:*** *We urge CMS to establish the organ donation rate threshold for OPOs based on a fixed median donation rate rather than on the basis of a variable performance rate*.

Establishing an appropriate transplant rate threshold measure is a considerably more complex and problematic task. For the reasons set forth above, we have considerable reservations about subjecting OPOs to a transplant rate performance metric: The transplant rate for organs procured by an OPO is an appropriate systems measure, an OPO is not solely—or even principally—responsible for transplantation rates. Ultimately, the transplant rate in any geographic area is the result of a multitude of factors, including, but not limited to, referral patterns by area nephrologists and dialysis facilities, the number of TCs and their organ acceptance practices, and the quality of the organs procured by the OPO. These factors vary significantly from one region to another. We do not believe that it is appropriate, for example, to require an OPO with a relatively small designated service area (DSA) and a single TC that may have conservative organ acceptance practices to have a minimum transplant rate based on the performance of OPOs in a DSA with numerous TCs that may have more liberal organ acceptance practices.

> ***Recommendation:*** *If the OPO Final Rule includes a Transplant Rate measure, we urge CMS to adopt a performance measure that focuses on the improvement in an OPO's transplant rate rather than on a comparison of the OPO's transplant rate with that of OPOs with different DSAs.*

III. "Flagging" and Its Consequences

In our view, while the OPO Proposed Rule includes a comprehensive analysis of the need for new OPO metrics and compelling rationale for the metrics that have been proposed, it does not set forth with sufficient specificity what will happen to the OPO—or to the patients or providers in the OPO's DSA—if an OPO is flagged for failure to meet the organ donation rate or the transplant rate thresholds. Specifically, it is unclear based on the proposed regulatory language and the statements in the preamble whether an OPO that fails to meet the organ donation and/or transplant rate thresholds will be decertified or whether it may be decertified. In light of the serious disruption in organ retrieval that necessarily will result from decertification and the uncertainty that OPO decertification would necessarily trigger for potential transplant recipients and providers in the area, we believe that it is critical for CMS to clearly delineate the consequences of an OPO's failure to meet one or both of the new metrics.

In so doing, we urge CMS to include in the final regulations intermediate sanctions that could be imposed short of decertification. For example, prior to the recent elimination of TC Medicare recertification outcomes requirements, TCs that failed to meet outcomes requirements could apply for a mitigating circumstances exception.

> ***Recommendation****: We urge CMS to institute a mitigating circumstances process for OPOs that fail to meet the new OPO outcomes metrics, to ensure that an OPO's certification status is not terminated in the event that its failure to meet these requirements is attributable to factors beyond its control.*

We note, too, that while chronic and substantial underperformance of an OPO can and should result in decertification, there may be closer cases that require CMS to carefully balance the increased organ availability that could result from re-bidding against the substantial disruption that would inevitably accompany decertification of the area's OPO. In such cases, CMS may wish to have the flexibility to impose intermediate sanctions and other requirements, rather than going through full decertification procedures.

> ***Recommendation:*** *We urge CMS to include in the OPO Final Rule authorization for the imposition of intermediate sanctions on an OPO that fails to meet outcomes requirements if the OPO is in substantial compliance with process requirements and if the OPO's compliance with outcomes requirements has improved over time. Such intermediate sanctions may include a requirement that the OPO enter into a Systems Improvement Agreement with CMS, which may, for example, require an OPO to replace its executive management team; require it to enter into a management contract with a high performing OPO; require it to institute new information systems or to commit other resources or mandate the performance of other improvement activities not specifically required in the OPO CfCs.*

Finally, we cannot overstate the potential disruption that decertification of an OPO could cause for TCs and patients in an OPO's DSA. While such disruption may be necessary in the case of an OPO that has a long history of chronic underperformance, it is critical that the transition be seamless and transparent.

> ***Recommendation:*** *We urge CMS to include in the OPO Final Rule a new OPO CfC that requires any OPO that fails to meet the CfCs or whose certification is terminated for any reason to cooperate fully with CMS in the transfer of its responsibilities and to make all information regarding its certification status public through written notice(s) to TCs donor hospitals, potential recipients and other affected patients and providers.*

IV. Other Issues

The OPO Proposed Rule also raises a number of other issues, discussed below.

First, under the OPO Proposed Rule, an OPO's performance with respect to the new outcome requirements would be evaluated based solely on its performance during the last year of its four year agreement with CMS. We believe that it is not prudent to shorten OPO evaluation period to one year, since the one year used for evaluation purposes may be turn out to be an outlier that is not reflective of the OPO's overall performance. In addition, we believe that shortening the evaluation period in this manner has the potential to impact an OPO's allocation of resources and limit its focus to the evaluation year.

> ***Recommendation****: We recommend that CMS consider an OPO's performance during the entire period covered by its contract with CMS in determining whether or not the OPO meets outcomes requirements, rather than limiting the assessment to the last year of a four year certification period.*

Second, we urge CMS to consider modifying those provisions of the current regulations that mandate a four year certification period for OPOs. We believe that there may be circumstances under which CMS wishes to extend the certification of an OPO for a period of less than four years. For example, an OPO that fails to meet the new outcomes requirements but makes substantial improvement in its donation or transplant rate (or any other additional outcomes measures included in the OPO Final Rule) may require evaluation to determine whether sufficient progress is being made to support continued certification. Likewise, in the event that CMS adopts a "mitigating circumstances" process comparable to that used when a TC failed to

meet recently repealed Medicare certification requirements, CMS may wish to extend certification of an OPO pending completion of the process and implementation of action plan.

Third, we urge CMS to maximize its own flexibility in assigning parts of a decertified OPO's DSA to different OPOs. The size and populations of the current 58 DSAs vary significantly, with some DSAs covering a large geographic area. In the event that an OPO fails to meet the new standards, CMS should retain the flexibility to break up the decertified DSA and award different parts of the DSA to different high performing OPOs.

> ***Recommendation***: *We urge CMS to remove the requirement that an OPO that submits an application to take over the responsibilities of a decertified OPO agree to take responsibility for the entire DSA served by the decertified OPO.*

We look forward to working with you to achieve the goal of doubling the number of transplants by 2030, while simultaneously minimizing the disruption for our patients and for providers.

Sincerely yours,

Lloyd E. Ratner, MD, MPH, FACS
President
American Society of Transplant Surgeons

ASTS
American Society of Transplant Surgeons

Attachment B

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March 1, 2021

The Honorable Liz Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date; Docket No.: CMS-3380-F2

Dear Administrator Richter:

ASTS is pleased that the Centers for Medicare and Medicaid Services (CMS) has chosen to reopen the comment period on the revised Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) finalized in a Final Rule published in November, 2020 (the "OPO CfC Final Rule" or the "Final Rule"). ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS appreciates CMS' recent focus on increasing access to transplantation, and we strongly support revision of the OPO CfCs to incentivize increased retrieval of organs suitable for transplantation.[1] With this overall objective in mind, when revisions to the OPO CfCs were initially proposed in November 2019, ASTS filed extensive comments suggesting modifications designed to maintain stability in organ procurement while incentivizing OPOs to increase retrieval of organs suitable for transplantation. Unfortunately, none of the changes we proposed were adopted in the OPO CfC Final Rule. We urge CMS to reconsider the full range of our policy and

[1] Kidney transplantation restores kidney function to a far greater extent than dialysis and is associated with improvements in health-related quality of life metrics and reduced risk of mortality compared to dialysis. The cost saving to the health care system that would result from increased access to transplantation is significant: Medicare spending for hemodialysis is $91,000; $76,000 for peritoneal dialysis, and $38,000 for transplantation. Furthermore, current overall adjusted mortality per 1000 patient-years rates is 166 for hemodialysis patients and 154 for peritoneal dialysis patients, compared to only 29 for transplant recipients. Since the shortage of organs suitable for transplantation is the single most significant facto limiting access to transplantation, we support CMS' efforts to incentivize improvements in OPO performance as a critical step necessary to increase organ availability. Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. Am J Transplant. 2011; 11: 2093-2109. Axelrod DA, Schnitzler MA, Xiao H, et al. An economic assessment of contemporary kidney transplant practice. Am J Transplant 2018;18: 1168–76.

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technical comments (see ASTS Comments on OPO Proposed Rule, February 20, 2020) as part of the current review of the Final Rule.

In order to facilitate the current re-evaluation, we highlight below those aspects of the OPO CfC Final Rule that we believe warrant special scrutiny.

I. An OPO's "Transplant Rate" should not be used to evaluate its performance so long as Transplant Centers (TCs) face substantial regulatory and financial incentive to maintain near perfect outcomes. However, if an OPO's Transplant Rate measure continues to be included in the Final Rule, it should focus on an OPO's Transplant Rate improvements and not compliance with a comparative threshold.

As indicated in our initial comments, we believe that it is highly problematic to use an OPO's Transplant Rate to measure OPO performance unless and until regulatory disincentives that discourage TCs from accepting organs and transplanting recipients who are viewed as "high risk" are eliminated. In particular, while CMS has recognized that patient and graft survival outcome metrics create disincentives for TCs to increase transplantation and has eliminated the use of such outcomes requirements under the Medicare conditions of participation, TCs continue to be strongly motivated to attain (or retain) near perfect patient and graft survival as the result of outcomes-based performance measures used by HRSA contractors (the Organ Procurement Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR)). See ASTS correspondence dated February 4, 2021 to Lee A. Fleisher, MD, Chief Medical Officer and Director of the Center for Clinical Standards & Quality (CCSQ).

In addition, such performance metrics should be risk adjusted to account for differences in the population of potential donors in each Donor Service Area. To fail to do so as proposed in the current CMS OPO metrics, will mislabel some OPOs as performing well and performing poorly without accounting for the differences in the populations that are dying as potential donors in the different DSA.

For example, performance on outcomes measures are reported publicly by the SRTR in the form of "star ratings" on each Transplant Center's Program Specific Report (PSR). Just to maintain a "three star" outcomes rating, 96% of a TC's kidney transplant recipients must have a functioning transplant at one year. The five-star rating system for TC outcomes is so volatile that almost half of kidney programs have a change in ratings within six months and more than half shift by two stars within four years.[2] Adverse outcomes for only one or two patients can have a major impact on star ratings, and thus on the TC's eligibility for third party contracts, on patient referrals, and on the TC's local reputation. Considering that TCs—not OPOs—make (and should make) clinically complex decisions regarding whether to accept an organ for transplantation, so long as outcomes measures continue to play an outsized role in TC performance evaluation, requiring OPOs to substantially increase their Transplant Rates sets up a potentially adversarial relationship between TCs and their area OPOs that is not in the best interests of transplant patients.

> *Additional Recommendation: If CMS determines that some measure focusing on OPO performance in placing organs for transplantation is appropriate, we urge adoption of a*

[2] Jesse D. Schold, Kenneth A. Andreoni, Anil K. Chandraker, Robert S. Gaston, Jayme E. Locke, Amit K. Mathur, Timothy L. Pruett, Abbas Rana, Lloyd E. Ratner, Laura D. Buccini, Expanding clarity or confusion? Volatility of the 5-tier ratings assessing quality of transplant centers in the United States. American Journal of Transplantation. 09 January 2018.

measure that focuses on improvements in performance rather than a comparative Transplant Rate measure.[3] (We likewise favor an absolute rather than relative metric.) We also believe it is critical that any new metrics be developed with the input of the entire transplant community and include input from associations representing transplant surgeons, transplant physicians, OPOs, patient organizations, and other affected stakeholders to achieve outcomes for which the metrics were designed.

II. **The Final Rule precludes CMS from recertifying or contracting with any OPO that fails to meet outcomes requirements regardless of whether any alternative is available, thus potentially leaving many areas of the country at risk of not having any OPO. For this reason, CMS should modify the Final Rule to give itself the flexibility to re-certify and contract with an underperforming OPO under specified conditions.**

The de-certification of an area OPO has the potential to result in extraordinary disruption in access to transplantation for considerable periods, potentially denying entire populations the opportunity to obtain life-saving treatment. For this reason, we are extremely concerned that the OPO CfC Final Rule places CMS in a regulatory straightjacket that will preclude the agency from retaining an underperforming OPO even if it commits to making any changes required by CMS and even if there is no other alternative available.

In particular, under the OPO CfC Final Rule, OPOs that fail to meet the outcome requirements in effect for the 2018-2022 certification cycle and Tier 3 OPOs identified based on their performance for the last assessment period for the 2022-2026 certification period must be decertified and are precluded from retaining their contracts. The Final Rule essentially assumes that at least one other OPO will bid for the contract for the service area of any OPO that is de-certified as the result of a failure to meet the outcomes requirements in effect for the 2018-2022 certification cycle and that at least one Tier 1 or Tier 2 OPO will bid for the contract for the service area of any OPO assigned to Tier 3 as the result of its performance during the final assessment period for the 2022-2026 certification cycle.

But what happens if no OPO wants to take over? The Final Rule—which is equally binding on CMS as on the affected OPOs—precludes the agency from allowing the de-certified OPO to maintain the contract, even if it were willing to make whatever organizational or operational changes CMS may demand. In this case, it appears that the de-certified OPO's service area will be left without any OPO unless and until a new organization that is eligible for certification materializes. (And since the CfC Final Rule does not exempt new organizations from the outcomes requirements, it is unclear how any new organization – which necessarily lacks an outcomes track record--could ever become eligible for certification.)

ASTS strongly believes that it is highly imprudent for CMS to so tightly constrain its own flexibility to meet the needs of potential recipients who happen to reside in areas served by underperforming OPOs. We believe that this problem could be addressed in either of two ways. First, we have drafted proposed modifications of the Final Rule that we believe would allow CMS the flexibility to work with an underperforming OPO if the agency concludes that the OPO is the sole OPO option reasonably available for the OPO's service area or that recertification of the OPO is in the best interests of potential recipients in the OPO's service area and the OPO enters into a Systems Improvement Agreement satisfactory to the Secretary (see Attachment A).

[3] For reasons also stated in our initial comments we also favor use of an absolute rather than a relative donation rate performance threshold.

Alternatively, if CMS needs additional time to address this issue but does not wish to delay implementation of new OPO outcomes measures, we urge the agency to finalize new definitions set forth at **42 CFR§ 486.302;** new outcomes measures set forth in **42 CFR § 486.318;** conforming amendments set forth at **42 CFR § 486.328**; and amendments of the QAPI requirements set forth at **42 CFR§ 486.348** but to refrain from finalizing the changes set forth in 42 CFR **§ 486.316 (Re-certification and competition processes)**, pending further consideration. In this manner, CMS can effectively provide OPOs with notice of the outcomes standards that will apply in the 2022-2026 certification cycle without putting itself in a regulatory straightjacket that has the potential to disrupt, delay, or completely deny access to transplantation in areas serviced by underperforming OPOs.

We appreciate the opportunity to re-engage with CMS on these important issues. Please contact ASTS Executive Director Maggie Kebler-Bullock at Maggie.Kebler@asts.org or on (703) 414-7870 if you have any questions regarding our comments or any other issues relating to transplantation system improvements.

Sincerely,

Marwan S. Abouljoud, MD, FACS, CPE, MMM
President
American Society of Transplant Surgeons

Cc:
Lee Fleisher, MD, Chief Medical Officer and Director, Center for Clinical Standards & Quality (CCSQ)
Diane Corning, Division of Non-Institutional Quality Standards, Clinical Standards Group
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Kristin Shifflett, Life Safety Code Subject Matter Specialist, CMS
Captain James Cowher, Director, Division of Continuing Care Providers (DCCP)
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Attachment A: Proposed Modifications of OPO CfC Final Rule

§ 486.316 Re-certification ~~and competition processes~~.

(a) *Re-certification of OPOs.* Based upon performance on the outcome measures set forth in § 486.318 and the re-certification survey, each OPO will be designated into either Tier 1, Tier 2, or Tier 3. The tier in which the OPO is designated will determine whether the OPO is re-certified ~~(Tier 1)~~, must compete to retain its DSA (~~Tier 2~~), or will receive an initial de-certification determination ~~(Tier 3~~).

(1) *Tier 1*. An OPO is re-certified for at least an additional 4 years, the OPO's DSA is not opened for competition, and the OPO can compete for any open DSA if it meets all of the following:

(i) It has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, and

(ii) It meets the outcome requirements as described in § 486.318(e)(4) for the final assessment period of the agreement cycle.

(2) *Tier 2*. An OPO is re-certified for at least an additional four years, the ~~An~~ OPO's DSA is open for competition and the OPO is eligible to compete to retain its DSA and for any open DSA if it meets all of the following:

(i) It has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, and

(ii) It meets the outcome requirements as described in § 486.318(e)(5) at the final assessment period of the agreement cycle.

(3) *Tier 3*. An OPO will receive a notice of de-certification determination under § 486.314 and cannot compete for any open DSA if it meets either of the following:

(i) Has been shown by survey to not be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; or

(ii) Has outcome requirements as described in § 486.318(e)(6) at the final assessment period of the agreement cycle; provided, however, that final assessment period outcomes requirements as described in § 486.318(e)(6) shall not serve as a basis for decertification if the Secretary determines that the OPO is the sole OPO option reasonably available for the OPO's service area or that recertification of the OPO is in the best interests of potential recipients in the OPO's service area and the OPO enters into a Systems Improvement Agreement satisfactory to the Secretary.

(b) *De-certification and competition.* If an OPO receives an initial notice of decertification: ~~fails to meet the outcome measures set forth in § 486.318(e)(6) at the final assessment period prior to the end of the agreement cycle, or it meets the requirements described in paragraph (a)(3) of this section:~~

(1) ~~CMS will send the OPO a notice of its initial de-certification determination and~~ The OPO has the right to appeal as established in § 486.314;

(2) If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs that qualify to compete for open service areas set forth in (c) of this section. The de-certified OPO is not permitted to compete for its open area or any other open area.

(3) The OPO competing for the open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(c) *Criteria to compete.* To compete for an open DSA, an OPO must meet the performance requirements of the outcome measures for Tier 1 or Tier 2 at § 486.318(e)(4) and (5), and the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 at the most recent routine survey. The OPO must compete for the entire DSA.

* * * * *

(f) *Extension of the agreement cycle for extraordinary circumstances*. OPOs can seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPOs that has affected the data of the final assessment period so that it does not accurately capture their performance. OPOs must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than the last day of the final assessment period.

(g) For the 2022 recertification cycle only, if an OPO does not meet one of the outcome measures as described in paragraphs §486.318(a)(1), (a)(3), (b)(1), or (b)(3), or has been shown by survey to not be in compliance with the requirements for certification at §486.303, including the conditions for coverage at §§486.320 through 486.360, ~~the OPO is de-certified.~~ CMS will send the OPO a notice of its initial de-certification determination; provided, however, that failure to meet one of the outcomes measures described in paragraphs §486.318(a)(1), (a)(3), (b)(1), or (b)(3) shall not serve as a basis for decertification if the Secretary determines that the OPO is the sole OPO option reasonably available for the OPO's service area or that recertification of the OPO is in the best interests of potential recipients in the OPO's service area and the OPO enters into a Systems

Improvement Agreement satisfactory to the Secretary. If an OPO that receives an initial decertification determination does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

ASTS
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Attachment C

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Surgical Standards for Surgeons Performing Deceased Donor Organ Procurements for Transplantation

ASTS Standards & Quality Committee

Approved by the ASTS Executive Committee: April 2023

Because it is the first stage of the organ transplantation process, high quality organ procurement is essential to successful transplantation, and good stewardship of donor family wishes necessitates comprehensive professional training and application of the highest standards to those who procure organs, particularly in view of the increasing technical complexities of the procedure.

The intent of the following standards for the procurement of organs is to establish criteria by which transplant centers and organ procurement organizations (OPOs) can ensure that, in addition to meeting any applicable licensure or third party payer requirements, individuals who procure deceased donor organs are appropriately trained to provide the highest quality organs possible from every deceased donor with consistency, safety and professionalism.

Criteria for Surgeons Performing Deceased Donor Procurements

1. A surgeon must have a US medical license or institutional license (form of restricted medical license to practice) and transplant training as outlined below:
    a. A surgeon with a US medical license should:
        i. Have completed an ASTS-accredited transplant fellowship with a total of 25 multi-organ procurements, including five (5) DCD procurements (Qualified Transplant Surgeon); or
        ii. Be in the process of completing an ASTS-accredited transplant fellowship and must have completed a total of at least 10 multi-organ procurements, including two (2) DCD procurements, with observation from a qualified procurement surgeon and approval from an attending surgeon(s) in his or her fellowship program; or
        iii. Have completed transplant training or organ procurement training in another format with a total of 25 multi-organ procurements (including five (5) DCD procurements) under the observation of a Qualified Transplant Surgeon, and obtain a letter of approval from that Qualified Transplant Surgeon.

    b. A surgeon with an institutional license, restricted medical license, or international degree should:
        i. Have completed transplant training or organ procurement training in another format; and

ii. Have completed 25 multi-organ procurements (including five (5) DCD procurements) under the observation of a Qualified Transplant Surgeon; and
iii. Provide documentation of review and approval from a Qualified Transplant Surgeon.

c. Regardless of age or experience, a surgeon who has not completed an organ procurement in the last six (6) years and is not a practicing transplant surgeon should only perform organ recovery in the presence of a Qualified Transplant Surgeon. Supervision of one procurement and approval prior to independent procurements is sufficient to perform independent recoveries.

Additional Recommendations

ASTS recommends that OPOs track the quality of the procurement services provided by those who procure organs for transplantation and that performance issues, including behavioral issues, be noted in the ACIN system and reported to the entity with which the procuring surgeon is affiliated. If poor performance leads to the loss of a potentially transplantable organ, a report must be filed with the Organ Procurement and Transplantation Network. A surgeon can lose transplant program or OPO privileges to perform donor recoveries if quality issues arise or if the surgeon fails to comply with with an established code of conduct.

ASTS
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Attachment D

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Surgical Standards for Surgeons Performing Normothermic Regional Perfusion (NRP)

Approved by the ASTS Council: January, 2026

American Society of Transplant Surgeons

Standards & Quality Committee

Chair: Marwan Kazimi, MD

1401 S. Clark Street Suite 1120 Arlington, VA 22202

Surgical Standards for Surgeons Performing Normothermic Regional Perfusion (NRP)

The American Society of Transplant Surgeons (ASTS) is supportive of normothermic regional perfusion (NRP) as a modality for procurement in Donation after Circulatory Death (DCD) to optimize organ utilization and transplantation. The position of the ASTS regarding the medico-legal and ethical concerns of NRP as well as the Society's recommendations regarding the logistical and technical standards of NRP have been addressed and the relevant papers are included in the bibliography.[i] Many of these issues related to NRP are outside the scope of this document, including training of non-surgeons in procurements and recommendations on tracking quality of organs transplanted after NRP procurements. ASTS does highly recommend that NRP be performed by surgeons with qualifications listed in the certification pathways below.

NRP procurements are novel procedures that apply existing techniques. Specific expertise is required of the surgical teams and the organ procurement organization (OPO) staff involved. The performance of these procedures requires that the surgeon is competent in technical skills and operative tactics beyond standard DBD or DCD procurements.

Due to variations in hospital and state regulations, NRP training is not available to all transplant fellows in the United States. Surgeons may be trained in NRP during fellowship, after fellowship, or via a combination of fellowship and post-fellowship experience. In this document, "trainee" does not imply a fellow, but also any surgeon in the process of learning to perform NRP.

The purpose of this document is to put forth recommendations regarding the training requirements and standards for transplant surgeons performing NRP. ASTS recognizes that NRP is a rapidly changing and innovating technology and will review this document on an annual basis.

1. **Medical Background and Prerequisites** *(as stated in the ASTS Surgical Standards for Surgeons Performing Deceased Donor Organ Procurements for Transplantation)*

    a. **Experience in Organ Transplantation**:

        i. *A surgeon must have a US medical license or institutional license (form of restricted medical license to practice) and transplant training as outlined below:*

            1. *Have completed an ASTS-accredited transplant fellowship with a total of 25 multi-organ procurements, including five (5) DCD procurements (Qualified Transplant Surgeon) as stated in the ASTS Surgical Standards for Surgeons Performing Deceased Donor Organ Procurements for Transplantation; or*

            2. *Have completed transplant training or organ procurement training in another format with a total of 25 multi-organ procurements (including five (5) DCD procurements) under the observation of a Qualified Transplant Surgeon, and obtain a letter of approval from one Qualified Transplant Surgeon.*

ii. *A surgeon with an institutional license, restricted medical license, or international degree should:*

1. *Have completed transplant training or organ procurement training in another format; and*

2. *Have completed 25 multi-organ procurements (including five procurements (with or without NRP) under the observation of a Qualified Transplant Surgeon; and*

3. *Provide documentation of review and approval from a Qualified Transplant Surgeon.*

4. *Regardless of age or experience, a surgeon who has not completed an organ procurement in the last six (6) years and is not a practicing transplant surgeon should only perform organ recovery in the presence of a Qualified Transplant Surgeon. Supervision of one procurement and approval prior to independent procurements is sufficient to perform independent recoveries.*

iii. Any surgeon performing NRP should be certified by the ASTS Procurement Certification Pathway (in development) or until this is developed, by **ACIN**: Association for Organ Procurement Organizations (AOPO) Credentials Information Network (ACIN).

2. **NRP Certification Pathway for A-NRP:**

   a. **Technical Skills and Procedural Training Phase 1 (5 cases/assistant)**

      i. **These 5 cases should be performed as proctored (two surgeon) cases**

      ii. **Key Areas of Assessment**

         1. **Organ Cannulation and Connection to NRP Circuit**: Surgeons must be skilled in cannulating vessels and connecting them to the NRP circuit without compromising organ integrity.

         2. **Assessing Organ Viability**: Training in assessing organ function in real-time, including monitoring for physiological indicators of organ health, such as blood flow, oxygenation, and metabolic parameters.

         3. **Managing Potential Complications**: Surgeons should be trained to handle complications like bleeding, equipment failure, or unexpected changes in perfusion dynamics.

         4. **Documentation**: Training should address standardized documentation of NRP (see addendum)

   b. **Technical Skills and Procedural Training Phase 2 (5 cases/primary surgeon)**

i. **These 5 cases should be performed as two surgeon cases (proctored)**

1. The surgeon in training should act as the primary cannulating surgeon for these cases.
2. Cannulation time within 10 minutes from incision must be achieved during these cases
3. Case logs should be maintained and provided when requested by appropriate regulatory bodies.

3. **Continuing Education and Skill Refreshers**

a. ASTS recommends that OPOs track organs discarded due to technique for NRP procurements as part of quality metrics.

b. As with all surgical skills, ASTS recommends ongoing education and learning for NRP in the form of:

i. **Attending Conferences and Workshops**: Keeping up with advancements in NRP by attending conferences, seminars, and continuing medical education (CME) events.

ii. **Case Review and Peer Learning**: Regular case reviews and peer learning sessions to discuss challenges, complications, and best practices in NRP.

Summary of Required Competencies for NRP:

- **Core Surgical Skills**: TACC certification preferable
- **Technical Proficiency**: Hands-on skill with NRP equipment and techniques.
- **Decision-Making Ability**: Competence in assessing and managing organ viability and potential complications.
- **Ethical and Communication Skills**: Training in ethical practices and effective communication with transplant teams.
- **Ongoing Education**: Commitment to continuous learning and staying updated with advancements in the field.

Addendum

ASTS recommend utilization of the previously developed ASTS Normothermic Regional Perfusion Form found at: https://cdn-links.lww.com/permalink/tp/d/tp_1_1_2024_06_26_newfils_1_sdc1.pdf

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[i] Wall AE, Merani S, Batten J, Lonze B, Mekeel K, Nurok M, Prinz J, Gil J, Pomfret EA, Guarrera JV. American Society of Transplant Surgeons Normothermic Regional Perfusion Standards: Ethical, Legal, and Operational Conformance. Transplantation. 2024 Aug 1;108(8):1655-1659. doi: 10.1097/TP.0000000000005115. Epub 2024 Jul 17. PMID: 39012935.

Croome K, Bababekov Y, Brubaker A, Montenovo M, Mao S, Sellers M, Foley D, Pomfret E, Abt P. American Society of Transplant Surgeons Normothermic Regional Perfusion Standards: Abdominal. Transplantation. 2024 Aug 1;108(8):1660-1668. doi: 10.1097/TP.0000000000005114. Epub 2024 Jul 17. PMID: 39012956.