March 30, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Submitted electronically via Regulations.gov

Re: ***CMS–3409–P — Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage***

Dear Administrator Oz:

The Association of Organ Procurement Organizations (AOPO) welcomes the opportunity to provide comments on CMS–3409–P. AOPO is the nonprofit trade association representing 47 federally designated Organ Procurement Organizations (OPOs), which collectively form the operational backbone of the nation's organ donation and transplantation system. Since its founding in 1984, AOPO has supported continuous improvement through collaborative learning, dissemination of best practices, engagement with donor families and transplant recipients, and the promotion of clinical and operational excellence. At its core, the organ donation system relies on public trust—trust that donated organs will be managed responsibly, allocated fairly, and used to save as many lives as possible. AOPO therefore envisions a system in which every donation opportunity is honored, and every viable organ reaches a patient in need.

OPOs perform a uniquely complex role within the healthcare system. They conduct community and professional education to promote donor registration, collaborate closely with hospitals to identify potential organ donors, provide compassionate support to families during profoundly difficult moments, manage the clinical recovery of organs, and coordinate organ allocation and placement across the country. This work integrates medical, logistical, regulatory, and family-support functions and is performed continuously, twenty-four hours a day, seven days a week. Nationwide, OPOs collectively partner with approximately 6,000 acute care hospitals, with each OPO working with between roughly 12 and more than 200 hospitals within a designated Donation Service Area (DSA). Maintaining public confidence in this system is essential because when trust erodes, donor registration and authorization rates decline, and fewer lives are ultimately saved.

Accountability and stability are not mutually exclusive; both are essential to maximizing the number of successful transplants. Regulatory oversight must be effective, operationally workable, and designed to avoid unnecessary system disruption. The Proposed Rule arrives as the organ donation community approaches

the conclusion of the inaugural four-year certification cycle established by the 2020 Final Rule (August 1, 2022, through July 31, 2026). CMS has indicated that it intends to maintain the core framework established in 2020 while using this rulemaking to clarify operational and interpretive questions that have arisen during implementation. AOPO encourages CMS to ensure that these clarifications promote consistent implementation, preserve the continuity of donation operations, and avoid unintended disruptions that could reduce organ donation and transplantation both now and in the future.

This rulemaking is also occurring within a changed administrative law environment. In *Loper Bright Enterprises v. Raimondo* (2024), the Supreme Court eliminated Chevron deference and clarified that statutes have a "single, best meaning" that agencies must independently interpret and defend. CMS expressly references *Loper Bright* in the Proposed Rule when discussing its interpretation of statutory certification authority. Because portions of this rule rely on revised statutory interpretations, clarity, precision, and consistency in the final regulatory text are particularly important to ensure durability, fairness, and predictable implementation. Accordingly, AOPO respectfully requests that CMS clearly identify the specific statutory authority supporting any requirements in the final rule that extend beyond clarifying implementation of the existing 2020 regulatory framework.

AOPO submits these comments in support of CMS's shared objective of maximizing organ donation and transplantation while safeguarding patient safety, public trust, and the continuity of donation operations. We also seek to offer targeted policy and technical recommendations that we believe will strengthen oversight, preserve system stability, and ensure that as many lives as possible are saved through transplantation.

These comments address several related issues. First, they respond to questions raised by Administrator Oz during our February 3, 2026, meeting and incorporate broader themes the Administrator asked AOPO to address, including conceptual considerations that extend beyond the specific regulatory text of the Proposed Rule. Second, at the request of CMS's Center for Clinical Standards and Quality (CCSQ), following a recent meeting, AOPO provides additional clarification regarding hospital waiver requests to work with OPOs outside of their designated service areas. The remainder of this letter presents AOPO's analysis and recommendations related to specific provisions of the Proposed Rule. Finally, included as an addendum is a set of technical questions regarding several proposals in the rule that AOPO respectfully requests CMS address either in the final rule or through subsequent subregulatory guidance to support consistent and predictable implementation.

I. Discussion with CMS Administrator and Leadership (February 3, 2026, Meeting)

AOPO appreciates the opportunity to respond to questions raised during a February 3, 2026 meeting with CMS leadership, including Dr. Mehmet Oz, regarding the genesis of the 2020 Final

Rule and the evolution of the donation system since implementation, as part of our comment. AOPO includes this context at the Administrator's explicit request to ensure a complete and transparent record regarding the origins of the current measurement framework.

AOPO also believes it is important to reiterate that the performance of the organ donation and transplantation system reflects the interaction of multiple stakeholders—including donor hospitals, transplant centers, OPOs, and the OPTN—each of which plays a critical and interdependent role in determining whether organs are recovered, accepted, and ultimately transplanted. While OPOs are responsible for identifying potential donors, coordinating donation processes, and facilitating organ recovery and placement, key determinants of transplantation outcomes—including donor hospital clinical practices, transplant center acceptance behavior, and allocation logistics—are not within an OPO's ability to control. Performance measurement frameworks should therefore be carefully designed to ensure accountability is appropriately aligned with the entity responsible for each stage of the donation and transplantation continuum.

AOPO recognizes that CMS' stated goal for the 2020 Final Rule was to accelerate improvement among OPOs by introducing competition and establishing a tiering framework based on two outcome measures to create performance pressure across all designated service areas (DSAs). CMS's preamble to the Proposed Rule reiterates the agency's view that "sustained regulatory pressure" and transparent performance metrics have contributed to improvements in median donation and transplantation rates and reflects CMS's continued intent to enforce the 2020 framework.

AOPO has consistently acknowledged the imperative to improve performance across the board and throughout the organ donation and transplantation ecosystem, which includes not only OPOs but transplant centers and donor hospitals. OPOs have continued to advance clinical practice and operational capabilities, including donation after circulatory death (DCD) and Normothermic Regional Perfusion (NRP) guidance and standards, donor management innovations, the adoption of Donor Care Units (DCUs) to optimize donor management and organ recovery, and broader quality-improvement infrastructure, with additional draft policies currently in the development process through the Organ Procurement and Transplantation Network (OPTN) NRP Workgroup, with which AOPO members are actively engaged. However, AOPO has also consistently raised concerns—during the 2020 rulemaking and thereafter—that the current performance measurement approach is not sufficiently workable or aligned with the clinical and operational realities of organ donation and transplantation or the incentives for transplant centers and donor hospitals. In particular, the framework's emphasis on competitive dynamics among OPOs may inadvertently shift attention away from collaborative learning and continuous quality improvement, which have historically driven advances in donation practice across the system. At the same time, organ non-use rates have increased in recent years, raising both resource and ethical concerns when viable organs are recovered but ultimately not

transplanted. These trends underscore the importance of aligning performance metrics and regulatory incentives across the entire donation and transplantation ecosystem so that all stakeholders work toward the shared objective of maximizing successful transplants.

The 2020 Final Rule adopted a new Donation Rate Measure.[1] CMS also changed the OPO Transplantation Rate to measure the number of transplanted organs from an OPO's DSA as a percentage of inpatient deaths among patients aged 75 or younger, whose primary cause of death aligns with organ donation eligibility. Unfortunately, these metrics create an incentive misalignment, as OPOs are evaluated by quantity, while transplant centers are assessed on quality.

CMS states in the Proposed Rule that the two outcome measures—donation rate and transplantation rate—capture different aspects of OPO performance because the numerators measure the number of donors and the number of organs transplanted. While these numerators are distinct, both measures rely on the same underlying denominator derived from estimated donor potential within a DSA. Furthermore, they are based on death data that is over two years old at the time it is available for application to OPOs and overestimates the potential donor pool. Because this denominator does not sufficiently account for differences in actual potential donors, hospital case mix, referral patterns, trauma and neurologic service availability, and other regional factors, variation in measured performance may reflect underlying characteristics of the DSA rather than differences in OPO operational effectiveness.

As a result, the measures risk attributing system-level outcomes solely to OPOs, even though organ recovery and transplantation outcomes depend on decisions and practices across multiple actors, including donor hospitals and transplant centers. In other CMS payment and performance models, the agency has recognized the importance of risk adjustment to ensure fair and meaningful comparisons across providers serving different patient populations. For example, in the Increasing Organ Transplant Access (IOTA) Model, CMS explicitly identified risk adjustment as a critical component of model design. A similar recognition of underlying clinical and operational variation should inform the evaluation of OPO performance, ensuring that comparisons across DSAs reflect operational effectiveness rather than structural differences in donor potential.

The rule also establishes a comparative performance threshold at the top 25th percentile, with automatic decertification triggered if an OPO falls below the median in either measure. As a result, 24 OPOs are currently classified in the lowest tier. According to the OPO Performance

[1] The measure assesses the number of organ donors in the OPO's DSA as a percentage of total inpatient deaths among patients 75 years old or younger with a primary cause of death that is consistent with organ donation. CMS intends to determine the total number of inpatient deaths with a primary cause of death that is consistent with organ donation from state death certifications.

Report released by CMS on April 27, 2023[2]—based on 2021 data, the most recent data available as of this writing—approximately 42 percent of OPOs nationwide would face automatic decertification if the assessment year were based on those twelve months of performance. CMS has not released an updated OPO performance report since that time; the next report, based on 2024 data, is expected to be published in spring 2026 through the CMS Quality, Certification, and Oversight Reports (QCOR) system. Until those updated data are available, policymakers and stakeholders are relying on performance assessments derived from data that are several years old, which may not fully reflect current operational performance or recent improvements across the organ donation system.

The statutory context underlying this is important. In 2000, § 371(b)(1)(D)(ii) of the Public Health Service Act,[3] as amended by the *Organ Procurement Organization Certification Act of 2000,*[4] requires that:

"[R]egulations be established for the certification and/or recertification process, which (1) "rely on outcome and process performance measures that are based on empirical evidence obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations," and (2) "use multiple outcome measures as part of the certification process.[5]*"*

Congress previously rejected CMS's reliance on limited outcome metrics alone to evaluate OPO performance and directed the agency to establish a recertification framework incorporating both process measures and multiple outcome measures over a four-year cycle. Congress further instructed CMS to look beyond donor potential alone and to account for additional factors within each OPO's DSA that are relevant to evaluating performance and increasing organ donation.

Nearly two decades later, Executive Order 13879, "Advancing American Kidney Health,"[6] directed HHS to improve the procurement and utilization of organs from deceased donors. CMS subsequently promulgated the 2020 Final Rule, establishing a three-tier recertification system based on two outcome measures: a donation rate and a transplantation rate. Tier 1 OPOs are automatically recertified; Tier 2 OPOs must compete to retain their DSAs; and Tier 3 OPOs are decertified. The first recertification cycle under these metrics concludes on July 31, 2026.

As raised during the February 3 discussion, the analytical foundation of the current two-measure framework can be traced in part to reports published in 2017 and 2020 by The Bridgespan Group, including *Reforming Organ Donation in America.*[7] These reports were funded by the Laura and

[2] Organ Procurement Organizations annual public aggregated performance report 2023
[3] 42 U.S.C. § 273(b)(1)(D)(ii).
[4] Pub. L. 106-505, Title VII,§ 701, 114 Stat. 2346.
[5] 78 Fed. Reg. at 43,671 quoting 42 U.S.C. § 273(b)(1)(D)(ii).
[6] Executive Order on Advancing American Kidney Health – The White House
[7] reforming-organ-donation-in-america-12-2018.pdf

John Arnold Foundation (now Arnold Ventures) and developed in collaboration with researchers affiliated with Penn Medicine and Organize (Organ Alliance, Inc.), none of whom are from or have performed the work of an OPO. The 2017 analysis underlying these reports was not peer-reviewed and was recently used to drive subsequent policy discussions. Authors and contributors included individuals affiliated with Bridgespan, Organize, and academic institutions, and funding disclosures confirm financial support for this work.

The Bridgespan analysis advanced the assertion that approximately 28,000 additional organs per year were available, but not being recovered or transplanted. As AOPO detailed in its March 4, 2021, comment letter submitted in response to HHS opening for additional comment the docket for "CMS-3380-F2: 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," that estimate rested on assumptions that are not clinically or operationally realistic. Specifically, the estimate assumed 100 percent of eligible decedents would authorize donation, and that eight transplantable organs per donor would be utilized in all cases, and that a transplant program would be available and willing to accept and transplant each organ. In reality, organ donation is voluntary, medical suitability varies widely, and organ utilization depends on biological constraints, logistical factors, and transplant-center acceptance practices. In fact, widely cited data show that only about 1–2% of deaths actually occur under conditions that make organ donation medically possible.[8] As a result, it is highly unlikely that every patient will authorize donation or that every donated organ will ultimately be used, as the assertion assumes. At the time of AOPO's prior comment submission, based on those factors, the average number of organs transplanted per suitable donor was approximately 3.45, not eight.

AOPO agrees that there remains a meaningful opportunity to increase organ recovery and transplantation and that continued progress is essential to reducing deaths among patients on the transplant waitlist. However, the pace and approach to achieving these improvements must reflect the realities of clinical practice, available technology, health system capacity, and the perspectives of donor families and the broader public. Sustainable progress is most likely to occur through collaborative quality improvement initiatives, shared learning across OPOs, donor hospitals, and transplant centers, and collective-impact approaches that align incentives across the entire donation and transplantation ecosystem.

While the Bridgespan report catalyzed national discussion about performance variation among OPOs, the analytical framework it advanced did not fully account for clinical realities, donor-family decision-making, organ-acceptance behavior at transplant centers, or the operational complexity of DSAs. Moreover, the reliance on state death certificate data as a proxy for donor

[8] Health Resources and Services Administration. Organ Donation and Transplantation Data and Reports. Available at: https://www.hrsa.gov/optn/data/data-reports

potential—an approach adopted in the 2020 Final Rule—continues to generate methodological concern given rates of inaccuracy, lack of necessary secondary diagnoses (e.g., COVID-19 status, cancer), the absence of key clinical indicators such as ventilator status at the time of death (an absolute requirement for donation to occur), and limited granularity of existing data.

AOPO does not revisit this history to relitigate past policy debates. Rather, these points directly respond to a question raised during the February 3, 2026, meeting with the CMS Administrator: "Where did these metrics come from?" The two-outcome measure framework was significantly influenced by a special interest-backed analytical model that assumes materially higher organ yield potential than clinical evidence supports is feasible and was incorporated into regulatory policy without the degree of validation, pilot testing, and iterative refinement typically associated with CMS measure development.

Long before the adoption of the 2020 Final Rule, OPOs had established a culture of continuous quality improvement, collaborative learning, and shared operational advancement to increase organ donation and transplantation. Since the implementation of the 2020 Final Rule, OPOs have continued to demonstrate measurable improvement in donation and transplantation, invest in donor care innovation, strengthen hospital partnerships, and expanded quality infrastructure such as AOPO's Improvement in Action (IMPACT) Program which is driving systemwide advancement through hands-on operational guidance, benchmarking, and tailored reviews to help OPOs identify opportunities for improvement and implement measurable improvements.

However, the structural limitations of the two-measure construct remain. The metrics continue to rely on an imperfectly calibrated denominator and are insufficiently risk-adjusted for medically complex donors, DCD prevalence, transplant center acceptance variability, and regional practice differences. As discussed earlier, CMS has recognized the importance of risk adjustment in the *Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Proposed Rule (90 FR 55342)*.

In the proposed rule, CMS notes that donor and recipient characteristics are beyond the transplant center's control and materially affect transplant outcomes and therefore warrant risk adjustment for transplant center performance measures. CMS's continued position that similar donor-related factors do not warrant risk adjustment for OPO performance metrics is difficult to reconcile and undermines system-wide coherence.

Moreover, the OPO CfC Final Rule applies uniformly to all OPOs and relies primarily on decertification as its enforcement mechanism. By contrast, the IOTA model is limited to selected kidney transplant hospitals and employs a broader framework of multiple, risk-adjusted measures across achievement, efficiency, and quality, using a point-based scoring system with defined financial incentives. This contrast highlights the inconsistency in CMS's approach, as the

agency recognizes the importance of risk adjustment and incentive-based accountability within the IOTA model but does not apply similar principles to OPO performance oversight.

These concerns further underscore the importance of and need for technical refinement of OPO performance metrics rather than rigid enforcement of measures whose analytic foundations remain contested. AOPO's current partnership with Econometrica reflects a commitment to developing independently validated, consensus-based measures aligned with CMS's Blueprint lifecycle, including pilot testing, stakeholder engagement, risk adjustment development, and formal endorsement review.

In short, accountability is essential—but it must rest on a scientifically sound, peer-validated measurement framework reflecting the operational and clinical realities of organ donation and transplantation while preserving system stability and public trust. It also must take into account the human factors associated with organ donation, and that competition and chaos may do more harm than good to overall efforts to increase organ donation and transplantation and to patients.

AOPO recommends CMS use this Proposed Rule as an opportunity to finalize implementation decisions that improve precision and fairness (definitions, attribution, thresholds, risk adjustment, and enforcement calibration), while creating a clear pathway to incorporate independently validated measures as they mature.

II. Econometrica and the Technical Basis for AOPO's Metrics Project

As discussed above, in 2025, AOPO and 53 out of 55 OPOs launched a major, multi-year initiative—supported by Econometrica and funded by OPOs, including those that are not AOPO members—to develop independently validated, data-driven performance measures accurately reflecting the role of OPOs across the full donation continuum and which support continuous quality improvement. The measures are being developed using the Donabedian Model, a widely used and CMS-recommended framework. The overarching goal is to create a common, evidence-based measurement system that enables OPOs and system stakeholders to identify improvement opportunities, collaborate on best practices, and advance the shared objective of increasing donation and transplantation rates to reduce deaths on the transplant waitlist.

These measures are not intended to replace state or CMS surveys focused on patient safety, nor are they designed to function as a competitive scorecard among OPOs. Instead, they are intended to support a responsive regulatory model in which OPOs and regulators work collaboratively to ensure accountability through measures that are meaningful, actionable, feasible, rigorous, evidence-based, replicable, verifiable, and aligned with clinical realities. Importantly, the measures are designed to build upon CMS's framework and generate clear, actionable insights that drive performance improvement.

The development timeline is highly relevant to CMS's policy considerations. Econometrica is validating, testing, and assessing each measure in accordance with CMS's Blueprint Measure Lifecycle process, guiding AOPO and participating OPOs through the structured pathway by which new measures are developed and submitted for consideration. To ensure methodological rigor and operational accuracy, Econometrica conducted seven on-site visits to OPOs, interviewed additional OPOs, interviewed donor families and transplant recipients, conducted a comprehensive literature review, and convened a Technical Expert Panel to inform measure specifications and attribution design. Members of the Technical Expert Panel represented a variety of sectors and disciplines within healthcare, including representatives with backgrounds in medicine, mathematics, quality improvement, healthcare administration, law and ethics, information technology, research, and patient and family advocacy. The breadth of Panel membership is a testament to the scope of non-OPO-specific expertise used to develop and inform the metrics development.

Round 1 measures—focused on referrals, approaches, authorizations, and donor conversion—are expected to be submitted to the Partnership for Quality Measurement (PQM) for endorsement in Spring 2026. Round 2 measures—including donor management, organs recovered per donor, utilization and transplantation, and adverse events—are expected to follow in Fall 2026.

Accordingly, CMS will have a near-term opportunity, beginning in Fall 2026, to incorporate independently developed, consensus-based measures once they are fully developed. Although AOPO and the OPO community have financially supported this effort, Econometrica's work is independent, methodologically rigorous, and aligned with CMS's own standards for measure development.

We respectfully request that CMS commit in forthcoming rulemaking to a transition pathway allowing for incorporation of these measures beginning in Fall 2026; provide regulatory flexibility to pilot or phase in endorsed measures within the recertification framework; and consider calibrating the timing and weight of enforcement decisions to allow for incorporation of independently validated, consensus-based measures as they become available. This approach would preserve accountability while promoting stability, clinical alignment, and sustained improvement across the organ donation system.

III. Risk of System Disruption from Large-Scale DSA Turnover

AOPO acknowledges and accepts CMS's authority to decertify OPOs in accordance with the CMS OPO CfCs. However, the prospect—estimated in prior CMS analyses and widely discussed within the community—of widespread DSA turnover affecting many OPOs due to the decertification cycle poses a significant risk to donation operations and transplant access across the entire system. AOPO strongly supports actions to strengthen our nation's donation and transplant

system, ensuring all stakeholders are held accountable. Should an OPO fall short of any regulatory, statutory, or legal standard or requirement, AOPO strongly supports federal and state oversight entities holding them accountable, as appropriate, whether through corrective actions or, if necessary and prudent, decertification implemented in a deliberate manner to mitigate disruption.

However, AOPO believes that measuring OPO performance with carefully designed, independently validated granular performance measures can prevent the imminent large-scale disruption to patients in the organ donation and transplantation system, while also guiding evidence-based continuous quality improvement and the positive change needed to save lives. Simultaneous large-scale removals would likely disrupt hospital referral pathways; interrupt donation operations; cause workforce instability and loss of institutional expertise; and raise geographic access concerns, particularly in rural and underserved regions[9]. Such instability poses a material risk of reduced donation and transplantation volumes during transition periods, even when long-term performance improvement is the objective. CMS should therefore seek, above all else, to ensure that performance measures result in meaningful improvements in OPO performance and are not based on zero-sum determinations. In addition, AOPO supports efforts to incorporate safeguards that preserve continuity and protect donation operations from destabilization. Given the complexity and interdependence of the organ donation and transplantation system, large-scale DSA turnover could reduce transplants in the short and medium term, even when undertaken with the objective of improving long-term performance.

Finally, while the proposed rule recognizes that sufficient data must be available before outcome measures can fairly reflect **data-driven, independently validated measurements to accurately and appropriately determine OPO performance on process and outcomes, which AOPO believes is a standard that the current metrics do not meet. As validated metrics are in development, we encourage CMS to incorporate guardrails that (1) phase transitions, (2) protect continuity of donation operations, and (3) avoid preventable disruption.**

IV. Strategies to Mitigate Disruption While Preserving Accountability

AOPO respectfully urges CMS to finalize a framework that maintains meaningful accountability while minimizing destabilization. As CMS considers implementation of the tier system, competition, successor assignments, and transition processes, AOPO encourages the agency to adopt a structured, phased approach that prioritizes continuity of operations and patient access. CMS should incorporate: conditional or provisional participation pathways with defined corrective action plans and measurable milestones; enhanced CMS technical assistance with oversight oriented toward sustained performance improvement rather than abrupt disruption;

[9] Rodrigue, J. R., Fitzpatrick, S., & McKown, B. (n.d.). *Performance metrics and the disproportionate impact of decertifying organ procurement organizations on minority populations*. Centers for Medicare & Medicaid Services.

regional continuity plans to protect referral pathways and recovery logistics; and clear transition metrics and timelines to preserve operational continuity.

AOPO also encourages CMS to consider whether a limited, time-bound "hold harmless" approach may be appropriate during the transition to more robust and validated performance measures. Under such an approach, CMS could continue to publicly report OPO performance data under the current framework while deferring large-scale decertification actions until improved, independently validated measures are tested and endorsed. During this period, OPOs would remain subject to enhanced oversight, including performance-improvement or corrective-action plans triggered by interim performance reports under the current regulations, with focused monitoring of the development and implementation of such plans, and targeted technical assistance consistent with CMS's broader quality-improvement approach across provider and supplier programs.

Such an approach would preserve transparency and accountability while avoiding destabilizing disruptions to donation operations that could occur if decertification decisions are based on measures whose analytic limitations remain unresolved. It would also provide CMS with the opportunity to incorporate findings from the ongoing multi-stakeholder metrics development initiative prior to making structural changes to DSAs, which could otherwise have significant implications for transplant access, hospital relationships, and system capacity.

Importantly, before advancing to decertification, AOPO encourages CMS to build on prior work by the Health Services Advisory Group (HSAG), which has emphasized performance improvement and the identification and dissemination of best practices, toward a more robust, standardized evaluation framework. This framework should incorporate operational data consistently defined and reported across OPOs, including emerging metrics and key performance indicators (KPIs) that capture process quality, timeliness, referral management, and family authorization practices. Incorporating these elements would enable CMS to distinguish between true performance variation and limitations in current measurement methodologies, while supporting value-based improvement and system-wide learning.

This approach is more consistent with existing Medicare regulatory frameworks governing provider compliance. The regulations governing Medicare Conditions of Participation provide for structured administrative processes when deficiencies are identified, including the opportunity for providers to submit corrective action plans that are prospective and improvement oriented. See, e.g., 42 C.F.R. §§ 488.24, 488.28, and 488.402–488.414, which outline CMS's authority to require plans of correction, impose remedies, and pursue termination only after appropriate process and opportunity for remediation. Notably, these frameworks emphasize progressive enforcement and do not generally rely on retroactive recoupment of payments, reinforcing a forward-looking compliance model.

In contrast, an immediate decertification framework tied to evolving or analytically constrained measures risks diverging from this longstanding regulatory paradigm. A phased, improvement-focused model—paired with transparent reporting, structured accountability mechanisms, and enhanced technical support—would better align with CMS precedent, including quality improvement approaches used in other programs, while safeguarding continuity of care and access to transplantation services.

Accordingly, AOPO respectfully urges CMS to adopt a phased, improvement-oriented implementation framework—including a time-limited hold harmless period, structured corrective action pathways, and enhanced technical assistance—prior to pursuing decertification actions based on validated performance measures. Such an approach would maintain accountability while preserving system stability, advancing equity, and protecting patient access to life-saving transplantation services.

V. Comments on Specific Provisions of the Proposed Rule

Before turning to specific regulatory provisions, AOPO believes it is important to frame several overarching structural elements of the Proposed Rule. While many of the amendments appear technical, taken together, they reflect meaningful shifts in enforcement posture, competitive structure, and regulatory discretion.

First, the Proposed Rule reaffirms the core tiering framework established in 2020. CMS makes clear that the two-outcome measure architecture remains intact, and enforcement will proceed as the inaugural four-year recertification cycle concludes. Rather than recalibrating the framework, the rule reinforces it. In other areas of healthcare, measures are maintained, updated, and retired on an annual basis to reflect advances in technology and protocols, and measures implemented for assuring patient safety are used to implement responsive regulatory approaches, such as corrective actions, before action is taken on certification.

Second, the Proposed Rule operationalizes tier status at the level of the Donation Service Area (DSA), rather than solely at the organizational level. This is a significant structural shift. By evaluating each DSA independently, CMS creates the possibility of partial retention or partial loss of service areas. This DSA-level accountability structure introduces strategic and operational implications that extend beyond traditional organizational recertification models. The result of this may be a decline in organizations willing and able to serve highly rural areas and areas with healthcare shortages, exacerbating disparities and deaths on the transplant waiting list.

Third, the rule confirms that Tier 1 and Tier 2 OPOs may compete for open DSAs, making competition continuous rather than episodic. In combination with CMS's revised interpretation of its certification authority, this provision signals an expansion of competitive dynamics within the system. However, organ procurement and transplantation, and the patients who benefit

from it, depend on system stability and predictability to align the many factors necessary for successful donation.

Finally, the Proposed Rule broadens CMS's QAPI and patient safety authority. While we agree that patient safety and quality are important, through expanded definitions, documentation expectations, and enforcement tools, the rule increases regulatory discretion. Taken together, these provisions represent both enforcement clarification and structural market redesign. We recommend instead that CMS utilize approaches more like what has been used elsewhere in healthcare and adopt a suite of performance and quality measures that include monitoring and measurement of donor and transplant patient safety.

With this broader framework in mind, AOPO offers the following comments on specific provisions of the Proposed Rule.

AOPO also seeks clarification regarding the timing and applicability of the policies proposed in this rulemaking. In stakeholder discussions, it has been suggested that many of the policies and interpretations in the Proposed Rule—other than those related to pancreata recovered for research—may apply to the current recertification cycle. However, this understanding is not clearly articulated in the Proposed Rule itself. While a recent CMS press release[10] outlines an updated timeline—including performance report issuance in Spring–Summer 2026 and potential recertification or decertification actions beginning now in late 2026 to early 2027—that appears to suggest alignment with the current recertification cycle, this linkage is not expressly stated in the regulatory text. Given that the inaugural four-year recertification cycle is already underway and concludes on July 31, 2026, clarity on which provisions CMS intends to apply to the current cycle versus future cycles is critical.

OPOs require certainty regarding the rules governing the measurement period under which their performance will be evaluated. Entities should not be held accountable for regulatory interpretations or requirements introduced after the performance period being evaluated has already begun—or after the performance period has concluded. Applying new policies or interpretive changes retroactively to an ongoing certification cycle would create uncertainty and undermine the predictability necessary for regulated entities to plan and operate effectively. Accordingly, AOPO respectfully requests that CMS explicitly state in the final rule whether any of the proposed policies will apply to the current recertification cycle and confirm that OPOs will not be held accountable for changes introduced after the relevant performance period is underway.

A. New and Revised Definitions (Proposed changes affecting 42 C.F.R. § 486.302 and related provisions)

[10] CMS Strengthens Patient Protections and Accountability in Organ Donation System | CMS

Adverse Event. AOPO supports CMS's emphasis on patient safety, but the final rule must clearly define adverse events in a manner attributable to individual actors and consistently identifiable. The Proposed Rule shifts adverse events from a definitional framework into a broader QAPI enforcement structure, expanding regulatory discretion. By removing detailed examples from the regulatory definition and embedding them within QAPI expectations, CMS is no longer confined to enumerated examples. This broader framing increases regulatory flexibility and may allow surveyors to interpret "risk" expansively, leading to greater variability in enforcement. It also increases documentation intensity, as OPOs would be required to proactively identify, track, analyze, and remediate a wider universe of events. Without clear thresholds and attribution standards, this approach risks transforming QAPI from a quality-improvement tool into a compliance-driven liability framework.

CMS should clarify that the loss of an organ or donor that is not attributable to the OPO's actions, omissions, or failure to follow applicable standards—such as a transplant center or donor hospital error occurring during recovery or transplant—does not constitute an adverse event for OPO accountability purposes. CMS should further clarify how attribution will be assessed in situations involving multiple actors (e.g., transplant centers, transport vendors, or donor hospitals).

CMS should also explicitly harmonize adverse event expectations with Organ Procurement and Transplantation Network (OPTN)/Health Resources and Services Administration (HRSA) patient safety reporting to avoid duplicative obligations and conflicting standards.

Donor / Organ / Pancreata for Research. The Proposed Rule's approach to pancreata recovered for islet cell research risks creating inconsistent treatment across the two outcome measures. If donors from whom pancreata are recovered for research are included in the donation rate, but excluded from the transplantation rate, CMS should explain and justify how this asymmetry advances program objectives and avoids incentives to "game" classifications. AOPO continues to urge CMS to adopt a coherent approach—either consistently counting such cases across measures or consistently excluding them—particularly where the OPO performs all of the same work for pancreas placed for research as it does for other organs placed for transplant including authorization, donor management, recovery, allocation, and transportation. If that work is credited for the donation rate, it is incongruent to not count it for the transplant rate. As it did in the initial comment on the 2020 proposed rule, AOPO maintains that pancreas should not be counted for either measure.

As AOPO understands it, the proposed rule's approach to pancreata recovered for islet cell research may have implications for performance measurement because the availability of islet cell research programs and related recovery practices can vary based on local clinical and research infrastructure. AOPO is concerned that these local factors could influence performance data in ways that are not directly tied to OPO operational effectiveness.

In addition, based on recent stakeholder discussions with CMS's Center for Clinical Standards and Quality (CCSQ), AOPO understands that the proposal to include pancreata recovered for research in the donation rate—but exclude those pancreata from the transplantation rate—may be the only policy in the Proposed Rule that CMS is considering applying to the next recertification cycle rather than the subsequent cycle scheduled to begin in April 2026. Because this potential timing distinction is not clearly articulated in the Proposed Rule, AOPO respectfully requests that CMS clarify in the final rule whether this interpretation is correct and specify the cycle in which any finalized policy would take effect.

The Proposed Rule also raises significant questions regarding research documentation. CMS should recognize that the overwhelming majority of deceased donor organ research is bench research exempt from Institutional Review Board (IRB) review. If IRB review documentation is required in defined circumstances, CMS should clarify that OPOs may rely on the principal investigator's home institution IRB review and are not separately required to arrange IRB review. CMS should define "qualified researcher" with objective criteria and ensure documentation requirements are proportional, not onerous, and relevant to patient safety or accountability.

Medically Complex Donors and Organs. CMS's proposed definitions acknowledge donor complexity and implicitly recognize that outcomes are influenced by factors outside the OPO's control. AOPO supports the concept of explicitly recognizing complexity but urges CMS to avoid an approach recognizing complexity while leaving tiering and enforcement unchanged. Establishing a medically complex donor category while declining to adjust the outcome measures (or provide meaningful accommodations) is incongruous and disadvantages OPOs whose donor populations include a disproportionately high percentage of medically complex donors, including high DCD percentages, which CMS recognizes in the proposed rule yield fewer organs.

The Proposed Rule acknowledges donor complexity by defining medically complex donors, including DCD donors and those with KDPI ≥ 50. However, the tiering methodology itself remains unchanged and unadjusted. Recognizing complexity without incorporating risk adjustment or recalibrating enforcement triggers creates structural tension. CMS should explain how medically complex donor populations will be operationalized within the comparative percentile framework to ensure fairness across DSAs with materially different clinical profiles.

Further, if CMS seeks to increase acceptance of organs from complex donors, CMS should consider mechanisms and incentives across the ecosystem—rather than holding OPOs accountable for acceptance decisions beyond their control, including but not limited to incentivizing transplant centers to utilize organs from complex donors, removing barriers that impact transplant center acceptance of organs from medically complex donors, ensuring metrics are aligned across the system for donor hospitals, OPOs and transplant centers, and rewarding transplant centers who accept medically complex organs.

B. Quality, Safety, and Oversight Changes (Proposed changes affecting 42 C.F.R. § 486.348 and related provisions)

QAPI Reporting, Thresholds, and Survey Expectations. AOPO supports Quality Assurance and Performance Improvement (QAPI) as a core framework for quality improvement and patient safety. However, CMS should clarify what constitutes an adverse event versus internally tracked quality signals (as detailed above), how surveyors will evaluate compliance, and what documentation formats and analytic methods will be deemed sufficient to demonstrate effective QAPI, root-cause analyses, corrective actions, and sustained improvement. The current definition appears overly broad and risks sweeping in matters—such as governance or administrative processes—that do not directly create immediate jeopardy for donors, recipients, or patients. CMS should ensure that the definition of adverse events is appropriately limited to clinical or operational failures that pose a direct risk to patient safety, rather than general performance or oversight concerns that are more appropriately addressed through routine QAPI monitoring and improvement processes.

CMS should also clarify how QAPI findings will be used in enforcement decisions, including determinations of "unsound medical practices" and any "urgent need" actions, and what procedural protections will apply before sanctions are imposed. Clear guardrails are necessary to ensure that QAPI remains a constructive quality improvement tool rather than a basis for punitive enforcement actions unrelated to immediate patient safety risks.

Death Declaration and Scope of OPO Responsibility. CMS references concern about the failure to verify death in accordance with applicable law and hospital policy.[11] However, OPOs and their clinical teams do not declare death; donor hospital staff do. CMS should clarify the standard for OPO responsibility, including the OPO's role to confirm that the hospital followed its policy and the policy complies with applicable law (local or state), not to independently evaluate or practice medicine with respect to death determination. CMS should clarify that OPOs do not independently evaluate or make the determination of death. CMS should also clarify that the medical community and OPOs appropriately follow distinct procedures for the declaration of brain death versus cardiac death.

Because the Proposed Rule links "unsound medical practices" to imminent-threat and immediate-termination authority, CMS should clearly delineate the scope of OPO responsibility from that of the hospital. Absent clarification, enforcement authority could extend beyond actions attributable to the OPO itself. Clear standards are necessary to preserve accountability while avoiding unintended and inappropriate expansion of clinical responsibility. AOPO also notes that the practice of medicine and the scope of clinical authority are governed primarily by state law and hospital medical staff governance structures. Accordingly, any federal enforcement

[11] 91 Fed. Reg. 4190, page 267

framework should recognize these boundaries and ensure that OPO accountability is aligned with responsibilities that OPOs are actually authorized to direct or control.

Testing for Exclusionary Conditions. CMS's examples that reference a failure to perform "necessary and customary tests" raise significant operational questions. CMS should clarify whether it intends to specify an exhaustive list of tests required to identify exclusionary conditions (i.e., specific active infections,), the expected timeframe for such testing, and how CMS will ensure requirements do not inadvertently delay recovery, increase non-use, or reduce transplants due to defensive testing practices. AOPO recommends CMS use the OPTN testing requirements as the definition of necessary and customary tests.

C. OPO Designation and Recertification Framework (Proposed changes affecting 42 C.F.R. §§ 486.316 and 486.318)

Multi-DSA Operation and Consolidation Decisions. AOPO requests clarification regarding how CMS will evaluate outcome measures when an OPO is designated to multiple DSAs and elects to merge or maintain separate DSAs. Because the Proposed Rule evaluates each DSA independently—and permits partial retention or partial loss of service areas—the unit of accountability effectively shifts from the organization as a whole to the DSA level. While this framework may preserve operations in certain regions, it also creates the potential for fragmented operational models and complex transition dynamics.

CMS should also clarify how mergers affect measurement periods, how much data is required before accountability attaches, and how CMS will prevent misalignment between operational transition timing and outcome-measure availability. When newly designated or reassigned DSAs are involved, CMS should specify which data period applies before performance accountability takes effect and how performance will be measured during transitional phases. Without clear standards, outcome measurement may not align with operational realities.

In addition, as the number of requests for hospital waivers continues to increase, CMS should provide guidance on how this may impact DSA assessment moving forward. Currently, when a hospital requests a waiver and it is granted, the county in which the hospital is located is split between the two OPOs based on the percent of Medicare inpatient deaths in the county at the waiver hospital and at all other hospitals in the county without reference to the actual donor potential from each hospital. However, this may not accurately reflect reality. Take for example a county with 5 hospitals in which 1 hospital has 20 potential donors and the other 4 hospitals each have 1 potential donor. If the hospital with 20 potential donors is granted permission to work with another OPO, splitting the population in this way advantages the new OPO and disadvantages the previous OPO in the metrics.

Competition Criteria and Contiguity. In the competition process, CMS states it will not apply tier status rigidly and will consider additional factors, including performance differences among competitors, sustained improvement, compliance history, success overcoming barriers, and contiguity as a tiebreaker. AOPO supports consideration of improvement trajectory and compliance history, but CMS should provide a clear, objective definition of "success overcoming barriers," specify what data and documentation CMS expects, and ensure the criteria are applied consistently and in a reviewable manner. CMS should also recognize the importance of continuity within donation service areas (DSAs) and prioritize the incumbent OPO where performance differences among competitors are not material. Incumbent OPOs maintain deeply established operational relationships with donor hospitals, transplant centers, and community partners that are critical to effective referral pathways, donor management, and organ allocation coordination. Preserving these relationships where appropriate can help avoid operational disruption and protect donation and transplantation volumes during transition periods.

The Proposed Rule also reflects CMS's revised interpretation of its certification authority, citing Loper Bright Enterprises v. Raimondo (2024), and asserts authority to certify entirely new OPOs and fill DSA vacancies with newly designated entities. CMS has previously stated that the purpose of the competition process is to identify the OPO best positioned to increase organ donation and transplantation within a DSA, including by evaluating how an organization has addressed and overcome barriers to donation within its service area. Demonstrated experience working within a DSA's unique hospital landscape, population health characteristics, and clinical infrastructure is therefore a critical factor in assessing performance. An entity without prior experience operating as an OPO would be unable to demonstrate how it has addressed these barriers or improved donation outcomes in practice. Accordingly, CMS should clarify how such entities would be evaluated within the competition framework and ensure that any certification process appropriately weighs demonstrated operational experience and performance in overcoming DSA-specific barriers**.** To the extent CMS has the statutory authority to incorporate such considerations into the competition and certification process, the agency should clarify how continuity and existing operational relationships will be weighed when evaluating potential replacement OPOs.

The organ donation and transplantation system is an integral part of our healthcare system and one of the few remaining sectors within healthcare that is still led by nonprofit organizations. As AOPO has stated before[12] and continues to believe that the certification of new OPOs should include a requirement that an OPO be a non-profit organization to ensure that the altruistic, selfless donation and gift of a life-sustaining organ are complemented by non-profit organizations, ensuring that the lasting gift reaches those in need.

[12] https://aopo.org/aopo-statement-on-cms-proposed-rule-on-opo-oversight/

AOPO also urges CMS to weigh contiguity more meaningfully, not merely as a tiebreaker, given the operational complexity and time sensitivity of organ recovery and distribution, and the efficiencies created by geographic proximity and the significant learning curve for newly designated OPOs to a DSA in a region or area in which they have never before operated and where they lack relationships with donor and transplant hospitals and the community.

While discretion can enable fairness, undefined discretion risks unpredictability and inconsistent outcomes across DSAs. Given that competition under the Proposed Rule becomes continuous rather than episodic—with Tier 1 and Tier 2 OPOs (including Tier 2 OPOs that have not been successful in competition but have not been decertified) - eligible to compete for open DSAs—CMS should provide objective, reviewable standards and transparent documentation expectations for factors such as sustained improvement, barrier mitigation, and contiguity to ensure consistent and equitable application.

Transition Timing and Continuity. CMS proposes flexibility to extend designation periods and, in limited circumstances, designate a successor without competition when time is insufficient. AOPO requests that CMS clearly define the circumstances that may trigger such actions, the notice and transparency obligations, and the available due process protections and criteria for selection of a successor under such circumstances.

As CMS finalizes these provisions in a post-Chevron environment in which statutory interpretation receives heightened judicial scrutiny, clarity and procedural precision are particularly important. Transparent standards governing transition decisions will strengthen the durability of the final rule and promote stakeholder confidence.

In all cases, CMS should prioritize continuity of donation operations and provide realistic timelines, recognizing that transitions involve complex operational, legal, and governance factors in addition to clinical operations.

D. Non-Renewal of Tier 2 OPO Agreements; Decertification, Removal, and Practical Effect

CMS proposes to define "non-renewal" in circumstances including when a Tier 2 OPO is unsuccessful in competition and is no longer designated to any DSA, while distinguishing that outcome from "decertification."

Under the Proposed Rule, a Tier 2 OPO that loses competition for its DSA—and is not reassigned—would face non-renewal and eventual removal from the service area, even if it has met outcome and process measures. This is a distinction without a difference. The legal and practical effects are the same; CMS has stripped the OPO of its DSA, and the OPO needs a DSA to be certified and function as an OPO. In practical terms, competition becomes existential for certain DSAs.

AOPO also urges CMS to reconsider the assumption that a competitive process may be used to require incumbent OPOs to compete to retain their designated service areas. The governing statute authorizes the Secretary to designate OPOs to serve specific DSAs and to terminate or redesignate OPOs that fail to meet applicable performance requirements. The statute does not establish or authorize a competition-based process through which incumbent OPOs must periodically compete to retain their DSAs. Requiring incumbent OPOs to compete against other entities, including entities without OPO operational experience, to retain a service area constitutes a material departure from the statutory designation framework.

Moreover, the operational consequences of removing an OPO from a DSA through a competitive reassignment process would be indistinguishable from decertification. Loss of designation, regardless of how it is characterized, would require transition of hospital relationships, workforce realignment, re-establishment of referral pathways, and reconstruction of the operational infrastructure necessary to support organ donation. Because the statute provides specific mechanisms to address underperformance through performance standards and decertification, CMS should not create an additional competition-based pathway to remove an OPO from a DSA.

CMS should also ensure that Tier 2 OPOs that meet outcome and process measures are treated equitably, and that the competition framework does not cause unnecessary disruption as performance improves. CMS should also clarify the availability of administrative review for consequential decisions affecting Tier 2 DSAs, particularly where the practical result is removal from the service area. Because competition outcomes are designated as final and not subject to traditional appeal rights, CMS should ensure that, at a minimum, procedural safeguards are commensurate with the operational and public health consequences of DSA removal.

AOPO also respectfully requests that CMS reconsider whether a complete absence of administrative review for competition determinations is consistent with longstanding CMS provider appeal frameworks and general administrative law principles. Decisions resulting in the loss of a DSA designation carry significant operational, economic, and public health consequences, including disruption to hospital referral relationships, workforce displacement, and impacts on transplant access. In analogous CMS programs, entities facing termination or non-renewal of participation agreements are afforded administrative review through established hearing processes. Providing a structured review pathway for Tier 2 competition determinations would promote transparency, procedural fairness, and consistency with broader CMS regulatory practice while preserving the agency's ability to implement timely decisions.

E. Appeals Process (Proposed changes affecting 42 C.F.R. § 486.314)

When considering what is at stake — loss of a DSA, partial decertification, or full decertification — the appeal window becomes critical. AOPO recognizes CMS's objective of clarifying appeals in the multi-DSA context and ensuring timely resolution. However, the Proposed Rule significantly

compresses key appeal timelines, most notably reducing the period to request a hearing from 40 business days to 15 calendar days.

Shorter timelines mean:

- Less time to gather data.
- Less time to prepare evidentiary submissions.
- Less time to coordinate legal and operational responses.
- Increased need for proactive documentation before any notice is issued.

Given the magnitude of consequences associated with DSA removal or decertification, CMS should ensure appeal timelines are operationally workable and preserve meaningful due process protections commensurate with the impact on hospitals, donor families, and transplant candidates.

At the same time, CMS extends the time for the hearing officer to issue a decision — up to 90 calendar days. So, the burden shifts toward rapid response by the OPO, with longer deliberation time on the CMS side. CMS should clarify how discretionary reviews will be exercised, the criteria for review, and how the record will be developed to ensure fair and transparent adjudication. Given the significance of certification and decertification determinations for patients, hospitals, and the broader transplant system, AOPO also encourages CMS to require—not merely permit—Administrator review of a hearing officer's decision. Requiring Administrator review for such consequential determinations would promote transparency, consistency, and fairness in the adjudication process.

F. Human Resources and Licensure (Proposed changes affecting 42 C.F.R. § 486.326)

CMS proposes licensure or registration expectations for personnel performing clinical duties. AOPO respectfully requests that CMS clearly define the roles covered by this proposal and confirm that licensure requirements apply only in circumstances where such licensure is required under applicable state law. The regulation of licensure and scope of medical practice has historically been the authority of state governments, and any federal requirements should recognize those boundaries. CMS should also clearly articulate the problem it is seeking to address through new licensure requirements and explain the evidence demonstrating why such requirements are necessary at this time.

It is important to recognize that the work performed by OPO staff is distinct from the practice of medicine performed by licensed healthcare professionals. OPO personnel provide operational coordination, donor management support, and family services, but do not independently provide medical care to patients prior to death. Donor management activities that occur prior to

declaration are conducted as a collaborative effort between the donor hospital's licensed clinical team and the OPO under established medical oversight and hospital protocols. Clinical care of the patient—including interventions associated with donation after circulatory death (DCD)—remains the responsibility of the hospital and its licensed clinical staff. In DCD pathways, the hospital's clinical team retains full responsibility for patient care decisions, including withdrawal of life-sustaining treatment, and OPO personnel do not direct or manage that care. OPO involvement occurs within a clearly defined framework and under medical oversight once donation has been authorized in accordance with applicable medical and legal standards. A recent CMS memorandum[13] further reinforces this division of responsibility, clarifying that OPOs may not be involved in decisions regarding withdrawal of life support or declaration of death, which remain the responsibility of the hospital's attending physician and clinical team. The Proposed Rule should therefore clearly recognize the operational and clinical division of responsibility between donor hospitals and OPOs to avoid inadvertently expanding the scope of licensure expectations to roles that do not constitute the practice of medicine.

AOPO also has significant concerns with the Proposed Rule's emphasis on state-based licensure requirements for OPO personnel. The organ donation workforce operates under well-established medical oversight structures within donor hospitals and transplant systems, and imposing new licensure or certification requirements for OPO personnel is unnecessary and risks creating substantial workforce disruption. Consistent with the aforementioned memorandum to State Survey Agency Directors, hospital–OPO agreements already require OPOs to provide qualified and appropriately trained personnel to perform donation coordination, family support, donor management guidance, and recovery coordination functions. Many OPO clinical staff currently perform critical operational and coordination functions that do not constitute the practice of medicine and therefore do not require professional licensure. Introducing new licensure expectations could materially reduce workforce capacity and impede the ability of OPOs to maintain timely and effective donation operations. CMS's recent survey memo likewise emphasizes trained and qualified personnel—such as designated requestors—rather than licensed personnel when describing the roles of OPO staff involved in donation coordination and family discussions. CMS should therefore clarify that additional licensure or certification requirements are not required for OPO personnel performing these roles.

In addition, the Proposed Rule appears to emphasize state-based licensure without recognizing existing models, such as the American Board of Transplant Certification (ABTC), including the Clinical Procurement Transplant Coordinator (CPTC) and Certified Transplant Preservationist (CTP). These national certifications and training standards represent nationally recognized competency-based qualifications for personnel involved in organ donation coordination and recovery operations. They have long supported patient safety, regulatory compliance, and

[13] Organ Procurement Organizations (OPOs) and Donor Hospitals' Responsibilities

system performance nationwide within established medical oversight structures in donor hospitals and transplant systems. If finalized without clarification—or without a clear pathway for recognition of nationally certified or otherwise qualified personnel as meeting qualification standards—the proposal could materially impede the ability of portions of the OPO clinical and operational workforce to continue providing services integral to the organ donation process.

Operational realities further underscore the importance of flexibility in personnel qualification frameworks. Many OPOs operate across multiple DSAs and, in some cases, across multiple states. Imposing new state-based licensure requirements for roles that are not currently subject to licensure could require staff to obtain and maintain multiple state licenses, creating significant administrative burden and exacerbating existing workforce constraints. At a time when the donation system is already facing significant disruption associated with potential large-scale OPO decertification, such requirements could create additional operational continuity challenges.

AOPO further requests clarification regarding how any new licensure or personnel qualification requirements will interact with existing hospital policies and oversight frameworks governing OPO personnel; and whether such requirements could have unintended implications for workforce mobility, cross-state operations, or the ability of OPOs to deploy qualified personnel efficiently across service areas.

CMS should ensure that the final rule preserves flexibility for qualified and appropriately trained personnel operating under established medical oversight and clearly reflects the distinct roles of donor hospitals and OPOs within the donation process. Any licensure or personnel qualification framework should support the continued functioning of OPO clinical teams without imposing new licensure requirements for roles that do not constitute the practice of medicine and without disrupting the operational workforce necessary to support effective organ donation.

Conflicts of Interest. CMS raises concerns about conflicts of interest arising from OPO relationships with tissue processors and other entities. OPOs already operate under robust nonprofit governance standards and IRS requirements and maintain formal conflict-of-interest policies and practices. The Internal Revenue Service (IRS), which oversees nonprofit and charitable organizations, requires an attestation on Form 990 in which nonprofit organizations must answer an express question regarding whether they maintain a written conflict-of-interest policy. There are also longstanding provisions under the Sarbanes-Oxley Act of 2002 which—while not directly applicable to nonprofit entities—have been widely adopted as governance best practices and are followed by many nonprofit organizations with respect to conflict-of-interest oversight.

In addition, a variety of conflict-of-interest governance recommendations have been developed by non-governmental entities such as the American Society of Association Executives (ASAE),

which has outlined essential elements of conflict-of-interest policies for associations. These widely recognized governance frameworks may provide a useful reference point should CMS seek to better understand existing nonprofit governance practices.

AOPO also notes that CMS does not impose provider- or supplier-specific conflict-of-interest regulatory requirements on other Medicare providers or suppliers. Any new requirements targeted specifically at OPOs should therefore be carefully justified and consistent with broader healthcare governance practices. AOPO further notes that HRSA has already initiated efforts to evaluate potential conflict-of-interest considerations within the organ donation and transplantation system. CMS should take this ongoing work into account to avoid duplicative or overlapping regulatory requirements.

Any CMS policy development should therefore be evidence-based, narrowly tailored, and consistent with governance norms across healthcare and nonprofit entities, rather than premised on generalized and often unsupported narratives.

Allocation Out of Sequence. CMS expresses concerns about the out-of-sequence allocation and its impact on fairness and public trust. AOPO urges CMS to coordinate closely with HRSA and OPTN to avoid duplicative or conflicting standards and to recognize ongoing stakeholder engagement in this area. Any CMS approach should balance fairness, utilization, and trust, and clearly identify what is expected of OPOs versus transplant centers and how those expectations align with OPTN governance processes. For example, the OPTN allocation out-of-sequence workgroup has three draft proposals submitted to HRSA that address the definition of an 'offer,' an expedited protocol for hard-to-place kidneys, and approaches to improve compliance with OPTN allocation policies.

Studies conducted by New York University (NYU) Langone Health, the New England Donor Services, Harvard Medical School, and the Brown University School of Public Health have highlighted the impact of changes to out-of-sequence allocation policies on organ utilization, specifically kidney recovery, use, and non-use. The study conducted by NYU Langone Health sought to assess the impact of an OPTN memorandum that raised the possibility of sanctions on OPOs for allocation out of sequence, and to examine the memorandum's effect on kidney recovery, nonuse, and kidney transplant rates. The study found that post-memorandum, allocation out of sequence decreased sharply; however, so did kidney recovery and transplantation. The study notes that "[w]hile loosely regulated [allocation out of sequence] threatened allocation equity, discouraging all [allocation out of sequence] without addressing barriers to placement efficiency, including allocation complexity and center heterogeneity in accepting lower-quality kidneys," may decrease transplant access.[14]

[14] https://pmc.ncbi.nlm.nih.gov/articles/PMC12826291/pdf/nihms-2132044.pdf

In the second study, deceased kidneys recovered by New England Donor Services were allocated strictly per the OPTN kidney match-run sequence without the use of allocation out of sequence. Compared to a prior 12-month reference period, overall kidney nonuse during the test period increased from 29.1 percent to 43.2 percent. Based on prior utilization rates, the study estimated that an additional 13 kidneys would have been transplanted if expedited placement had been used, and its findings suggested that "eliminating rescue allocation without a standardized alternative may increase nonuse and underscore the need for transparent, nationally defined" strategies.[15]

Automated Electronic Referrals. AOPO supports modernizing the organ donation and transplantation system through automated electronic referrals and appreciates CMS's solicitation of public comment on this topic. Electronic referral is a practical, system-level improvement that can reduce missed or delayed notifications, streamline coordination between donor hospitals and OPOs, and improve the speed and reliability of donor evaluation and matching—without compromising patient safety or clinical judgment. Today, many hospitals still rely on manual referral processes, often by phone, to notify OPOs when a patient's death is considered imminent based on clinical criteria and when withdrawal of life-sustaining interventions or potential donation is being discussed. Studies and operational experience have shown that OPOs are not consistently notified of all potential donors, or that notifications are delayed, particularly in high-volume or resource-constrained settings. These gaps can result in lost donation opportunities and introduce unnecessary administrative burden for hospital staff and OPO personnel.

Automation of deceased donor referrals using standardized clinical triggers can address these operational challenges by ensuring timely, objective notification to the local OPO when defined clinical indicators are documented in the electronic health record (EHR). When technology identifies relevant indicators—such as documentation consistent with severe brain injury or other qualifying clinical criteria information can be transmitted to the hospital's OPO in real time, allowing the OPO to initiate prompt donor suitability evaluation, coordinate with the care team, and reduce reliance on subjective decision-making or manual workflows by busy hospital staff. When properly designed, electronic referrals can promote real-time information sharing among stakeholders, streamline donor-recipient matching based on clinical criteria, reduce administrative burdens, and enhance reliability in the referral pathway—thereby increasing the likelihood that organs are recovered and reach patients who need them.

AOPO also notes that Congress has recognized the promise of electronic referral and is advancing bipartisan legislation directly addressing the policy objectives CMS identifies in this Proposed Rule. The bipartisan *Removing Burdens for Organ Donation Act* reflects a common-sense,

[15] https://www.amjtransplant.org/article/S1600-6135(26)00096-1/fulltext

bipartisan policy direction toward modernization through workflow automation and interoperability. We encourage CMS to work with Congress toward advancing these efforts.

Operational experience reinforces the value of electronic referrals. Several OPOs began implementing electronic referral solutions years before Congress and policymakers began emphasizing this approach as an innovative strategy to improve organ donation and transplantation. For example, New England Donor Services (NEDS) implemented an electronic health record–based referral system beginning in 2021 that integrates hospital EHR data with OPO workflows to facilitate earlier identification of potential donors and more timely evaluation of donation opportunities. Early results from this effort demonstrated improvements in donor identification and operational coordination within participating hospitals

Most recently, in 2023, the Arkansas Regional Organ Recovery Agency (ARORA) (now known as Southern Legacy of Life) partnered with InVita Healthcare Technologies to launch an interoperable service linking 12 partner hospitals, enabling automatic identification and immediate electronic donor referral. The program generated more than 1,000 referrals of potential donors and achieved substantial operational efficiencies, including more than 340 hours of staff time saved that would otherwise have been spent on manual referral calls. ARORA also reported significant increases in referrals of ventilated patients, accompanied by increases in donors and organs transplanted.

While individual experiences vary by hospital and region, this example demonstrates that electronic referral can be both feasible and impactful when integrated into hospital workflows, providing OPOs with timely access to the information needed to evaluate and coordinate donation opportunities.

As CMS considers how to advance automated referral policy, AOPO encourages CMS to provide clear implementation guardrails and interoperability expectations while avoiding unfunded mandates or overly prescriptive technical requirements that would impede adoption across heterogeneous EHR environments. CMS should also ensure any future approach aligns with HRSA/OPTN requirements and supports donor hospitals and OPOs through practical guidance and phased implementation. In AOPO's view, electronic referral modernization represents a "win-win"—reducing burden, improving reliability, lowering costs, and increasing the likelihood that donation opportunities result in lives saved

VI. Conclusion

AOPO appreciates CMS's engagement and reiterates our unwavering commitment to restoring and strengthening public trust in the organ donation and transplantation system. We share CMS's goal of maximizing organ donation and transplantation. To achieve this, CMS should ensure that

accountability, data integrity, patient safety, and system stability advance in tandem. AOPO urges CMS to:

1. Address the implementation-critical clarifications identified in this letter (and summarized in Appendix A), including effective dates and applicability; attribution principles and reporting thresholds; and due process and administrative appeal protections commensurate with the consequences for DSAs, hospitals, and patients;
2. Align requirements with OPTN/HRSA where there is overlap to avoid duplicative burdens;
3. Provide clear, objective standards for medically complex donors and incorporate risk adjustment;
4. Correct inconsistencies in pancreas-for-research treatment across outcome measures and clarify proportional research documentation expectations;
5. Ensure competition/non-renewal frameworks are transparent, equitable, and stability-preserving, including clear transition expectations;
6. Preserve meaningful due process protections and workable administrative appeal timelines; and
7. Sequence major enforcement actions to avoid destabilization while validated, consensus-based measures are finalized through Econometrica.

AOPO stands ready to work collaboratively with CMS to improve performance and protect the continuity of donation operations—so that more patients receive life-saving transplants.

Thank you for your consideration.

Sincerely,

Jeffrey Trageser

AOPO President

Executive Director, Lifesharing

(Appendix A follows.)

Appendix A: Requested Clarifications and Technical Questions

AOPO respectfully requests that CMS address the following questions in the final rule and/or accompanying guidance:

1. **Effective Dates / Applicability.** What are the effective and implementation dates for each major policy change in the Proposed Rule? Will any changes apply to the current agreement cycle ending July 31, 2026, and if so, how will CMS address fairness concerns where surveys and compliance expectations would change mid-cycle?

2. **Outcome Measures Remain Central.** CMS maintains the existing two outcome measures. What is CMS's plan and timeline to incorporate additional, attributable process measures beyond those framed as Conditions for Coverage, and how will CMS evaluate whether the current outcomes framework and the accompanying measures are producing unintended destabilization?

3. **"Process Measures" Characterization.** CMS emphasizes process measures and QAPI requirements. What is CMS's legal and analytical basis for re-characterizing Conditions for Coverage as "process measures" for purposes of recertification, where the statute contemplates both process and multiple outcome measures?

4. **Appeals and Due Process.** How does CMS justify truncating appeal timelines and limiting flexibility (including removing "modification" authority) given the severity of consequences for DSAs, hospitals, and patients? What safeguards ensure due process is preserved?

5. **Adverse Events vs. Unsound Medical Practices.** Will CMS clarify that "unsound medical practices" are a subset of adverse events, rather than a separate category that risks capturing governance and systems issues without imminent patient harm?

6. **Adverse Event Thresholds.** What thresholds (severity, frequency, actual vs. potential harm) will CMS use to determine what is "reportable" as an adverse event versus internally tracked QAPI signals?

7. **Alignment with OPTN/HRSA Reporting.** How will CMS harmonize adverse events and patient safety reporting expectations with OPTN/HRSA requirements to avoid duplicative standards?

8. **QAPI Documentation Standards.** What specific documentation formats, analytic methods, and evidence will surveyors deem sufficient to demonstrate effective QAPI, root-cause analyses, corrective actions, and sustained improvement?

9. **Medically Complex Donor Definition.** How will CMS define "medically complex donors," including whether KDPI alone will be determinative, whether thresholds will vary by organ type, and whether other factors (e.g., DCD status, age, comorbidities) must be incorporated?

10. **Risk Adjustment / Fairness for Complexity.** If CMS recognizes that medically complex donors are harder to place, how will CMS adjust performance expectations so OPOs are not disadvantaged for serving DSAs with more complex patient and donor profiles (e.g., higher DCD percentages)?

11. **Death Declaration.** What is the standard for an OPO to "ensure" death has been declared according to state law, given hospital care teams declare death? Is CMS placing OPOs in the position of practicing medicine? How will CMS treat cases where a hospital's declaration process is deficient, and will any parallel accountability apply to hospitals?

12. **Testing for Exclusionary Conditions.** Does CMS intend to specify an exhaustive list of "necessary and customary tests" to identify exclusionary conditions (active infections,)? What timeframe will CMS expect for testing, and how will CMS avoid disincentivizing timely recovery/placement and increasing non-use due to delays? Will inclusion of a test on a potentially exhaustive list refer or infer changes to reimbursement as these tests become mandatory?

13. **"Inappropriately High Neurologic Function."** What does CMS mean by "pursuing patients with inappropriately high neurologic function as potential donors"? What thresholds and clinical criteria apply? What does "pursuing" encompass? How will CMS avoid unintended exclusion of donors such as amyotrophic lateral sclerosis (ALS) or spinal cord injury patients and avoid deterring appropriate DCD evaluation pathways?

14. **Transport Issues Categorization.** Why does CMS include "transport practices and procedures" as a potentially "unsound medical practice," given transport failures may be entirely outside OPO control, including weather related delays and mishandling by airline personnel? Will CMS establish a separate category with defined thresholds to address systemic transport failures distinct from clinical safety practices?

15. **Pancreata for Research — Outcome Metric Consistency.** How does CMS justify counting certain pancreata recovered for research in the donation rate but excluding them from the transplantation rate, and how will CMS ensure the resulting asymmetry does not create gaming incentives or distort tiering?

16. **Research Documentation Burden.** Will CMS confirm that for research activity (particularly bench research), OPOs may rely on the Principal Investigator's (PI) institutional IRB determination where applicable and that documentation requirements

will be proportional to research type? How will CMS define "qualified researcher," and what documentation is required?

17. **Licensure Scope.** Which roles are considered "personnel performing clinical duties" under proposed licensure requirements? Does this apply to physicians only, nurses, recovery staff, coordinators, or others? Will CMS confirm licensure is required only where state law requires it?

18. **Credentialing, Privilege, and NPDB.** How does CMS anticipate OPO credentialing requirements interact with hospital credentialing frameworks? Are OPO-to-OPO credentialing communications protected by peer review privilege? Are adverse credentialing decisions reportable to the National Practitioner Data Bank?

19. **Competition Criteria — "Overcoming Barriers."** CMS indicates "demonstrated success overcoming barriers to donation" will be considered as part of competitions for DSAs. What is the definition, how will it be measured, what documentation is required, and what standards ensure consistent, reviewable application?

20. **Contiguity Meaning.** What constitutes "contiguity" and how will it be weighted? Is contiguity strictly geographic adjacency, or are there other factors? How will CMS reconcile contiguity with prior selections involving non-contiguous DSAs?

21. **Transition Cooperation and Proprietary Materials.** CMS proposes cooperation requirements during transitions. What is CMS's authority to require transfer of proprietary policies, procedures, or operational materials? What is the minimum required cooperation versus voluntary sharing, and how will CMS set realistic timelines?

22. **Successor Assignment Without Competition.** In what circumstances will CMS bypass competition and designate a successor OPO due to insufficient time? What criteria will apply, what notice will be provided, and what due process protections will exist?

23. **Use of QAPI in Enforcement.** How will CMS use QAPI findings and adverse event trends in enforcement determinations, including "urgent need" actions, and what procedural protections will apply before sanctions are imposed?

24. **Ecosystem Alignment.** How will CMS ensure expectations for medically complex donor optimization and utilization are aligned with transplant center incentives and responsibilities, such that OPOs are not held accountable for decisions beyond their control?