June 9, 2026

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

Re: Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2027 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1849-P)

Dear Administrator Oz:

The Association of Organ Procurement Organizations (AOPO) welcomes the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Fiscal Year 2027 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes proposed rule (CMS-1849-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 nationwide. This work integrates medical, logistical, regulatory, and family support functions and is performed continuously, 24 hours a day, 7 days a week.

Nationwide, OPOs collectively partner with approximately 6,000 acute care hospitals, with each OPO working with roughly 12 to more than 250 hospitals within its designated Donation Service Area (DSA). The significant variation reflects differences in geography, population density, hospital distribution, and regional healthcare infrastructure across DSAs. Some OPOs serve large, densely populated metropolitan regions with extensive hospital networks and major academic medical centers, while others cover predominantly rural or geographically expansive areas with fewer hospitals spread across multiple states or territories. In addition, DSAs vary considerably in population size, donor potential, trauma center concentration, transplant center presence, and healthcare utilization patterns, all of which influence the number and type of hospital partnerships required to support organ donation activities. Despite these operational differences, OPOs collectively supported 46,129 organs transplanted from deceased donors, which marked a 2% increase from 2024. On average, 134 organ transplants are performed every day, resulting in 40,054 lives saved through deceased organ donation.

To continue the upward momentum in organ donations and lives saved, AOPO has undertaken an extensive, multi-pronged campaign to reach 50,000 organ transplants in 2026 through sharing best practices among OPOs, maximizing organ utilization, and driving innovation. Specifically, AOPO has identified several ways to fulfill this pledge, including automated transfer of data from electronic health records at donor hospitals to OPOs for potential donors, expansion of new perfusion technologies to preserve organs for longer periods, and enhanced tracking technology to improve the transportation and delivery of organs.

However, these ambitious goals and investments in perfusion technology, data sharing, and enhanced tracking needed to save more American lives are colliding with an increasingly complex and volatile regulatory environment for OPOs. OPOs are quickly approaching the conclusion of the 2022–2026 re-certification cycle on July 31, 2026, which will mark the first time CMS uses the outcome-based tier system finalized in the December 2020 final Conditions for Coverage (CfC) rule to make re-certification and de-certification determinations. Performance data released by CMS — which remains more than two years behind real-time operations — indicate that as many as 10 OPOs could be assigned to Tier 3 status, placing them at risk of decertification, while an additional 16 OPOs could fall into Tier 2, making their Donation Service Areas (DSAs) open to competition. Collectively, this would place approximately 26 of the nation's 55 DSAs in a competitive process that has never been implemented before. That would mean approximately 70 percent of the U.S. population may have an OPO that is in flux, potentially leading to disruptions in organ donation and transplantation.

Additionally, CMS proposed major changes to the OPO CfCs in the January 2026 Notice of Proposed Rulemaking, further revising the 2020 final rule. Proposed changes include the creation of a new multi-DSA operational model allowing a single OPO to serve multiple donation service areas; removal of longstanding regulatory barriers that have effectively prevented the certification of new OPOs for decades; a newly created distinction between non-renewal and decertification that would allow Tier 2 OPOs that lose competition to remain certified without an assigned service area; expanded Quality Assessment and Performance Improvement (QAPI) requirements, including annual assessments of medically complex donor policies and performance; and new clinical staff licensure verification requirements. CMS estimates these proposed changes would impose approximately $19.1 million in first-year costs and $6.3 million in recurring annual costs across the OPO community.

Furthermore, CMS has intensified its survey and enforcement posture in two recent sub-regulatory actions. In May 2026, after many surveys had already been completed and others were underway, CMS issued a comprehensive revision to Appendix Y of the State Operations Manual, which governs how federal surveyors inspect OPOs for compliance with the Conditions for Coverage. The revised Appendix Y details a rigorous six-task survey process, conducted on an unannounced basis, in which surveyors review a minimum of 10 donor records, at least five personnel files, death record review logs from three hospitals over three months, four years of advisory board and governing body minutes, and a wide range of agreements, protocols, and policies.

Separately, in March 2026—after the close of the four-year certification cycle and after surveys had already been completed or were underway—CMS issued a memorandum to State Survey Agency Directors purporting to clarify and reinforce the respective roles and responsibilities of OPOs and donor hospitals during the organ donation and procurement process. The memorandum directs surveyors to investigate allegations of noncompliance through staff and patient interviews at both OPOs and hospitals and instructs surveyors to interview donor families or legally authorized representatives regarding their experience with the consent process, including whether they felt rushed, pressured, harassed, or

obligated to donate. Critically, the memorandum adopts a strict enforcement posture, stating that "[n]oncompliance related to this issue must be cited once identified, even if the deficiency has been corrected at the time of the survey." The memorandum further directs surveyors to cite either one or both entities—the OPO and/or hospital—if required agreement provisions are missing or if either party fails to comply with applicable regulatory requirements. While OPOs support strong accountability and consistent oversight standards, the memorandum's timing, and expanded scope of surveyor inquiry into sensitive family interactions and end-of-life care decisions create significant operational and interpretive challenges during an already highly scrutinized recertification period.

AOPO shares CMS' commitment to transparency, program integrity, and accountability across the organ donation and transplantation system. At the same time, the changes contained in the IPPS proposed rule would fundamentally restructure the payment methodology for non-renal organ acquisition costs, just as OPOs are facing major certification, survey, enforcement, and operational changes. CMS should evaluate the proposed OPO reimbursement framework considering this rapidly shifting and intensifying regulatory and compliance environment. Specifically, CMS proposes extending reasonable cost reconciliation and related oversight from renal organ acquisition to non-renal organ acquisition, requiring Medicare Administrative Contractors (MACs) to establish and publish non-renal standard acquisition charges (SACs) and histocompatibility lab (HCL) rates, and tightening cost-allowability rules.

Unlike many other Medicare providers and suppliers, OPOs operate in a highly unpredictable environment where costs fluctuate based on donor availability, transplant center acceptance decisions, transportation logistics, clinical complexity, organ utilization patterns, and technological and clinical innovation. OPOs must sustain 24/7 staffing, transportation coordination, clinical recovery capabilities, laboratory services, and hospital relationships regardless of fluctuations in donor volume or organ placement outcomes. Policies that create prolonged reimbursement delays, retroactive repayment obligations, or reimbursement uncertainty may impair OPOs' ability to make the ongoing investments necessary to maximize donation and transplantation.

AOPO is particularly concerned that:

- Reversing decades-long OPO reimbursement policies based on a broad interpretation of a narrow statute without considering OPOs' reliance on the current non-renal organ acquisition cost methodology exceeds CMS' statutory authority.
- The current reimbursement framework better preserves the operational stability and flexibility that OPOs need to maintain and increase organ procurement and transplantation. By contrast, a zero-margin non-renal organ acquisition reimbursement methodology and contractor-established rates based on historical cost data would shift significant financial risk to OPOs and may lag real-time cost increases by 12 months or more, creating a rate-setting mismatch for urgent procurement activity that must respond immediately to changing clinical, logistical, and market conditions**.** Such policies threaten OPOs' mission to recover and place organs, especially from medically complex donors, unintentionally discouraging investments in innovation, transportation logistics, organ preservation technologies, cybersecurity infrastructure, and organ utilization initiatives.
- CMS's analytical assumptions regarding approximately $100 million in alleged "excess" non-renal revenue appear overstated and are not fully transparent, making it unclear how CMS arrived at this estimate. Further, the analysis may not fully account for timing differences, donor variability, non-utilized organ costs, year-over-year operational volatility, and the unique fixed and standby costs associated with maintaining 24/7 organ recovery infrastructure.

- Retrospective reconciliation and contractor-established organ-specific SACs could create significant cash flow instability and administrative burden. Moreover, the proposal would likely require additional taxpayer-funded resources for Medicare Administrative Contractors (MACs) to conduct expanded monitoring, auditing, reconciliation, and oversight activities.
- Abrupt implementation of these policies could destabilize portions of the donation and transplantation infrastructure and conflict with broader U.S. Department of Health and Human Services (HHS) modernization goals and CMS initiatives to incentivize recovery of organs from medically complex donors.

Accordingly, AOPO recommends that CMS:

- Retain the existing reimbursement framework for non-renal organ acquisition costs.
- Decline to finalize a reimbursement methodology that effectively requires OPOs to operate with no margin or that applies broad reimbursement changes to allowable costs beyond services associated with Medicare transplant beneficiaries. If CMS nevertheless pursues additional changes, the agency should first study reasonable margin approaches for organ-specific costs, including reviewing comparable policies for critical access hospitals and other reasonable cost-based reimbursement frameworks.
- Utilize targeted oversight and audit mechanisms rather than universal retrospective reconciliation.
- Decline to adopt contractor-established organ-specific SACs for non-renal organs.
- Further evaluate the assumptions and methodologies underlying CMS's financial analysis.
- Consider donor family aftercare services, including bereavement and donor recognition, allowable costs.
- Preserve flexibility for locally tailored and national public education and donor outreach activities, including participation in initiatives conducted in partnership with national organizations, as the Health Resources and Services Administration (HRSA) alone does not provide sufficient public education, awareness, or donor engagement resources to support nationwide donor registration and organ donation efforts. CMS should continue to recognize these activities as allowable costs. CMS should also preserve flexibility for hospital education, clinical coordination, employee engagement, and staff recognition initiatives that support workforce recruitment, retention, morale, and readiness among specialized donation personnel. These activities are integral to maintaining a stable, high-performing organ donation infrastructure and should likewise continue to be recognized as allowable and necessary costs within the organ donation system.
- If CMS finalizes any structural payment changes, it should adopt a phased implementation timeline with clear sub-regulatory guidance, transition safeguards, and stakeholder engagement before each phase takes effect.

AOPO offers these recommendations to preserve CMS' payment integrity objectives while avoiding unnecessary disruption to the organ procurement infrastructure that supports organ availability, workforce retention, innovation, and long-term transplantation capacity.

AOPO provides the following detailed comments in five parts. First, AOPO explains OPOs' unique operations and why payment stability is necessary to maximize organ acquisition and transplantation. Second, AOPO addresses CMS' financial analysis, data limitations, and burden estimate. Third, AOPO explains why CMS' proposal to extend kidney acquisition cost policies to non-renal organs exceeds the agency's statutory authority and fails to account for settled reliance interests. Fourth, AOPO explains why CMS should not adopt a zero-margin payment policy that would undermine OPOs' mission to increase

organ donation and save lives. Finally, AOPO responds to specific proposals and offers targeted recommendations, guardrails, and phased implementation timetables if CMS proceeds.

I. Background: OPO Operational Realities and the Importance of Payment Stability

A. OPOs Maintain Continuous Readiness in a Highly Unpredictable Environment

OPOs operate unlike traditional episodic healthcare providers. Organ donation opportunities are unpredictable, time-sensitive, and geographically dispersed. Therefore, OPOs must maintain continuous operational readiness 24 hours per day, 7 days per week, regardless of fluctuations in donor volume or organ utilization. This infrastructure includes:

- Clinical recovery teams;
- Organ preservation and perfusion capabilities;
- Transportation coordination and logistics;
- HCL services;
- Hospital development and referral relationships;
- Staff to allocate organs to patients on the match run;
- Family support and authorization services;
- Staff to take and screen referrals;
- Clinical staff to perform donor management; and
- Community outreach and donor education initiatives.

Many of these costs are fixed or semi-fixed and cannot be scaled down in response to temporary fluctuations in donor availability, organ utilization, or reimbursement timing. OPOs must also make rapid, real-time operational decisions based on evolving donor circumstances, transplant center acceptance patterns, weather events, transportation limitations, and clinical considerations. Even modest reductions in operational flexibility can translate into fewer organs recovered, fewer organs transported successfully, fewer medically complex donors pursued, and ultimately fewer transplants performed. These operational realities should inform CMS' evaluation of any reimbursement methodology that depends on retrospective reconciliation, historical cost data, or delayed rate adjustments.

B. Organ Procurement Costs Are Operationally Complex and Variable

OPOs operate in a clinically and operationally dynamic environment where costs fluctuate significantly due to factors often outside the OPO's control. Donor complexity, organ utilization decisions, transplant center acceptance practices, transportation availability, geographic distance, weather events, and staffing availability all materially affect procurement costs from case to case and year to year.

In addition, OPOs frequently incur substantial costs associated with organs that are recovered but ultimately are not transplanted. These costs include donor management, testing, transportation coordination, and recovery preparation activities, and are critical to maximizing organ donation and transplantation opportunities and cannot always be predicted prospectively.

Accordingly, reimbursement methodologies that rely heavily on historical averages or prior-year cost data may not adequately capture current-year operational realities in a timely manner.

C. Stable Reimbursement Supports Organ Availability, Workforce Retention, and Innovation

Stable reimbursement is essential to maintaining the infrastructure necessary to pursue every viable donation opportunity. OPOs routinely invest in staffing, training, transportation, organ preservation technology, cybersecurity infrastructure, data systems, quality improvement initiatives, and clinical innovation in order to maximize organ recovery and transplantation.

Policies that create substantial uncertainty regarding reimbursement levels expose OPOs to significant retroactive repayment obligations, or reduce reimbursement below the level necessary to cover reasonable and necessary costs, may:

- Reduce operational flexibility;
- Limit investments in innovation and utilization initiatives;
- Constrain staffing and infrastructure development;
- Increase financial volatility; and
- Ultimately reduce the system's ability to maximize organ donation and transplantation.

AOPO is concerned that the proposed reconciliation framework could unintentionally shift organizational focus away from long-term innovation and continuous improvement toward financial risk management and reserve preservation.

D. Payment Policy Changes Should Be Evaluated in the Context of Broader HHS Modernization Efforts

The national organ donation and transplantation system depends upon close coordination among OPOs, transplant hospitals, donor hospitals, laboratories, transportation providers, and federal oversight agencies. Significant payment policy changes affecting OPOs, therefore, have implications beyond reimbursement alone.

AOPO is concerned that the abrupt implementation of retrospective reconciliation and contractor-established SACs, including the expansion of this payment model to non-renal organs, could destabilize portions of the existing procurement infrastructure, particularly for rural and smaller OPOs. The impact will vary based on the size and composition of each DSA, including geographic area, demographics, donor volume, and transplant center characteristics. This concern is heightened given simultaneous system-wide modernization efforts occurring across HHS, HRSA, CMS, and the Organ Procurement and Transplantation Network (OPTN).

AOPO is also concerned that the proposed reimbursement framework may unintentionally conflict with CMS's broader CfC competition and decertification efforts, including the proposed multi-DSA operational model and increased competition among OPOs. If OPOs are expected to assume responsibility for additional DSAs or expand their operational footprint following competition cycles, organizations must maintain sufficient financial stability and operational flexibility to absorb that additional operational and financial risk. A reimbursement framework characterized by retrospective reconciliation, delayed settlements, and effectively zero-margin reimbursement may reduce the willingness or capacity of OPOs to expand operations into additional service areas, particularly in geographically large or operationally complex DSAs.

Accordingly, any major payment reforms should:

- Be carefully phased in over time;
- Include clear transition policies and safeguards;
- Be informed by additional stakeholder engagement and operational analysis; and
- Avoid consequences that could disrupt organ procurement and transplantation activities.

II. CMS Financial Analysis and Data Limitations

A. CMS's Stated Payment Integrity Rationale

CMS states that its proposal is intended to strengthen payment integrity and align non-renal organ acquisition reimbursement more closely with reasonable-cost principles already applied within the kidney acquisition framework. As part of its justification, CMS cites internal analyses suggesting independent OPOs collectively received approximately $100 million in non-renal revenues above reported costs. CMS further expresses concern that the current reimbursement methodology may lead to inconsistencies in payments and create opportunities for cost shifting between renal and non-renal acquisition activities.

AOPO appreciates CMS's interest in ensuring accurate reimbursement and recognizes the importance of evaluating payment methodologies over time. AOPO shares CMS' focus on being good stewards of federal funding and preserving the resources of the Medicare program. Importantly, OPO cost reports related to renal organ acquisition are already subject to annual review and audit by Medicare MACs, providing an existing mechanism for oversight and evaluation of cost appropriateness and illustrating the timing and cash-flow variability inherent in organ acquisition reimbursement. However, AOPO believes additional analysis and stakeholder engagement are necessary before drawing broad conclusions regarding systemic overpayment.

B. CMS's Analysis May Not Fully Reflect Organ Procurement Operational Realities and the Cost-Effectiveness of Organ Transplantation

AOPO is concerned that CMS's analysis may not fully account for the operational and financial realities of organ procurement. Specifically, aggregate comparisons between annual revenues and costs may not adequately capture:

- Timing differences between cost incurrence and reimbursement;
- Delays associated with organ placement;
- Variability in donor volume and donor complexity;
- Fluctuations in transplant center acceptance behavior; and
- Significant year-to-year operational variability across OPOs.

AOPO is also concerned that CMS proposes extending the kidney acquisition reconciliation methodology to non-renal organs without fully addressing the operational implications for determining Medicare's share for extra-renal organs. Under the kidney acquisition framework, all usable kidneys intended for transplant are generally treated as Medicare organs, except organs sent to military hospitals, VA hospitals, or foreign countries. CMS appears to propose extending this same assumption to non-renal organs. However, non-renal organs differ substantially in utilization patterns, recipient populations, procurement complexity, and operational variability. AOPO is concerned that applying the kidney methodology across organ types without additional analysis may not accurately reflect the operational and financial realities of non-renal organ procurement.

Procurement activity, utilization rates, and clinical complexity vary substantially by organ type. Kidney transplantation occurs at a significantly greater scale and volume than the procurement of organs such as pancreas, intestine, heart, or lung, where lower case volume and greater clinical variability may produce substantially larger year-to-year cost fluctuations. As a result, reimbursement methodologies modeled on kidney acquisition reimbursement may not adequately account for the operational and financial realities of lower-volume non-renal procurement, in which a relatively small number of complex procurement episodes can materially affect annual costs and utilization patterns.

OPO operational experience further demonstrates that receivables, payables, utilization patterns, and procurement costs can fluctuate substantially from year to year, even within the same donation service area. Apparent revenue surpluses in a particular reporting period may therefore reflect timing-related accounting differences, temporary utilization variation, or unusually high-volume periods rather than sustained operating margins.

In addition, aggregate national averages may obscure significant variation among OPOs. Geographic complexity, transportation logistics, donor demographics, organ utilization patterns, transplant center behavior, and rural service-area challenges differ substantially across donation service areas and may materially affect operational costs and financial performance.

AOPO is also concerned that CMS's financial analysis appears focused primarily on organ acquisition reimbursement levels without fully evaluating the potential downstream impact on Medicare expenditures and patient outcomes if the proposed reimbursement structure reduces organ recovery activity or transplant volume. Organ procurement and transplantation operate within a broader continuum of care in which successful transplantation frequently reduces long-term Medicare expenditures associated with ongoing treatment of end-stage organ failure, repeated hospitalizations, mechanical circulatory support, dialysis, and other advanced chronic disease management costs.

If retrospective reconciliation delays reimbursement for higher-than-SAC procurement episodes involving medically complex donors, OPOs may face significant cash-flow pressures and increased financial uncertainty associated with pursuing comprehensive donor authorization, organ recovery, and placement efforts. Over time, these financial conditions could discourage operational investment in complex donor management and organ recovery practices that are necessary to maximize transplantation opportunities, particularly for lower-volume extra-renal organs. Any reduction in transplantable organ supply could adversely affect patients on transplant waiting lists while simultaneously increasing downstream Medicare expenditures associated with prolonged treatment of advanced heart failure, liver failure, and end-stage lung disease.

CMS has long recognized that kidney transplantation generally produces better clinical outcomes and lower long-term Medicare expenditures than continued dialysis. Accordingly, policies that facilitate donor authorization, organ recovery, and transplantation have the potential to generate substantial savings for the Medicare program over time. Conversely, reimbursement policies that reduce financial predictability or discourage investment in donor recovery activities may inadvertently limit transplant opportunities, with downstream implications for both patient access and Medicare spending.

Although much of the literature evaluating Medicare savings focuses on kidney transplantation due to the significant costs associated with dialysis, the broader policy implications are particularly relevant to the non-renal acquisition costs addressed in this rule. OPOs must maintain the infrastructure, personnel, clinical expertise, and 24/7 operational readiness necessary to pursue all medically suitable donation

opportunities across organ types, regardless of whether a transplant ultimately occurs. Reimbursement policies that create financial uncertainty around non-renal recovery activities may discourage investments in donor pursuit, donor management, and organ utilization efforts, potentially reducing transplant opportunities and undermining broader Medicare and public health objectives.

These considerations may be particularly relevant as CMS simultaneously evaluates validated OPO performance metrics and testing approaches designed to increase organ authorization and utilization rates. To the extent OPOs are expected to pursue more resource-intensive donor management and authorization practices in support of improved performance metrics, reimbursement policies that materially reduce operating flexibility or increase financial uncertainty may inadvertently undermine those objectives. **Prior to implementing any reimbursement changes, CMS should conduct a thorough cost-benefit analysis of the risk to patients in need of an organ transplant and the indirect costs to Medicare of lower transplant volume, including medical care for organ failure, if these proposals reduce OPOs' ability to pursue all potential donors.**

C. CMS Should Revise Its Estimated Reporting Burden and Costs to Reflect the Work Required to Operationalize These Proposed Payment Changes

AOPO respectfully submits that CMS's estimated reporting burden significantly understates the operational and administrative resources required to implement the proposed changes. While CMS estimates that OPOs would incur no additional recordkeeping burden and only an average additional annual reporting burden of 10 hours and approximately $785.40 in associated compliance costs per OPO/HCL, this estimate does not accurately reflect the scope of system-wide operational, financial, and compliance modifications that would be necessary under the proposed framework.

CMS's estimate appears limited to the incremental time associated with completing revised Medicare cost reporting requirements and does not account for the substantial upstream administrative infrastructure necessary to operationalize the proposal. In practice, OPOs would likely need to overhaul internal accounting methodologies for non-renal organs, revise cost allocation systems, implement new workflows to track and compare actual costs against contractor-established standard acquisition charges, and continuously monitor receivables and liabilities in anticipation of annual reconciliation. OPOs would also need to modify documentation and auditing processes to comply with expanded prudent buyer and allowable cost standards, including potentially significant changes to employee morale, public education, and professional education accounting practices.

One OPO reported devoting approximately 32 staff hours per month solely to reconciliation-related activities under existing renal organ reimbursement requirements. This experience suggests that the operational burden associated with expanding reconciliation methodologies to non-renal organs could be substantially greater than CMS estimates, particularly given the increased variability, lower volume, and more complex cost structures associated with heart, lung, liver, and pancreas procurement.
Further, the proposed estimate does not adequately account for the personnel and operational resources that would be required across legal, compliance, finance, reimbursement, and information technology departments to implement and maintain compliance with the proposed policies. OPOs frequently rely on manual or semi-manual cost allocation methodologies rather than large-scale hospital accounting systems. As a result, compliance with enhanced reconciliation, documentation, and auditing requirements would likely require substantial new administrative infrastructure, ongoing staff training, and potentially outside consultant or legal support.

AOPO therefore urges CMS to substantially revise its burden estimate to more accurately reflect the true operational complexity and administrative costs associated with the proposed reconciliation and reporting framework. At minimum, CMS should conduct additional stakeholder engagement with OPO financial and reimbursement personnel to better understand the real-world operational burden associated with implementing these proposals prior to finalization.

Implementation would require, at a minimum, the following workstreams:

- Building processes to track actual costs against SACs and manage potential receivables, payables, and repayment exposure ahead of annual reconciliation;
- Expanding documentation, compliance, audit, legal, IT, and finance functions to support new allowable-cost requirements, cost allocation standards, reimbursement documentation expectations, and retrospective reconciliation activities;
- Revising public education, professional education, and donor-family support programs to conform to updated cost allowability guidance;
- Developing solvency planning, reserve, and lender-communication strategies to manage possible large recoupments; and
- Preparing for increased cost disputes, appeals, and discretionary Administrator review.

D. CMS Should Provide Greater Transparency Regarding Its Methodology and Assumptions

AOPO encourages CMS to provide greater transparency regarding the methodology and assumptions underlying its financial analysis, including:

- The treatment of non-utilized organ costs;
- Allocation methodologies between renal and non-renal acquisition activities;
- Distributional analysis across individual OPOs rather than aggregate averages;
- The extent to which timing differences contribute to reported variances; and
- Sensitivity analyses accounting for operational volatility.

AOPO also recommends CMS engage directly with OPOs and other stakeholders to better understand the practical and operational implications of the agency's assumptions before finalizing major structural payment reforms.

AOPO further urges CMS to evaluate whether narrower and less administratively burdensome alternatives could achieve the agency's payment integrity objectives without imposing universal retrospective reconciliation across all non-renal organ acquisition activity. Such alternatives may include targeted audits, sampling methodologies, focused review of outlier claims, enhanced documentation requirements, prospective guardrails, or phased pilot testing prior to nationwide implementation.

III. CMS' Proposal to Apply Kidney Acquisition Cost Policies to Other Organs Exceeds Its Statutory Authority

CMS cites its authority under section 1881(b)(2)(A) of the Social Security Act (42 U.S.C. § 1395rr(b)(2)(A)), which Congress amended in June 1978 in the End Stage Renal Disease (ESRD) Program Amendment (Pub. L. 95-292) to limit payment for organ procurement to the reasonable costs incurred by the OPO or HCL as defined in Section 1861(v) of the statute. To expand the renal organ procurement payment methodology to non-renal organs, CMS reasons that "Pub. L. 95-292 refers to the costs of procuring *organs*, thus

including both kidneys and non-renal organs when requiring payments to be made at reasonable cost for the actual costs incurred." CMS also cites the legislative history and congressional intent in passage of the ESRD Program Amendment (Pub. L. 95-292) as evidence of its statutory authority. Specifically, CMS cites S. Rep. No. 95-714, 95th Cong., 2d Sess. 12-13 (1978) and H. Rep. No. 95-549, 95th Cong., 1st Sess., 14 (1977).

CMS relied on this statutory authority to establish its current reasonable cost-based payment methodology for renal organs in a final rule issued in December 1978 (43 FR 58370). CMS notes that in 1978, Medicare covered only kidney organs for transplants, which is why the agency did not address non-renal organ acquisition costs in that final rule. However, when the agency expanded coverage to non-renal organ acquisition costs, it established payment policies through notice-and-comment rulemaking that did not address reasonable cost reimbursement and reconciliation for non-renal organs. All of the non-renal OAC reimbursement policies established by CMS are more than 20 years old, with many on the books for 30-plus years. Below are the dates that CMS adopted payment policies for non-renal organs:

- 52 FR 33034, September 1, 1987 (heart);
- 55 FR 8545, March 8, 1990, and 56 FR 15013, April 12, 1991 (liver);
- 60 FR 6537, February 2, 1995 (lung);
- 64 FR 41497, July 30, 1999 (pancreas); and
- 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001).

Reversing decades-long OPO reimbursement policies based on a broad interpretation of a narrow statute without considering OPO's reliance on current non-renal organ acquisition cost methodology exceeds CMS' statutory authority and is arbitrary and capricious. First, CMS is proposing an overly broad expansion of a narrow statute squarely focused on organ acquisition costs for kidneys for patients with ESRD in the ESRD Program Amendment (Pub. L. 95-292). Although the statute uses the word "organ," it is linked to kidneys by the first phrase in the statutory provision, which states: "[w]ith respect to payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals determined to have end stage renal disease…" Thus, this statutory provision is narrower than CMS' argument that Congress intended Pub. L. 95-292 to apply to all organs.

Similarly, the legislative history as described in the Senate Finance Committee report cited by CMS is concerned with organ procurement and processing costs for kidneys. The report provides, "[f]or example, when an organ procurement agency provides a kidney to a transplant hospital…" and "… a kidney may be handled by several agencies before it is delivered to the transplant hospital…" The report does not mention non-renal organs.

The Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024) overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and held that courts must exercise independent judgment in determining whether an agency acted within its statutory authority under the Administrative Procedure Act (APA), rather than deferring to the agency's own interpretation of an ambiguous statute. In *Loper Bright*, the Court reasoned that "such statutes, no matter how impenetrable, do – in fact, must – have a single, best meaning. That is the whole point of having written statutes; 'every statute's meaning is fixed at the time of enactment.'"

Under this new judicial framework, CMS's interpretation of section 1881(b)(2)(A) as applying to all organs, not just renal organs, would be scrutinized independently by a court to determine whether it is the single,

best interpretation of the statute. As explained above, the plain language of the statute, as well as the Congressional record, is contrary to CMS's expansive interpretation and supports an argument that CMS's proposal exceeds its statutory authority by stretching the bounds of Congress's directive in 1978. Furthermore, by linking the meaning to the time of enactment, the decision in *Loper Bright* reinforces the discrepancy between section 1881(b)(2)(A), which established Medicare reimbursement for end-stage renal disease (ESRD) dialysis treatments and transplantations, and CMS' proposal to expand kidney reimbursement policies to non-renal organs.

Furthermore, CMS failed to assert this statutory authority in prior rulemaking. As explained by CMS in the proposed rule, the agency established payment policies for non-renal organs that did not involve reconciliation or contractor-established SACs on an ad hoc basis between 1987 and 2001. The statutory authority CMS relies on this FY 2027 IPPS proposed rule predated each of those final rules, yet the agency did not choose to assert this authority when initially establishing reimbursement policies for each non-renal organ. By consistently failing to apply reconciliation and contractor-established SAC policies to non-renal organs over the last three decades, CMS signaled that it had interpreted its authority for renal and non-renal organs differently and is now reversing course without explaining what changed between the previous final rules and the current ones. During five separate rulemaking cycles, CMS established a precedent that payment to IOPOs for non-renal organ acquisition costs did not include reconciliation and contractor-established SACs, which it claims is now contrary to what Congress intended in statute.

Finally, CMS' reasoning is not sufficient to overcome decades of IOPO reliance on the current non-renal organ acquisition cost methodology. Since 1987, IOPOs and HCLs have operated under a reimbursement framework that did not include reconciliation or contractor-established SACs for non-renal organs. These entities structured their operations, made capital investments, negotiated contracts, and set procurement budgets in reliance on CMS' longstanding payment methodology. CMS' proposal to upend this framework without a more detailed explanation acknowledging these reliance interests raises serious concerns under the APA, as the Supreme Court has held that an agency must "examine the relevant data and articulate a satisfactory explanation for its action" (*Motor Vehicle Manufacturers Association of United States Inc. v. State Farm Mutual Automobile Insurance Company*, 463 U.S. 29 (1983)) and when an agency changes policy that resulted in serious reliance interests it must provide a "more detailed justification" (*Federal Communications Commission v. Fox Television Stations, Inc.*, 566 U.S. 502 (2009)). Here, despite the considerable reliance interests of IOPOs, CMS does not include any new Congressional directive, updated factual findings, or detailed policy justification to explain what has changed since the agency made the deliberate choice not to apply the renal reconciliation model to non-renal organs in each of its prior rulemakings.

The plain language and corresponding legislative history of 1881(b)(2)(A) do not support CMS' interpretation as the "single, best" meaning of the statute as required in the post-*Loper Bright* judicial environment and because CMS did not provide a detailed justification for its reversal as required under the APA, the agency should not move forward with its proposed payment policies and should instead retain the existing OPO non-renal organ acquisition reimbursement methodology. At a minimum, if CMS proceeds with any policy changes, the agency must provide clear and detailed legal and policy rationale for departing from longstanding reimbursement practices on which OPOs and HCLs have relied for decades and adopt meaningful transition protections to preserve operational stability and continuity of the organ donation and transplantation system during implementation.

IV. CMS Should Not Adopt a Zero-Margin Payment Policy that Would Undermine OPOs' Mission to Increase Organ Donation and Save Lives

If CMS moves forward, its proposed overhaul of OPO reimbursement policies for non-renal organs would effectively result in a zero-margin payment model for organ procurement services. OPOs already operate in a relatively low-margin environment with significant operational variability, particularly in organ recovery and placement activities. Those limited margins are reinvested directly to expand and retain clinical staffing, transportation coordination, donor hospital engagement, organ preservation capabilities, community engagement, and technology modernization initiatives to increase organ utilization and transplantation rates. Under the proposed rule, after accounting for Medicare sequestration, reimbursement for non-renal organs could fall below actual acquisition costs.

A no-margin or negative-margin payment rate is inconsistent with the statutory and public-health mission of OPOs because OPOs must do more than merely recover the cost of a discrete, successful organ recovery. CMS itself cites section 371(b)(3)(B) of the Public Health Service Act (PHSA), under which OPOs are responsible for conducting and participating in systematic efforts, including professional education, to acquire all usable organs from potential donors and to assist hospitals in establishing and implementing protocols for routine inquiries about organ donations by potential donors. CMS further acknowledges that OPO public education activities are intended to increase awareness of organ donation and donor registration.

A payment methodology that removes all operating margin would materially impair OPOs' ability to make the sustained investments necessary to identify donors, educate hospital clinical teams, support donor families, preserve organs, and increase donor registration and the number of organs available for transplantation. A no-margin or negative-margin payment model would also increase pressure to preserve reserves for financial volatility rather than deploy resources toward OPOs' public health responsibilities under section 371(b)(3)(B) of the PHSA.

Additionally, the proposed policy is especially problematic because organ donation requires OPOs to pursue uncertain opportunities in real time. CMS summarizes prior OPO comments, explaining that reconciling non-renal organ acquisition costs would undercut OPOs' ability to procure marginal organs, leading to fewer organs and, therefore, fewer transplants. Those commenters also explained that the cost of procuring, or attempting to procure, medically complex organs that were later found unsuitable for transplantation could result in losses, as there would be no revenue from those organs. Although CMS responds that reasonable costs of procuring or attempting to procure an organ intended for transplant are allowable even if the organ is later found unsuitable, the proposed retrospective reconciliation framework still shifts substantial operational, timing, and audit risk onto OPOs.

A zero-margin policy would also impede OPOs' ability to invest in new technologies and operational innovations including machine perfusion technologies, predictive analytics, interoperable donor data systems, enhanced organ tracking systems that can increase organ donations and transplants – something critical to not only ensure OPOs can take advantage of the newest, most innovative technologies, but also to ensure organ donation and procurement remains on the cutting edge of science for the benefit of transplant recipients. Technologies and process improvements in organ preservation, perfusion, transportation coordination, donor management, data systems, and clinical education often require upfront investment before they yield measurable increases in organs recovered and transplanted. If an OPO is permitted only to recover retrospectively audited costs, with no margin to reinvest in emerging tools, pilot programs, training, infrastructure, and quality-improvement initiatives, the payment system will systematically favor the status quo over innovation. That result would be particularly harmful in a field

where incremental improvements in preservation, allocation logistics, donor identification, and clinical collaboration can determine whether a donated organ is ultimately transplanted or lost.

These concerns are not unique to organ procurement. Analyses examining the financial pressures facing the U.S. blood supply system have similarly warned that prolonged reimbursement compression and diminishing operating margins can erode resiliency, reduce investment in innovation, and weaken emergency readiness long before outright operational failure becomes visible.[1] Independent assessments prepared for HHS concluded that blood collection agencies face substantial fixed infrastructure and surge-capacity obligations that are not adequately captured through traditional supply-and-demand reimbursement dynamics alone. The same considerations apply to OPOs. Like the blood system, organ procurement infrastructure depends upon continuous operational readiness, geographic coverage, transportation coordination, specialized clinical staffing, and the ability to respond immediately to unpredictable medical circumstances regardless of fluctuations in donor volume or utilization patterns. Policies that impose prolonged reimbursement uncertainty or effectively require zero-margin operation may unintentionally weaken the long-term resiliency, modernization, and operational flexibility necessary to maximize organ donation and transplantation

For these reasons, AOPO respectfully urges CMS not to finalize the proposed expansion of the renal organ acquisition payment methodology to non-renal organs. If CMS nevertheless proceeds with changes to the non-renal reimbursement framework, the agency should first evaluate whether a reasonable operating margin should be incorporated into any organ-specific reimbursement methodology and examine analogous Medicare payment policies, including those applicable to Critical Access Hospitals (CAHs), to inform that analysis.

While CAHs and OPOs serve different clinical functions, they share several important operational characteristics. Both maintain 24-hour, seven-day-a-week readiness, sustain specialized staffing and infrastructure regardless of fluctuations in service volume, perform essential public health functions, operate under extensive federal oversight and certification requirements, and must remain capable of responding to unpredictable patient and community needs. These fixed readiness costs exist irrespective of the number of patients served, admissions, donors, or organs recovered in a given year.

Importantly, even entities such as CAHs, which often operate on relatively narrow margins, are not generally expected to operate at or below cost. According to the Medicare Payment Advisory Commission (MedPAC), CAHs have a median all-payer operating margin of approximately 2.4 percent. Moreover, CAHs benefit from significantly more diversified revenue streams, including Medicare inpatient and outpatient payments, Medicaid reimbursement, and commercial insurance revenue.[2] OPOs, by contrast, perform a highly specialized but vital clinical function and rely almost exclusively on organ acquisition reimbursement to support their operations. Unlike hospitals and many other Medicare providers, OPOs generally lack the ability to offset reimbursement shortfalls through commercial payer contracts, ancillary service lines, or other revenue sources.

Accordingly, if CMS determines that a standardized reimbursement methodology is appropriate for non-renal organ acquisition activities, the agency should ensure that the methodology recognizes the substantial fixed costs associated with maintaining continuous donation and recovery readiness and

[1] The U.S. Blood System: Under Pressure | The Hematologist | American Society of Hematology
[2] July2025_MedPAC_DataBook_SEC.pdf

allows for a reasonable margin that supports operational stability, innovation, and continued investment in efforts to increase organ donation and transplantation.

In addition, any final reimbursement framework must recognize the full range of reasonable and necessary costs required to sustain organ procurement operations. AOPO and Congress through the annual appropriations process have repeatedly requested that CMS provide greater clarity regarding allowable and non-allowable organ acquisition costs. AOPO appreciates CMS's effort in the proposed rule to establish several bright-line standards governing allowable and non-allowable costs. However, the proposal does not fully account for certain costs that are integral to the OPO mission and essential to maximizing organ donation and transplantation. These include donor-family aftercare, counseling and bereavement services, relationship-building with hospital management and staff to develop donation champions, and long-term relationship-building with community groups to further the goal of registering more donors.

Organ procurement is inherently time-sensitive, clinically complex, and operationally uncertain. OPOs must be able to pursue every medically appropriate donation opportunity without concern that necessary expenditures will later be deemed non-allowable. Recognition of these statutory and mission-driven costs—which extend beyond the technical act of organ recovery itself—is critical to preserving operational stability, supporting continued performance improvement, and advancing the Administration's and transplant community's shared goal of increasing organ utilization and achieving 50,000 deceased-donor transplants annually.

V. Specific Policy Comments and Implementation Safeguards

A. CMS Should Establish an Audit-Based Approach to Preserve Program Integrity Rather than Reconciliation of Organ Acquisition Costs for Non-Renal Organs

CMS proposes extending its existing kidney acquisition framework to require formal reconciliation of non-renal organ acquisition costs for independent OPOs and HCLs, beginning with cost reporting periods on or after October 1, 2027. Under current policy, OPOs establish non-renal acquisition charges prospectively and bill transplant hospitals or other OPOs for those charges, with no formal reconciliation process. CMS proposes replacing this with a system in which MACs review reported costs for reasonableness, necessity, and patient-care relevance, and reconcile payments received (or receivable) against allowable costs, with retroactive adjustments for overpayment or underpayment. If a reasonable-cost determination shows overpayment or underpayment, CMS proposes a lump-sum adjustment directly between the contractor and the OPO or HCL.

AOPO agrees CMS and the MACs should have clear authority to ensure costs are reasonable, necessary, and patient-care related, but believes routine reconciliation with lump-sum recoupments will introduce substantial cash flow uncertainty for OPOs, thus reducing their ability to invest in the staff, logistics, and technology necessary to maximize donation and transplantation. To ensure solvency in the event of an unknown, substantial overpayment, OPOs will need to reserve a sizable sum that would no longer be available to hire new staff, invest in new technology, and build new transportation networks to facilitate more organ procurement and transplants. These concerns are particularly acute as CMS simultaneously contemplates expanded multi-DSA operational models, which may require OPOs to assume additional service areas and operational responsibilities. In other words, a lump-sum repayment fund will substitute for investments that would otherwise save lives and improve transplant outcomes.

Furthermore, year-end settlement swings can vary significantly—even within a single OPO—ranging from small payables to multi-million-dollar receivables or liabilities, depending on donor volume and utilization trends. While many OPOs have monthly tracking technology that enables them to continuously evaluate how their costs compare to their revenues and make adjustments throughout the year, smaller, less-resourced OPOs may not have this capacity and, as a result, may be underprepared to repay a sizeable lump-sum overpayment. In the event of extreme financial hardship, an OPO may be required to file bankruptcy or cease to do business, which may result in a reduction in organ procurement and transplantation.

In addition, reconciliation introduces material cash flow and liquidity risks. Cost report settlement may occur more than a year after costs are incurred, requiring OPOs to maintain reserves or access lines of credit to manage potential repayment obligations.

To illustrate the significant lag between when costs are incurred and when payment is finally reconciled, consider the following timeline based on one OPO's experience for 2024. The OPO submitted its cost report in late May 2025, and a tentative settlement payment for its receivable, with a holdback, was received in August 2025. The OPO only recently received notice of its 2024 desk review in spring 2026 and does not expect a final Notice of Program Reimbursement (NPR) until approximately August 2026 based on historical experience. In this example, approximately 20 months will have elapsed since the close of the 2024 cost reporting period and roughly 15 months since submission of the cost report before final reconciliation occurs. This process already presents significant timing and cash-flow challenges for kidney acquisition costs and should not be extended to non-renal organs.

Reliance on historical cost and utilization data — which already lag current operational realities — creates additional risk that contractor-established SACs will fail to reflect real-time procurement conditions. Further, expanding reconciliation, desk reviews, and audit activities to encompass all organs would require substantial additional taxpayer-funded resources from the MAC to oversee, analyze, and administer the expanded reimbursement framework. Accordingly, CMS may substantially understate both the administrative complexity and the true governmental costs associated with implementing the proposed policies.

Finally, AOPO wishes to draw CMS' attention to a potentially serious consequence of expanding reconciliation to non-renal organs. OPOs have seen substantial increases in the cost of new technology in recent years, which has led to an increase in successful transplants. There is a possibility that for-profit vendors could take advantage of a policy to make OPOs "whole" for their allowable costs by unjustifiably increasing their rates. Applying a prudent buyer standard to OPOs as CMS proposes does not resolve this issue because cheaper alternatives may not exist and OPOs, which are limited in geographic reach and face unpredictable volume, are not in a position to negotiate lower rates with technology vendors.

For these reasons, AOPO respectfully urges CMS not to proceed with the annual reconciliation of non-renal organ acquisition costs to lump-sum repayment obligations. In lieu of annual reconciliation, CMS should build on its current audit process to determine whether OPOs adhere to reasonable cost principles. In the event that an audit reveals a concerning level of non-allowable costs, the contractor may reconcile all non-renal organ acquisition costs.

If CMS moves forward, the agency must ensure there is a minimal lag between OPOs incurring costs and CMS finalizing reconciliation, and that OPOs do not face insolvency due to repayment obligations. To this end, AOPO recommends the following:

- MACs must finalize reconciliation within six months of an OPO's cost report submission.
- OPOs should have the ability to request extended repayment schedules in the event an overpayment will cause a Medicare provider or supplier financial hardship, similar to existing policies at 42 C.F.R. § 401.607.
- MACs should cap or otherwise calibrate overpayment amounts for small OPOs and OPOs serving largely rural areas, particularly at the outset of this new policy.

B. CMS Should Not Replace OPO-Established Non-Renal SACs with Contractor-Established Organ-Specific SACs

CMS proposes to require contractors to establish and publish organ-specific SACs for non-renal organs and HCL testing rates. Under the proposal, contractors would calculate those rates by dividing projected or actual costs by the number of usable organs procured, update them annually based on cost report data, and retain exclusive authority to adjust them. If an independent OPO's SACs were underestimated, the contractor could provide only a lump-sum adjustment during the accounting period, subject to reconciliation at cost report settlement.

AOPO respectfully opposes this proposal and urges CMS to maintain the current prospective reimbursement methodology for non-renal organ acquisition costs, while strengthening guardrails for allowable and non-allowable costs under Medicare's reasonable cost principles.

The current framework better preserves the operational stability and flexibility OPOs need to maintain and increase organ procurement and transplantation. By contrast, contractor-established rates based on historical cost data would shift significant financial risk to OPOs and may lag real-time cost increases by 12 months or more, creating a rate-setting mismatch for urgent procurement activity that must respond immediately to changing clinical, logistical, and market conditions.

Current renal policy appropriately permits mid-year adjustments when unexpected cost increases arise, including increases attributable to new technology, inflation, higher fuel prices, or other economic changes. Comparable flexibility is necessary for non-renal organ acquisition to account for real-time changes in compensation, transportation and fuel costs, supply chain conditions, specialized testing, vendor pricing, contractor adjustments, cybersecurity needs, and technology adoption. Without timely rate adjustments, OPOs facing substantial unanticipated costs could be forced to reduce or delay procurement activity, undermining CMS' goal of increasing transplantation.

If CMS nevertheless finalizes a contractor-established SAC methodology, AOPO recommends CMS require contractors to make timely adjustments during the accounting period, rather than relying solely on a one-time lump-sum adjustment after costs have been incurred. CMS should also require contractors to consider both prior-year costs associated with procuring each type of non-renal organ and the OPO's reasonable estimate of projected current-year costs.

AOPO further recommends CMS study and establish an appropriate reasonable margin for organ-specific SACs. OPOs, like other essential health care entities that serve critical community needs, must maintain high fixed costs regardless of volume and must operate 24 hours per day, seven days per week. CMS should evaluate comparable Medicare payment frameworks, including policies applicable to CAHs, federally qualified health centers (FQHCs), and rural health clinics (RHCs), to determine whether similar principles could inform a reasonable and administrable OPO reimbursement margin.

Finally, CMS should establish targeted supplemental payments to address extraordinary procurement costs and qualifying new technologies. Such payments should include outlier payments for unusually high-cost procurement episodes, including medically complex donors, extraordinary travel or logistical challenges, specialized testing, unusual preservation needs, or other circumstances that cause procurement costs to materially exceed the applicable charge. CMS should also establish new-technology add-on payments for technologies and services that substantially improve procurement effectiveness, patient safety, organ preservation, logistics, cybersecurity, or transplant outcomes.

For these reasons, AOPO respectfully urges CMS not to finalize contractor-established non-renal SACs. At a minimum, if CMS proceeds, it should require current-year rate adjustment authority, require consideration of projected current-year costs, establish a reasonable margin, and create targeted supplemental payment mechanisms for outlier procurement episodes and qualifying new technologies. These safeguards would allow CMS to pursue payment integrity without undermining the timely operational decisions needed to maximize organ recovery and transplantation.

C. CMS Should Cover All Reasonable and Necessary OPO Costs and Tailor Reasonable-Cost Principles to OPOs

Across each of the following cost categories, AOPO urges CMS to apply reasonable-cost principles in a way that reflects OPOs' statutory and operational responsibilities. Costs that support donor identification, donor-family support, staff and hospital engagement, staff readiness, professional education, public education, and organ procurement capacity are not ancillary to the OPO mission. They make up the infrastructure necessary to pursue every viable donation opportunity.

1. Prudent Buyer Standard

CMS reinforces that OPOs are subject to Medicare's reasonable cost framework and strengthens the application of the prudent buyer standard, under which providers must demonstrate costs are necessary, efficient, and consistent with market norms. CMS provides examples of situations where excess costs may be disallowed and notes contractors may compare prices paid by providers to comparable purchasers, use Form 990 compensation data, use federal per diem rates as benchmarks, and evaluate whether costs are substantially out of line with similar institutions.

AOPO supports a general prudent buyer standard for OPO overhead and administrative costs (e.g., office space, IT support) and requests modification of the standard to reflect unique clinical operations of OPOs, which center around urgent, high-stakes procurement activities. A general prudent buyer standard is not sufficiently tailored for organ procurement operations, which are subject to market constraints based on limited vendors and suppliers. OPOs do not operate in a typical healthcare market where multiple suppliers compete on price and negotiate with providers. For organ procurement costs, there may only be one recovery team available at any given hospital and only one air carrier to transport an organ.

In rural areas, transportation options are limited, especially during weekends/holidays. Additionally, flight availability can result in charter flights for recovery teams and/or a perfusionist to reach the donor hospital. New technologies cannot be sourced from multiple vendors because the technology will vary. OPOs and transplant centers have seen significant increases in costs for technologies which have helped increase the number of organs transplanted.

As such, AOPO respectfully recommends CMS establish a "prudent buyer" standard for organ acquisition costs. An organ procurement prudent buyer standard should account for the expenses necessary to procure organs in urgent situations, variations in geographic costs, and the limited availability of specialized recovery, preservation, and transport services.

2. Donor Family Aftercare and Bereavement Services

Although the agency makes numerous proposals to more clearly delineate allowable and non-allowable organ procurement expenses, CMS does not directly address family aftercare and bereavement services. OPOs emphasize providing resources, education, and ongoing support to help families of donors in their healing process. Many OPOs hold annual remembrance events for donor families to honor their loved ones, provide grieving materials, and offer support groups. Additionally, OPOs facilitate connections between donor families and organ recipients through letters or, in some cases, direct contact. These services are not merely altruistic. Helping donor families with their bereavement and recognizing their loved ones promotes trust in the organ donation process and leads to a positive experience for donor families. In turn, donor families who have a positive experience become advocates for organ donation with their family, friends, and community.

Moreover, the Medicare Conditions for Coverage at 42 C.F.R. § 486.326 require OPOs to have "a sufficient number of qualified staff to provide information and support to potential organ donor families." If OPOs are required to provide information and support to organ donor families as a condition of participating in Medicare, then the costs of complying with that requirement should be considered reasonable and necessary costs of organ procurement and, thus, allowable expenses. **AOPO respectfully requests CMS to confirm that expenses incurred by OPOs for aftercare and bereavement programs for donor families, including grief support, connection with recipients, and donor recognition events, remain allowable costs.**

3. Entertainment and Public Education and Outreach for Organ Donation Awareness

CMS proposes to specify that costs incurred by providers for entertainment, including costs associated with entertainment activities, or that are entertainment-related, are not allowable costs. These include tickets, admission fees, or entry to sporting or other events, including national or professional sporting events; sponsorship of sporting events, teams or athletes, including race car drivers or motorsports activities; sponsorship of floats in national parades; concert, theater, or performing arts events, professional musicians or other entertainers; wine tours or alcoholic beverages; retreats held at spas or luxury resorts, spa services or treatments; golf outings, ski trips, cruises and similar recreational excursions. Allowable costs include reasonable costs incurred by OPOs to engage in public education within their donation service area to increase awareness of organ donation and increase donor registration.

OPOs have an obligation to educate the public about organ donation and what it means to be registered. OPOs need to use all forms of media and public outreach to connect the donation message with the public. Misinformation among the public, a lack of trust in medical institutions, and negative media have harmed donation and increased donor registry revocations. Additionally, nationally, teens are registering for their first driver's licenses at a lower rate. Youth and public education programs are designed to address this trend. For example, in Michigan, only 34% of teens register when they first get their license. This number used to be closer to 50%. Data from one OPO's public education program shows that after teens learn

about donation, 70% are more open to registration. Being registered is by far the single greatest determinant of whether a potential donor becomes one.

AOPO acknowledges and greatly appreciates HRSA's organ donation campaign. OPOs supplement these efforts through both local and national efforts, including high school and driver's education programs, partnerships with driver's license bureaus, workplaces, faith-based outreach, media relations, and a wide variety of community events. Local advertisements, such as billboards, can often be more cost-effective than one-time events as they can reach large segments of the community. OPO experience demonstrates that donor registration and family authorization typically require multiple interactions over time, and limiting outreach to one-on-one engagement may reduce effectiveness.

AOPO urges CMS to continue to allow certain costs for national initiatives to reach as many potential donors as possible and incentivize collaboration in the community around best practices. We suggest CMS establish reasonable guardrails, such as disallowing costs for activities duplicating HRSA's nationwide donation efforts. Not only could limiting nationwide efforts result in fewer organ donor registrations and family authorizations but we are concerned that a distinction between nationwide and local public education efforts could be easily blurred in today's media environment. Internet-based content, especially stories and posts on social media platforms, transcends the boundaries of designated service areas.

Furthermore, CMS's proposal introduces ambiguity regarding allowable outreach activities. **Currently, broader community engagement strategies—such as billboards, radio campaigns, school-based education, and donor recognition events—are allowable. CMS should confirm that these costs remain allowable under the rule.**

4. Activities for Employees and Non-employees of the Provider

CMS proposes to reverse its current policy of allowing "[c]osts incurred by providers for purposes of employee morale, specifically, for an annual employee picnic, an annual Christmas or holiday party, an annual employee award ceremony or for sponsorship of employee athletic programs (for example, bowling, softball, basketball teams, etc.)" to the extent that they are reasonable. If finalized, these employee events would be non-allowable. CMS suggests alternatives to improve employee morale, such as "[f]lexible work schedules, wellness programs, recognition for achievements, and creating a positive workplace culture" in addition to employee fringe benefits.

Despite CMS's statements in this proposed rule, OPOs are often unable to offer flexible work schedules or wellness programs to employees who are often required to travel long hours and distances on short notice to procure a potentially viable organ. Moreover, OPOs compete with local hospitals for limited clinical and non-clinical staff members. The costs of training new staff are significant, and employee engagement events are beneficial for retaining staff and keeping training costs low for Medicare. For example, one OPO reported that, for donation coordinators to be fully self-sufficient and manage cases, training takes more than 18 months. Employee retention also has patient benefits, as fully trained staff allow OPOs to maximize the number of viable organs procured and transferred.

AOPO respectfully urges CMS to retain its longstanding policy of allowing costs for employee morale, engagement, and retention initiatives. While AOPO supports reasonable guardrails around these activities, employee engagement efforts should not be limited solely to one or two organization-wide events per year, as retention initiatives often include ongoing team-based recognition, wellness, training,

and workforce support activities necessary to sustain a highly specialized workforce. We recommend that CMS establish reasonable parameters for allowable employee morale and engagement costs, including consideration of federal per diem principles where appropriate. Particularly if CMS moves forward with a zero-margin reimbursement methodology for OPOs, reimbursing these activities will be critical to recruit and retain clinical and non-clinical staff for demanding jobs with long, often unpredictable hours.

5. Alcoholic Beverages

CMS proposes to codify longstanding guidance that costs incurred by providers to furnish alcoholic beverages to anyone are not allowable costs. **AOPO agrees OPOs' costs to furnish alcohol are not related to patient care and supports this proposal.** AOPO strongly supports any instances where alcohol impedes the safety of OPO staff, patients, families, and others being fully investigated and holding individuals who breach this guidance accountable.

6. Professional Education and Travel

CMS proposes to establish the types of professional education provided by OPOs to the clinical staff of hospitals should be focused on organ donation to acquire all usable organs from potential donors. Professional education, such as meetings, seminars, and presentations on organ donation to acquire all usable organs from potential donors, where continuing education credits are not given, and where the attendees are clinical staff, such as OPO staff, donor hospital staff, and physicians, is allowable. OPO-sponsored seminars where continuing education credits are given and where the attendee is on the OPO staff are allowable to the extent that they are patient care related, reasonable, and necessary. However, if an attendee is not on OPO staff, the costs are not allowable.

Additionally, CMS proposes to specify that costs incurred by providers:

- For employee travel, costs are generally allowable to the extent they are patient care related, reasonable, and necessary. Costs for travel not related to patient care are not allowable costs.
- To conduct, or send its employees or staff to, patient care related professional education refresher programs, seminars, and workshops that increase the quality of patient care or operating efficiency of the provider, are generally allowable costs to the extent they are patient care related, reasonable, and necessary.
- For entertainment and vacation travel expenses such as travel on cruises or to resorts or spas, or transportation to entertainment or sporting events, are not allowable costs regardless of whether they are or are not incurred in connection with professional educational seminars or continuing education.
- Related to the personal use of provider vehicles are not allowable costs.

Under section 371(b)(3)(B) of the PHSA, OPOs are responsible for "conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors," and "assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors." Without an obligation on the part of donor hospitals to participate or require hospital staff to participate in education efforts, OPOs need flexibility to incentivize hospital staff to attend education sessions with meals and continuing education credits.

This proposal to not allow costs related to education with continuing credits for non-employed staff would disadvantage medical directors, who may be contractors and not W-2 employees, as well as recovery

surgeons and perfusionists. CMS does not provide an adequate explanation about why there should be a distinction of coverage for continuing education credit professional events based on whether a clinical staff person's employment status, and we do not believe coverage should hinge on this distinction. Moreover, AOPO is concerned CMS would disallow reimbursement for professional education for non-clinical staff, who are mission-critical for OPOs because they maintain operations and compliance, which are foundational for clinical staff effectiveness. Many of these roles require continuing education as a condition of professional licensure or certification.

AOPO recommends CMS modify its proposal to allow OPOs to incentivize participation in professional development events with continuing education credits and to allow costs for professional education for non-clinical staff, including finance, IT, and HR professionals, who must stay apprised of developments in tax, technology, benefits, and compliance more broadly to effectively fulfill their roles for OPOs. Reasonable travel and related expenses for non-clinical staff should be allowed to avoid disincentivizing the maintenance of trained, credentialed staff who support the OPO's mission.

7. Meals Provided to Employees and Non-Personnel

CMS proposes to specify that costs incurred by providers for meals sold to visitors and meals for their employees or staff (including executives and management) and non-personnel (including attending physicians) are not allowable costs. CMS is also proposing to specify that the costs of meals and refreshments provided to attendees at educational events, including attendees of OPO-sponsored seminars (with or without continuing education credits) are not allowable costs.

OPOs, unlike hospitals, can cover vast geographical areas. Bringing staff onsite requires staff to travel long distances for training and meetings that are essential to advance donation and should include reasonable meeting expenses like meals. Moreover, meals served to personnel who must remain on-call on the premises during mealtimes are reasonable and related to patient care because they facilitate immediate responsiveness to organ procurement opportunities. **AOPO urges CMS to create narrow exceptions to this proposal to allow the costs of meals during educational events and for staff required to remain on-call or on-site for extended shifts (e.g., 12-hour or 16-hour shifts) so long as the amount does not exceed the applicable Internal Revenue Service (IRS) per diem amount.**

D. CMS Should Provide Detailed Guidance Before Enforcing New Overhead Allocation and Cost Reporting Requirements

CMS proposes to codify overhead cost allocation rules that currently appear in cost reporting guidance, with the stated goal of ensuring costs are accurately assigned and preventing inappropriate cost shifting that could overstate or understate Medicare reimbursement.

Based on the limited information in the proposed rule, it is not clear whether – and how – this proposal impacts OPOs. Without specific examples about what needs to be adjusted, OPOs will be at risk of non-compliance through no fault of their own. **To ensure OPOs can comply with the intended changes, CMS should provide concrete sub-regulatory guidance, including updated cost report instructions and examples, to facilitate compliance with these requirements. If such sub-regulatory guidance is not released shortly after the final rule is published, CMS may need to further delay or phase in these requirements.**

E. Appeals Reforms Should Preserve Predictability, Fairness, and Due Process

CMS also proposes changes to the appeals process so that a party to CMS reviewing official decision may request Administrator review, and the Administrator may also take review on his or her own motion. CMS proposes the following timeline for Administrator review:

- A party, or CMS, may request the Administrator review a CMS reviewing official decision within 15 days of their receipt of a final CMS reviewing official decision.
- The Administrator must issue a Notice advising the parties of his or her intent to review or to decline to review within 30 days of the Administrator's receipt of a request for review from CMS or any party to the CMS reviewing official's decision. A Notice that the Administrator is declining to review need not set forth the basis for the Administrator's decision to decline review of the CMS reviewing official's decision.
- If the Administrator declines to review the reviewing official's decision or the Administrator does not issue a determination regarding review of the reviewing official's decision within 30 days of the Administrator's receipt of a request to review, the decision of the CMS reviewing official is final.
- Upon issuance of a Notice, within 30 days of a request for Administrator review of a CMS reviewing official decision, if the Administrator is declining to review the reviewing official's decision, the CMS reviewing official's decision becomes final.
- Within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the Administrator may issue a Notice of Review on his or her own motion. If the Administrator does not issue a determination regarding his or her own motion review within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the decision of the CMS reviewing official is final.
- If the Administrator does not issue a written decision that affirms, reverses, modifies, or remands the CMS reviewing official's decision within 60 days of the date of issuance of the Notice of Review, the CMS reviewing official's decision becomes final.

AOPO supports a timely and efficient appeals process, but is concerned that the proposed Administrator review timelines and discretionary review criteria could reduce predictability and fairness for OPOs challenging contractors and CMS reviewing official decisions. Increased review procedures, including discretionary Administrator review, are likely to increase the legal costs and risk of reasonable cost disputes for OPOs.

If CMS moves forward with Administrator review changes, the agency should provide clear parameters for the scope and standard of Administrator review including whether review will be de novo, deferential to contractor determinations, or limited to identified issues on appeal, ensure the parties have sufficient opportunity to prepare and submit supporting documentation relevant to an appeal, and require a Notice declining review to include a brief explanation to better inform OPOs' understanding of the reasonable cost principles.

F. CMS Should Delay and Phase in Any Finalized Payment Changes

CMS proposes a one-year delay in these reimbursement changes, making them effective beginning October 1, 2027. CMS believes this delay is necessary to allow the agency to update the IOPO/HCL cost report and for IOPOs and HCLs to prepare for increased reporting and contractor oversight.

As discussed throughout this letter, these proposals represent a wholesale shift in how OPOs are paid and would require substantial changes to workflows. OPOs need time to prepare for the breadth of new requirements, including revising internal procurement policies, renegotiating vendor contracts, restructuring public education programs, retraining staff on new cost parameters, and updating financial systems. These policies also could significantly affect debt covenants for OPO borrowing and require time to educate lenders, update forecasts, and negotiate new covenants or waivers. Implementing these changes all at once could create a compliance gap that results in unintentional cost disallowances.

While AOPO strongly urges CMS to retain the existing non-renal organ acquisition cost policies, if the agency moves forward, AOPO supports a one-year delay and urges CMS to implement these sweeping proposals over three years, as outlined below, to preserve OPOs' viability. A phased approach allows CMS sufficient time to develop sub-regulatory guidance, including revised Medicare Cost Reports, before implementation, reducing ambiguity for OPOs during implementation.

Fiscal year	Effective date for policy
FY 2028	Prudent buyer standard and allowable cost modifications
FY 2029	Cost allocation principles and appeals changes
FY 2030	Contractor-established SACs for non-renal organs

Conclusion

AOPO appreciates CMS's continued commitment to strengthening transparency, accountability, and stewardship within the Medicare program and shares the agency's goal of ensuring organ acquisition reimbursement reflects reasonable and necessary costs directly tied to patient care and organ procurement activities. AOPO also encourages CMS to evaluate these proposals within the broader context of ongoing federal efforts to modernize and strengthen the nation's organ donation and transplantation system, including HRSA modernization initiatives, OPTN reform efforts, implementation of the Increasing Organ Transplant Access Model, and enforcement of the performance-based tiering system for OPOs. Taken together, these initiatives represent one of the most consequential periods of simultaneous operational, financial, certification, and enforcement transformation in the history of the organ procurement system. Policies that reduce operational flexibility, discourage investment in innovation, or introduce significant reimbursement uncertainty may unintentionally undermine these broader federal objectives and ultimately affect the nation's ability to increase transplantation, reduce waitlist mortality, and save more lives through organ donation.

OPOs remain deeply committed to maximizing organ donation and transplantation, supporting donor families, and serving patients awaiting lifesaving transplants in communities across the country. At the same time, the proposals in the FY 2027 IPPS Proposed Rule represent a significant structural change to the financing and operational framework that supports the nation's organ procurement system. While AOPO supports appropriate oversight and clear guardrails for allowable costs, the proposed retrospective reconciliation framework, contractor-established organ-specific SACs, expanded prudent buyer standards, and related administrative changes collectively risk introducing substantial financial volatility,

operational uncertainty, and administrative burden into a system that depends on continuous readiness, rapid clinical response, and sustained investment.

AOPO respectfully urges CMS to carefully consider the potential downstream implications these proposals may have on organ availability, workforce retention, innovation, transportation and preservation infrastructure, and long-term transplantation capacity. If CMS determines to finalize any structural payment changes, AOPO urges CMS to do so only through a phased approach with clear guidance, transition protections, and meaningful stakeholder engagement. Policies that unintentionally discourage innovation, reduce operational flexibility, delay investment, or divert resources toward reserve preservation and compliance management risk affecting not merely reimbursement administration, but the number of organs ultimately recovered, transported, and transplanted. The operational stability of the organ procurement system is inseparable from the nation's ability to increase transplantation, reduce waitlist mortality, and save more lives.

AOPO and its member OPOs remain committed to working collaboratively with CMS, HRSA, Congress, transplant centers, donor hospitals, and other stakeholders to strengthen accountability while preserving the operational stability necessary to pursue every viable donation opportunity and save more lives through transplantation.

Sincerely,

Jeffrey Trageser
AOPO President
Executive Director
Lifesharing