ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS

Saving and enhancing lives through organ, eye, and tissue donation.

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September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
PO Box 8013
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements

Dear Administrator Brooks-LaSure:

On behalf of the Association of Organ Procurement Organizations (AOPO), thank you for this opportunity to comment on changes to Calendar Year (CY) 2023 payment policies under the Medicare Physician Fee Schedule. AOPO is the national representative of 49 federally designated nonprofit Organ Procurement Organizations (OPOs) in the United States, which serve millions of Americans combined. AOPO is dedicated to providing education, information sharing, research, technical assistance, and collaboration with OPOs, other stakeholders, and federal agencies to continue this nation's world-leading transplant rates while consistently improving towards the singular goal of saving as many lives as possible.

We appreciate the agency's desire to continue to improve the organ donation and transplant system, a goal we share. We also thank the agency for soliciting stakeholder feedback on its proposals. To this end, we would respectfully request:

- **An extension on the request for information (RFI) elements of this rule** so that we have time to collect more data internally from our member OPOs, as well as from the United Network for Organ Sharing (UNOS) so we can more aptly answer the detailed questions, particularly those that are quantitative in nature. Several of our members have made separate data requests to UNOS, and many are still awaiting responses. We are eager to engage in robust dialogue, but additional time would yield more substantive responses from AOPO and other stakeholders. We would also encourage CMS to directly request OPTN to provide this data to OPOs in a timely manner and that CMS provide OPOs a minimum of 60 days to analyze and provide more robust answers to these questions.

- **A multi-stakeholder dialogue in the form of a workgroup**, which we feel would be the most effective way to engage in a meaningful discussion with CMS on these multifaceted issues that impact a multitude of stakeholders and elements of this complex system. That said, we have done our best to address CMS' specific questions in this letter.

- **Clarify that CMS intends to continue allowing organs that are procured for transplant purposes but later deemed unusable and subsequently donated to research to qualify as allowable costs under its proposed new methodology.** This clarification will allow important potentially groundbreaking research to continue.

- **Implement a system that provides OPOs access to payer data that is up-to-date, real-time, and available at the point of placement.** This system must be fully rolled out and tested prior to rolling out any new payment methodology in which CMS would limit Medicare standard acquisition charges (SACs) to only reimburse for organs ultimately transplanted into Medicare beneficiaries or make changes to its reimbursement policies for non-renal organs. If these payment methodology changes were to be advanced without such a payer database in place, it could be financially devastating to OPOs because the impact of any cost reductions would be multiplied across all payers in the system, not just Medicare. Community outreach and other critical functions filled by OPOs would immediately suffer, likely reversing much of the progress made in recent years to expand the pool of eligible donors and therefore the number of organs available for transplant.

- **CMS reconsider its proposal to financially reconcile non-renal organs in the same way they do kidneys.** Due to important and unique differences that exist in the non-renal market, applying this same reconciliation policy to non-renal organs would severely undercut the ability of OPOs to budget forecast and therefore continue investing in community outreach and other important activities, as well as their ability to recover more organs, particularly marginal organs.

We have concerns that several of the potential significant policy changes included in this rule would have unforeseen implications that could harm patient care, as we explain in greater detail below. We also have several questions pertaining to how CMS plans to ensure the necessary logistics are in place for implementation of these policy proposals, including how CMS intends to maintain up-to-date insurer information for potential transplant recipients and how that information would be shared with OPOs and other stakeholders in a sufficiently timely manner. These are just some of the outstanding questions that speak to the complex nature of the proposals included in this rule. We urge CMS to consider all stakeholder comments and downstream impacts of these proposed policy changes, including whether their implementation would have a net positive impact on our shared goal of expanding the donor pool recovering more organs and saving more lives. If CMS were to finalize these proposals, we also believe it would be vital for any reimbursement policy changes to be reflected in updated performance measures that would ideally be unified across stakeholders.

I. Research Organs

AOPO appreciates CMS' interest in ensuring Medicare dollars are spent to benefit Medicare beneficiaries. However, we continue to have strong concerns that CMS' proposed approach to remove research organs from the numerator and denominator of Medicare usable organ could have significant adverse implications that would seriously harm the field of research while providing nominal, if any, savings to Medicare.
First, it is important to clarify that it is already the case the OPOs do not count organs intended for research towards organ acquisition costs. Accordingly, the only "research" organ costs that are counted are those considered viable for potential transplant until they are later deemed unviable for any number of clinical reasons, many of which are not possible to be known until the organ has already been recovered from the donor. In these circumstances, in the interest of having some value behind the resources that have already gone into retrieving that organ and honoring the final wishes of the deceased and their loved ones, OPOs reach out to research institutions and look to give these organs another meaningful purpose. These costs are nominal and are typically reimbursed by the transplant hospital or research organization itself, which is rectified in the Medicare cost report (216-94) on worksheet A-5, through a revenue offset against organ

acquisition costs.

If an organ has not already been recovered when it was deemed unviable for transplant, transplant hospitals often will not charge an excision fee, particularly when they are excising other organs from the same donor. As a result of all of these industry-wide efforts to keep costs for research organs low, any fees Medicare would pay for research organs are nominal, typically limited to packaging, solution, and courier cost, typically a few hundred dollars. Any nominal savings recuperated would likely be eclipsed by the administrative costs it would take to separate out these costs.

We worry that finalizing this policy could run the risk of perversely disincentivizing OPOs to attempt to recover organs that have already been deemed unviable for transplant for fear that they would not be able to count these costs in the same way that they would for attempting to recover organs later deemed unviable. **We urge CMS to clarify that expenses incurred to recover organs that were initially considered viable for transplant that are later deemed unviable and donated to research can and should continue to count as allowable Medicare organ acquisition costs.**

Finalizing this policy as proposed would yield a minimal, if any, financial benefit to Medicare but could have a potentially detrimental impact on the field of research, which has important implications for the future of organ transplant and disease research in general, of which Medicare beneficiaries are one of the most direct benefactors. One organ donated can save a single life, but an organ donated to research could potentially impact thousands. We are at a groundbreaking moment where exciting new technologies like lung perfusion are expanding the boundaries of transplant as we know it. Current practices that are now considered standards of care began as research, such as pumping kidneys. Groundbreaking discoveries like this have the potential to save thousands of additional lives each year but cannot continue if one of the researcher's most significant sources of organs for their research dissipates virtually overnight as a result of this policy. We urge CMS to reconsider the impact this proposal would have on research, particularly in the context of the limited savings it would produce.

II. Determining Medicare's Share of Organ Acquisition Costs

Presently, OPOs charge the same SAC to all transplant hospitals, which are the entities that ultimately determine the recipient payer and contract directly with payers. Any pricing variation occurs strictly in the contracts between transplant hospitals and payers, which does not directly impact OPOs or our SACs. This means OPOs cannot directly charge commercial payers' different rates the same way other healthcare entities do. Accordingly, even though Medicare does not technically set OPO SACs for private payers, it inevitably sets the rate for the entire market. It also means the impact of any decrease in Medicare payment rates would be multiplied across payers for a magnified and potentially devastating impact.

While non-Medicare SACs could be separated and reconciled via the Medicare cost report retroactively, this would require changing the entire OPO reimbursement structure, and would entail additional administrative burdens that would eat into any cost savings achieved. Most importantly, due to its retroactive nature, it would likely cause potentially detrimental cash flow disruptions as explained in greater detail in the below section on non-renal organs.

Accordingly, if CMS were to proceed with the proposed methodology to only reimburse for organs ultimately transplanted into Medicare beneficiaries, OPOs would need to establish separate SACs for non-Medicare patients. For a system like this to function well, we would need to have access to payer data at the time of placement, which is not currently the case. This would likely be logistically complex and

expensive to implement in part because this information would have to be available in real time to avoid critical care delays. The data would also have to be consistently reviewed to ensure it remains accurate and up-to-date, which would require frequent re-verification of each individual on the organ transplant waiting list, a potentially massive undertaking. It is also unclear whose responsibility that would become. It would be critically important to get this system up and running and thoroughly tested before implementing significant changes to reimbursement policies to avoid system-wide instability.

It is also unclear how unusable organs would be accounted for in such a system. All payers, including Medicare, should take some responsibility for these costs that are inherent to organ transplant. Because the SAC is applied across all payers, these costs would need to be incorporated in some capacity. This policy change would directly undercut Medicare's goal to expand the use of marginal organs.

- **Are you able to quantify the revenue your facility has received over the past 5 years resulting from Medicare's organ counting policy because acquisition costs were assigned to Medicare usable organs for THs, or Medicare usable kidneys for IOPOs, that were transplanted into non-Medicare beneficiaries? If so, what are the amounts? Describe the impact of the revenue reduction resulting from an alternate organ counting methodology, both in absolute terms and relative to your IOPO, or transplant program and hospital as a whole.** This impact would vary by OPO and the amount of Medicare penetration in their markets. Several member OPOs have submitted data requests to UNOS to calculate the impact but did not hear back in time to analyze the results and include them in our comments. This is one of the reasons we would respectfully request an extension for the RFI portions of this proposed rulemaking. CMS could also ask that UNOS and/or transplant hospitals calculate this data and/or make it readily available to OPOs.

- **Describe how THs and OPOs currently support organ acquisition costs financially. What revenue and income streams (for example, grants, fundraising, etc.) support these activities?** Organ acquisition costs are solely supported through reimbursement from Medicare (for renal only) and through transplant hospitals who directly contract and negotiate with payers. As nonprofits, OPOs must use organ acquisition reimbursement from all payers, including Medicare, to cover the costs of direct acquisition, as well as the plethora of responsibilities we are expected to serve within our local communities and the transplant ecosystem, such as efforts to expand the organ donor pool and advance health equity through education and outreach. For those OPOs that do have separate foundations, that funding goes almost universally to supporting functions like community outreach which otherwise have no direct funding sources of their own.

- **Do other payors pay equitably to share in the costs to acquire organs for transplant for their patients? If so, under an alternate organ counting methodology for Medicare would all payors, including Medicaid, continue to equitably share in the cost to acquire organs for transplant? Is the cost to acquire an organ for transplantation into a Medicare beneficiary different than the cost to acquire an organ for transplantation into a non-Medicare beneficiary? If so, what factors contribute to the difference in organ acquisition costs?** From the OPO perspective, there is no difference. Again, OPOs do not know the payer status of the organ recipient, so we charge transplant hospitals the same regardless. Transplant hospitals are responsible for contracting with payers; we are not privy to those contract negotiations.

- **If an alternate organ counting methodology were implemented, are there any timing issues for implementation that we should consider regarding other payors, including State Medicaid Agencies, to address their organ acquisition and/or transplant payment methodologies?** Given the

magnitude of the proposed changes and their impact on how standard acquisition charges are developed, OPOs would need sufficient advance notice to perform the necessary cost adjustment calculations, develop new pricing structures, and have these changes approved by our respective OPO leadership, which operate on varying annual cycles. As a result, we strongly recommend that any changes of this magnitude be implemented with no fewer than two years of advance notice. ***We strongly recommend that CMS ensure a recipient payer database is instituted and made available to OPOs and all appropriate stakeholders before finalizing any reimbursement policy changes.***

- **Will your facility perform less transplants if revenue is eliminated from Medicare under an alternate organ counting methodology? If so, why and how? Will your facility perform less organ acquisitions if revenue is eliminated from Medicare under an alternate organ counting methodology? If so, why and how? Describe what services your TH or IOPO may need to reduce or change to accommodate a reduction in revenue from Medicare stemming from an alternate organ counting methodology to count only organs transplanted into Medicare beneficiaries to calculate Medicare's share of organ acquisition costs.** AOPO leadership and its 49 member OPOs are focused on improving the donation and transplantation system through addressing diversity and equity issues, adopting new technologies, and sharing best practices. Thanks in large part to these efforts, the total number of organs transplanted has continued to break records each year for the past nine consecutive years. 2021 marked an important milestone: the first time the total number of organs transplanted exceeded 40,000 with all three of the most common types of organs each setting their own individual volume records. 2021 also marked the 11th consecutive year of growth for deceased donation and marked a more than 10% increase from the year prior. These important milestones could not be reached without critical efforts on the part of OPOs, in collaboration with other stakeholders, to expand the base of donors and drive constant innovation to push the boundaries of which organs can be safely transplanted to save additional lives. Continued improvement depends on OPOs' ability to invest in important initiatives such as community education and outreach, donor registry expansion initiatives, new initiatives around innovation, electronic communication, transportation tracking, health equity, etc.

  Unfortunately, it is these very OPO functions beyond direct organ acquisition and reimbursement that are precisely what would be forced to take a direct financial hit as a result of decreased reimbursement under this and other proposed policies in this rule. Accordingly, OPOs would not be able to invest as much as they do presently into efforts to innovate and educate in order to expand the number of donors and organs available for transplant, which will unfortunately undercut current CMS and AOPO objectives to do just that, and ultimately result in fewer overall transplants. In addition, if this methodology were to be finalized, OPOs would need additional staff to analyze and verify the separate payer data, a potentially massive undertaking. In addition to reducing our overall reimbursement, we would face significant increased staffing costs as well. If CMS wants to continue going in the promising direction of expanding the number of donors and organs available for transplant, it needs to be expanding, not reducing OPO resources. It is AOPO's goal to achieve 50,000 transplants in 2026 but we cannot do this without CMS' support. We are asking CMS to build on, not stymie the important strides the organ system has been making over the last several years, particularly the strides that has been achieved with deceased donation in the last few years.

III. Non-Renal Organs

As explained in greater detail in our responses below, AOPO has concerns with CMS' proposed new methodology of treating non-renal organs in the same way they treat renal organs, including cost

reconciliation. Due to the nature of how kidney costs are reconciled along with non-reimbursable costs that we are currently expected to cover, OPOs operate at a loss when it comes to renal organs. If this were to be replicated across all organ types it would be financially untenable, even as nonprofits. Under such a model, funding to support crucial activities like community engagement to expand donor lists and initiatives to advance health equity in the organ donation and transplantation system would directly suffer. Equally important, under such budgetary constraints, OPOs would not be financially able to continue pursuing promising new innovations and technologies that allow them to push the boundaries of organ transplant, particularly with so-called marginal organs, to the same extent they are now. This will slow, and potentially even regress the important progress that is being made to expand the number of usable organs, transplants, and ultimately the number of lives saved.

- **Does the current lack of reconciliation and settlement of non-renal organ acquisition costs disincentivize IOPOs from procuring non-renal organs? Does it create an inequity in organ procurement for renal vs. non-renal organs? Would a potential policy approach that included a requirement to reconcile and settle non-renal organ acquisition costs better support the transplant ecosystem? Does the current policy of not reconciling and settling IOPOs' non-renal organ acquisition charges lead to excessive non-renal SACs?** Reconciling non-renal organs would unfortunately have the opposite of the intended effect. Due to the large fluctuations in transportation and technology costs associated with non-renal organs, it makes a one-size-fits-all pricing system much more difficult to implement and less appropriate than it is for kidney transplants. Reconciling non-renal organs after-the-fact would subject OPOs, as well as CMS, to unpredictable and potentially major financial swings, making it difficult to accurately budget forecast. As a result, OPOs would have no choice but to increase their financial reserves to put them in a position to weather such financial uncertainties, which would eventually translate into higher costs to Medicare and other payers. OPOs would also have to operate in a more risk-averse fashion, making them less able to pursue certain "marginal" non-renal organs, particularly those traveling greater distances and/or with perfusion technology costs. As a result, exciting new technologies would likely take a major step back, and possibly even cease to exist, dealing a striking blow to this and other promising new technologies that could potentially save thousands of additional lives every year. Additionally, OPOs and other stakeholders that do continue to take on these risks in order to push the boundaries of transplant and save more lives would place themselves in severe financial jeopardy compared to other OPOs, which is the opposite incentive CMS should want to create. Over time, such a policy could eventually drive innovation out of the transplant system.

- **How often and to what extent do IOPOs have non-renal organ acquisition costs that exceed the revenue they receive for those non-renal organs procured? Are there particular situations or items, or services where an IOPO's non-renal organ costs would exceed the nonrenal SAC amount received from the TH (or other IOPO) for the organ(s) procured? Are there specific high-cost items or services associated with organ procurement that potentially could increase a SAC? If yes, please explain. What rules or parameters should CMS consider to account for these items or services when developing a potential methodology for how IOPOs calculate their SACs?** As noted above, non-renal organs are far less frequent and more variable in cost compared to kidneys due to a range of factors. Among the most common reasons for these variations are variable transplant costs across geographic regions, perfusion and other innovative technology costs (particularly for lungs), and transportation costs, which are becoming increasingly more variable as the donation and transplant system becomes more national in scope. These same points also relate to the policy clarification in the December 2021 Inpatient Prospective Payment System rule in which CMS stated that non-renal SACs are intended to be an average, and additional charges may not be added. We feel that for the aforementioned reasons

about non-renal organs being far less frequent and more highly variable in cost, allowing OPOs to charge additional, justified costs on an individual basis would be the most effective strategy to keep per-organ SAC fees lower and overall system costs both leaner and more predictable, provided OPOs can provide reasonable justification and documentation for the additional charges. Alternatively, at a minimum, OPOs should be permitted to develop separate SACs for important cost differences, such as locally recovered organs versus imported organs, or perfused verses non-perfused organs, though we note this would be more burdensome to maintain and less exact than our proposal to permit certain add-on charges for individual circumstances, provided they can be verified through documentation. We strongly urge CMS to revisit this proposed reconciliation methodology, as well as its previous policy disallowing OPOs to charge additional costs on an ad hoc basis.

- **How would contractor review, reconciliation, and settlement of IOPOs' non-renal organ acquisition costs affect the transplant ecosystem? Would there be any effect on those waiting for a non-renal transplant or on transplant hospitals? Would CMS's adoption of a policy approach that required reconciliation and settlement of non-renal organ acquisition costs cause IOPOs to procure fewer organs, more organs, or about the same number of organs for transplant? If so, how and why?** As nonprofits, budget predictability is extremely important to OPOs. To prepare for reconciliation, OPOs will need to increase their financial reserves, resulting in a higher SACs for all payers, including Medicare. OPOs would also have to take a more conservative approach to other more scalable areas of their budget forecasting, such as community outreach, etc. Being able to charge transportation and other fees as appropriate allows us flexibility and confidence to budget and allocate funding for community outreach and other important roles OPOs play in their community, such as efforts to expand the donor pool to ensure equity in the transplant system. As noted earlier, this proposed policy could put OPOs and other stakeholders that are actively pushing the boundaries of transplant to save more lives from so-called marginal organs and donors in financial jeopardy for pursuing organs that are more complex or expensive to procure, resulting in fewer lives saved and eventually even putting some of the most groundbreaking OPOs and other stakeholders at risk of closure.

  It is important to note that MACs already review Medicare cost reports and as part of reconciling payments for kidney transplants, they have to review non-renal costs, which are also included in Medicare cost reports. All OPO cost reports are subject to a desk audit by the MAC and if chosen, an on-site audit. These processes which are already in place provide oversight of all SAC charges, including for non-renal organs, while allowing sufficient flexibility to account for the fact that the circumstances and costs for each transplant are unique, particularly in the non-renal market. Financially reconciling non-renal organs the same way kidneys are currently reconciled would fail to properly take into account these important variances which are particularly acute in the non-renal market.

- **[CMS has] heard from stakeholders that some IOPOs have lengthy internal processes to adjust their SACs. Do IOPOs have the ability to respond quickly to cost changes that might necessitate a SAC adjustment? How frequently do IOPOs currently need to adjust their SACs due to cost changes that are higher or lower than usual?** AOPO appreciates CMS' point that SACs can be updated. However, the primary issue is not a steady increase in costs over time; it is the inherent, highly unpredictable nature of non-renal transplant costs, which would impact CMS in the same way it would impact OPOs in the sense that both sides would require additional cash reserves to cover the "what ifs." Single organs can vary hundreds or even thousands of dollars from the SAC, so updating SACs would not be effective solution unless the price is essentially re-set after each non-renal organ transplant, which is impractical. Each time a SAC is updated, that entails additional data collection, analysis and approval

that requires additional staff time and therefore incurs additional expense, which must eventually be passed onto payers. Due to the uniquely intersected nature of the donation and transplantation system, continuously updating SACs would create major complications in transplant hospitals' pricing negotiations with private payers, causing further downstream disruptions to the system.

IV. Renal SACs

CMS is considering a methodology under which renal SACs would align with non-renal in that OPOs would set their own SAC and would not need to submit to MAC and could adjust kidney SACs throughout the year to account for cost changes as necessary. Do IOPOs believe that being in control of their kidney SAC, as they are of their non-renal organ SACs, would improve their fiscal stability? More flexibility is always welcome. AOPO notes that OPOs can propose adjustments to kidney SACs during the year and that MACs typically do not disapprove of a proposed fee change, but can take a while to respond, which can slow down the process. Accordingly, AOPO would support this change. However, we reiterate that there are major intrinsic differences between non-renal and renal recovery costs, and we do not feel it would be appropriate to universally apply the same policies and processes to both, particularly with regards to reconciling non-renal organs.

V. Tracking Exported Organs

Exported organs need to continue to be universally tracked and reported to a single entity in some way, whether that is CMS, UNOS, or another entity. This work is critical for OPOs to accurately price SACs, particularly as organs are increasingly transported outside of their local donation service areas. Given the other proposals in this rule, this data would also need to be combined with payer data and made available real-time via a national database.

VI. Allowing Organ Recovery Costs for Potential Deceased Donors

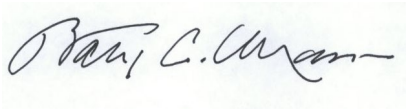
AOPO strongly supports CMS' proposal to allow a donor or transplant hospital to incur costs for hospital services attributable to a deceased donor or donor whose death is imminent for organ recovery purposes. We agree with CMS that failure to provide these services to the potential donor may compromise the viability of organs, limit organ donation, and would not honor the donor or donor family's wishes to donate organs and we encourage CMS to finalize this policy as proposed.

VI. Conclusion

As the nation's leading voice for OPOs, AOPO represents the thousands of dedicated OPO professionals who acutely understand the implications that any policy changes, including those proposed in this rule, would have on the organ donation and transplant community and the thousands of lives it impacts every year. Once again, we appreciate this opportunity to provide feedback and hope CMS gives our feedback, as well as all industry stakeholders, serious consideration, particularly considering our concerns with the possible unintended consequences these policies could have on transplant patients and the progress the industry has been working diligently over the last several years to make, including expanding the donor pool and making strides in new technological innovations to recover more organs, drive more transplants, and save as many lives as possible. We would welcome future opportunities to engage with CMS and our fellow stakeholders, particularly an opportunity to engage in a multi-stakeholder workgroup to discuss these complex issues and proposed methodology changes in real time. We also reiterate our request for a deadline extension on the RFI components of this rule, which we would use to provide more robust,

data-informed responses to the individual questions. If you have any questions about the content of this letter, please contact Mark Cribben, Director of Government Affairs, at mcribben@aopo.org.

Sincerely,



Barry C. Massa
President
Association of Organ Procurement Organizations