American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

June 25, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: [CMS-1752-P]; RIN 0938-AU44; Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates, et seq. (IPPS Proposed Rule" or "Proposed Rule")

Dear Administrator Brooks-LaSure:

As President of the American Society of Transplant Surgeons (ASTS), I am writing to express ASTS' deep concerns about the IPPS Proposed Rule. ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

We are greatly concerned about the substantial organ acquisition cost (OAC) payment reductions proposed in the IPPS Proposed Rule: The most impactful of these is a proposed modification of the longstanding methodology used by the Medicare Program to determine the portion of organ acquisition costs payable by the Medicare Program, a proposal that, according to CMS' own budget analysis, would result in a reduction of over $4 billion in payment to Transplant Centers for their organ acquisition costs (OAC) over the next ten years. This proposed change would disrupt the OAC infrastructure of the 262 transplant centers that today supply an estimated 36% of the organs procured in the United States. We outline below our reasoning for CMS to delay its implementation of these payment reductions, pending further study and consultation with the affected providers, professional associations, and patient groups.

These proposed reductions would impact Transplant Center OAC infrastructure for all organs, including kidneys, for which Medicare is the single largest payor under Medicare's End Stage Renal Disease program. It is puzzling[1] to us that CMS is proposing to substantially cut back on its support for kidney transplantation at a time when:

- It has been universally acknowledged that kidney transplantation is the treatment of choice for those with End Stage Renal Disease (ESRD) and, based on the most recent USRDS data, has the potential to save $55,556 per patient per year over dialysis.[2]

[1] The Proposed Rule suggests that the Cost Apportionment Proposal was put forth at least in part because CMS understands that a significant number of organs procured in the United States are shipped overseas. Scientific Registry of Transplant Recipients (SRTR) data does not appear to support this view.

[2] The USRDS 2020 Annual Report reports that the cost of a transplant averages $37,304 PPPY and dialysis averages $91,860 PPPY.

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- The waiting list for kidney transplants alone has reached over 90,000.
- The national goal, announced as recently as 2019, is to "help more Americans escape the burdens of dialysis" by doubling the number of kidney transplants performed by 2030.
- ESRD Demonstration Programs are being implemented to incentivize dialysis facilities and nephrologists to encourage living donor transplantation and to refer Medicare patients for inclusion on transplant waiting lists.
- CMS has issued a Request for a Proposal for a contractor to implement a Kidney Transplant Learning Collaborative whose goal is to increase kidney transplantation by 15% over five years.
- Transformative changes to the organ allocation system are straining individual transplant centers' resources by mandating broader organ sharing across geographic areas.
- Transplant Centers and OPOs are just beginning to experiment with centralized organ recovery that have been shown to increase organ acquisition and decrease costs—experiments that almost certainly could not continue if the proposed reductions are implemented.

The IPPS Proposed Rule includes no analysis of the potential impact of the proposed OAC payment reductions on organ availability or on transplantation more generally and does not consider the potential cost impact of delays in transplantation of ESRD patients and the retention of Medicare beneficiaries on dialysis. We also believe that the proposed changes will substantially increase administrative burden on Transplant Centers at best and would be virtually impossible to implement at worst. For these reasons, while we understand and appreciate the need for the Medicare Program to ensure that it pays no more than its fair share of organ acquisition costs, we urge CMS to delay its implementation of these payment reductions, pending further study and consultation with the affected providers, professional associations, and patient groups.

Preliminarily, we note that the Proposed Rule includes a number of transplant-related proposals that we support, including CMS' proposal to formalize current cost-reporting guidance in regulations; to clarify the definitions of Transplant Hospital and Transplant Program, and to redefine Hospital-based Organ Procurement Organization (HOPOs) and Independent OPOs. We believe the effort to codify the OAC rules will benefit transplant providers by clarifying a number of longstanding ambiguities.

While we recognize that the Proposed Rule includes many substantive changes that will impact both Transplant Programs and OPOs, these comments focus primarily on proposed changes in the way CMS will determine the portion of total OAC payable by Medicare (the "Cost Apportionment Proposal"), since we anticipate that the Cost Apportionment Proposal, if adopted, will have the greatest impact on the field of transplantation and on our patients. Our views on other provisions of the Proposed Rules are set forth in the Attachments to this comment: Attachment A addresses CMS' Request for Information on the need to update surgeons' fees for the recovery of deceased organ kidneys; Attachment B addresses our concerns about CMS' proposal to deny OAC payment for living donor follow-up visits; and Attachment C addresses CMS' proposal to exclude Medicare recipients of organs transplanted under a research protocol from the Medicare ratio. We respectfully request that CMS refrain from finalizing these and any of the other transplant-related proposals in the IPPS Proposed Rule, pending further study of the potential impact of these changes on Transplant Programs and on our patients.

I. CMS' Current Cost Apportionment Methodology was Intended to—And Does—Incentivize Organ Recovery and Support Transplant Centers' Organ Recovery Infrastructure.

The Nation's 262 Transplant Center Hospitals–constituting approximately 4% of Medicare certified hospitals in the country—currently recover over one third of deceased donor organs. This commitment to organ procurement is no accident. It is the direct result of the organ acquisition rules that the IPPS Proposed Rule seeks to change.

A Transplant Hospital's organ procurement activities do not necessarily benefit the candidates on that Hospital's Transplant Center waitlist: Organs are allocated based on Organ Procurement and Transplantation Network (OPTN) organ allocation policies and, due to recent changes in these policies, are increasingly utilized for recipients at other Transplant Centers (Recipient Transplant Centers).

For over three decades, the Cost Apportionment Rules has assumed that organs procured by a Transplant Hospital and transplanted at a different Transplant Hospital are transplanted into a Medicare recipient. The IPPS Proposed Rule would change this accounting rule: Under this proposal, the Donor Transplant Hospital would be required to ascertain the insurance status of all recipients of organs sent to other Transplant Hospitals and to count only certain (and not all) organs transplanted into Medicare recipients.

The current methodology was initially adopted both because the Medicare Program recognized that there was no established system for tracing the insurance status of organ recipients and because it recognized Medicare's unique role in supporting Transplant Hospital activities for the transplant ecosystem to operate effectively—including, for example patient communications and outreach, transplant evaluation, pre-transplant testing, waitlist management and a myriad of other services reimbursed through OAC payment. Neither circumstance has changed: As discussed below in Section V of these comments, there is still no established system for tracing the insurance status of organ recipients; and the need for Transplant Center hospitals to maintain the infrastructure necessary to maximize transplantation is even more pressing now than it was at the inception of the system, in light of today's extraordinarily long—and growing—transplant waitlists.

The preamble of the 2022 IPPS Proposed Rule appears to suggest that the sole reason for the current cost apportionment rule was the lack of insurance tracing mechanisms at the time the system was initially established. However, this view ignores the history of this cost apportionment practice: A number of ASTS members active in transplantation at the time and involved in initial discussions with CMS (then HCFA) have indicated that, in fact, the current methodology was intended to incentivize Transplant Hospitals to dedicate their resources to transplant-related infrastructure. If the agency had not intended to provide this incentive, it could have simply used each Donor Transplant Hospital's own Medicare ratio to determine the Medicare ratio of Donor Hospital organs transplanted elsewhere. On a national basis, such a system would have resulted in Medicare's paying for the reasonable costs of organs transplanted into all Medicare (but no non-Medicare) recipients. The fact that this simple system was not adopted suggests that the decision of CMS—then HCFA—to assume that organs transplanted elsewhere were transplanted into Medicare patients was intended to support Transplant Program infrastructure that is not otherwise payable.

II. Adopting the Proposed Cost Apportionment Change in FY 2022 Has the Potential to Significantly Undermine Transplant Programs' Current OAC Infrastructure and Result in Reduced Patient Access to Transplantation.

If the Cost Apportionment Proposal is implemented without change in FY 2022, it has the potential to jeopardize organ availability and reduce patient access to transplantation. Based on cost report data

from 2019, on average, Donor Transplant Hospital Medicare reimbursement will be reduced by about $1.7 million per Transplant Hospital per year, with reductions of over $2 million for 23 Transplant Hospitals and reductions in the $3-$4 million range for Transplant Hospitals that retrieve the greatest number of organs transplanted elsewhere. These cuts are likely to have a significant disproportionate impact on access to transplantation for minority populations who comprise a substantial portion of those on transplant center waiting lists and will have a particularly devastating financial impact on academic medical centers and children's' hospitals. Yet, CMS evidently did not perform any analysis of the potential impact of the Cost Apportionment Proposal on organ availability or access to transplantation; nor did CMS consider the additional dialysis and related costs that may result from Medicare's reduced support for Transplant Center OAC.

If the Cost Apportionment Proposal is adopted without change and implemented on October 1, 2021, the items and services reimbursed as OACs would begin to operate at a loss virtually overnight. We recognize that, conceptually, if but only if all non-Medicare payers were to provide payment for OAC utilizing Medicare reasonable cost principles (i.e., paid for the Transplant Center's Standard Acquisition Charge (SAC)), organ procurement activities conducted by Transplant Hospitals would—at least theoretically—break even. Unfortunately, this ideal state of affairs does not reflect today's reality: Medicaid recipients constitute almost 9%[3] of organ recipients, and, while state Medicaid payment systems vary, they generally do not provide for full payment of Transplant Center SACs. Nor is this the standard method private insurers use to reimburse or contract with transplant centers. The majority of organ transplants covered by private payers are funded through approximately six large private insurance companies. In most cases, these companies have negotiated contracts that pay Transplant Hospitals based on case rates that stipulate the cost of the organ implanted will be covered 'at the OPO's invoice. The substantial difference in the cost of an OPO SAC or "invoice" versus a Transplant Hospital's internally developed SAC (which accounts for and 'spreads' all pre-transplant service costs over each useable organ) would necessitate re-negotiation of most existing contracts. Patient access and Transplant Hospital support for organ acquisition activities will depend on the willingness of this small number of commercial payors to re-negotiate with every Transplant Center in the US simultaneously – and to agree to cover expanded Transplant Hospital SACs. Renegotiation efforts may be peremptorily ignored by commercial payors and increased payment is likely to take months or years to achieve. Unless and until commercial payer and Medicaid rates can be renegotiated to increase payment for Transplant Hospitals' OAC, transplant-related activities are highly likely to be operated at a loss and Transplant Hospitals will be forced to cut back.

While the overall impact of this change (if adopted) on organ availability and access to transplantation is difficult to predict, a number of likely repercussions can be identified:

- Children's hospital transplant programs are particularly likely to be adversely impacted. In fact, it is estimated that children's hospitals will absorb an estimated 6% of the projected payment reductions, potentially jeopardizing the financial viability of pediatric transplant programs.

- This change, if adopted, is likely to significantly impact access to transplantation of non-renal organs: Estimates based on work performed by Brigitte Sullivan, an independent transplant

[3] DuBay DA, MacLennan PA, Reed RD, et al. Insurance Type and Solid Organ Transplantation Outcomes: A Historical Perspective on How Medicaid Expansion Might Impact Transplantation Outcomes. *J Am Coll Surg*. 2016;223(4):611-620.e4. doi:10.1016/j.jamcollsurg.2016.07.004. https://pubmed.ncbi.nlm.nih.gov/27457252/

consultant, based on FY 2019 cost reports (Attachment D) suggest extraordinary payment reductions affecting non-renal organs, as follows:

Organ	% Decrease in Total OAC
Heart	-14%
Intestine	-2%
Kidney	-7%
Liver	-11%
Lung	-9%
Pancreas	-8%

- Finalizing these OAC payment reductions as proposed is very likely to jeopardize the financial viability of a growing number of innovative programs that have increased the number of organs procured from deceased donors (donor yield). These programs utilize Transplant Hospitals to procure organs from patients initially identified as potential donors by other community hospitals—for example, by transferring patients who are potential deceased organ donors from community hospitals to specialized care areas within Transplant Hospitals that are equipped and trained to maximize donor yield. In novel collaborations in Texas and Alabama, organs transplanted per donor rose from 2.74 to 3.10 (Alabama) and 2.96 to 3.49 (Texas). The ability to count all donor organs as Medicare organs is a critical driver in these innovative partnerships.

- The proposed payment reduction is particularly likely to reduce the availability of donation after circulatory death (DCD) organs. For example, in three cities—San Antonio, Texas; Charleston, South Carolina; and New York, New York—OPOs are working with a Transplant Hospital to transfer potential cases of donation after circulatory death (DCD) from outlying community hospitals that lack the infrastructure or support to perform donor management and organ procurement in these cases. In other cases, Transplant Hospitals accept transfers of potential DCD donors from community hospitals that do not engage in DCD procurements for religious reasons. In these cases, it is unknown at the time of transfer where (or if) those organs would be ultimately transplanted (and if the cost for the transfer and donor care would be reimbursed).

- Increased use of organs at risk of discard ("so-called "marginal" organs) and a reduced discard rate are major components of CMS' efforts to increase access to transplantation. However, successful transplantation of organs at risk of discard often requires extensive –and expensive—organ rehabilitation (for example, through ex-vivo perfusion). Significant reductions in Medicare payment for organ acquisition costs will likely undermine efforts to increase Transplant Hospital acceptance of such "marginal" organs for transplantation by making significant expenditure for organ rehabilitation unaffordable.

- Transplant Hospitals that have invested heavily in programs intended to increase living donor transplantation rely on the current cost apportionment methodology to help cover the costs of working up potential living donors who ultimately cannot—or decide not to—donate an organ. Such costs can be significant; are not generally paid by Medicaid and are not always payable by commercial payers. Additionally, there is a statement in the proposed rule that the only registry fees allowable for reporting as an organ acquisition cost are those for the Organ Procurement

and Transplantation Network (OPTN). This eliminates reporting of fees for living donor registries which have contributed to approximately 20% of living donor kidney transplants over the past five years. In 2019, an estimated 660 Medicare beneficiaries received successful transplants as part of these types of registries.

- Medicare payment for Transplant Hospitals' OAC includes payment for a myriad of pre-transplant activities without which no patient would be transplanted, and which are not covered or insufficiently covered by Medicaid and other third party payers. Precipitous cutbacks of Medicare payment for transplant infrastructure of this kind have the potential to significantly slow pre-transplant activities and increase waiting times.

We strongly believe that these and other potential repercussions on organ availability, access to transplantation, and cost should be examined thoroughly before CMS determines whether to implement so significant a change in payment for OAC.

III. The Project Impact of the Cost Apportionment Proposal on Medicare Costs should be Studied Further.

We believe that the projected impact of the cost apportionment proposal on Medicare Costs requires further study. The Impact Statement accompanying the Proposed Rule states that finalizing the Cost Apportionment Rule Proposal without change would result in Medicare savings of $230 million in FY 2022, $1.74 billion over 5 years, and $4.150 billion over 10 years.

We believe that both the short and the long term cost implications of the Cost Apportionment Proposal are considerably less certain than this Impact Analysis would suggest. CMS' estimates are based in large part on a special SRTR data run indicating the payer mix of organ recipients. We note that this data is not consistent with the payer mix data published in the SRTR's annual data reports; does not include Medicare recipients for which Medicare served as a secondary payer; and includes living donor transplants, which are much more likely to be covered by private payers. All of these factors suggest that the Impact Analysis overestimates potential Medicare savings. On the other hand, a comprehensive analysis conducted by independent transplant consultant Brigitte Sullivan, suggests that CMS' Impact Analysis may <u>understate</u> potential reductions in OAC payment that would result if the Cost Apportionment Proposal were adopted without change. Under these circumstances, we believe that further study of the potential impact of the proposal is necessary, if only to more accurately calculate potential Medicare savings and the payment reductions that Transplant Hospital OAC infrastructure will have to absorb.

Moreover, it does not appear that CMS has taken into account the potential impact of the Cost Apportionment Proposal on OPO SACs, which may significantly mitigate Medicare savings. Under current rules, Transplant Hospitals have no financial incentive to charge OPOs for all of the direct and indirect costs associated with organ procurement (i.e., the Transplant Hospital SAC), because revenues received from the OPO for these services are offset against the amounts charged for them by the Transplant Hospital. As a result, many Transplant Hospitals charge OPOs nominal amounts for the services involved in procuring organs, rather than charging OPOs for the Transplant SACs, as would be required by the Proposed Rule. If the Cost Apportionment Rule is adopted, Transplant Hospitals will be required to—and will have a financial incentive to—charge OPOs for all direct and indirect costs involved

in organ procurement.[4] Over time, the higher Transplant Hospital SACs paid by OPOs will result in higher OPO SACs for all organs (including deceased donor kidneys, for which Medicare is the primary payer). We believe that higher OPO SACs for deceased donor kidneys and other organs will mitigate Medicare cost savings resulting from adoption of the Cost Apportionment Proposal.

In addition, if the Cost Apportionment Proposal results in even a modest reduction in the availability of deceased donor kidneys, Medicare cost savings will be further mitigated. For example, based on the analysis set forth in Attachment E, an estimated 824 deceased donor kidneys would be lost if adoption of the Cost Apportionment Rule results in just a 5% decrease in deceased donor kidneys from donors less than 65 years of age (generally transplantable organs). Since Medicare program costs are approximately $55,553 per patient per year higher for an ESRD patient on dialysis than for a transplanted patient, the additional cost to the Medicare program over a five-year period would be $228,890,720 over five years and 457,781,440 over 10 years.

IV. Finalizing the Proposed Cost Apportionment Change Would Result in Underpayment of Medicare's Portion of Organ Acquisition Costs Unless CMS also Modifies Other Rules Not Addressed in the Proposed Rule.

Under current cost reporting rules, amounts received by a Donor Transplant Hospital from an OPO for organs ultimately transplanted at another Transplant Center are offset against otherwise allowable costs. This revenue offset is appropriate if—but only if—all such organs are treated as Medicare organs for cost apportionment purposes. Under the Proposed Rule, a Donor Transplant Hospital would not be authorized to include such organs as Medicare organs—but the Proposed Rule does not suggest or imply any change to the revenue offset rules. Unless the revenue offset rules are changed, the net result would be underpayment of the organ acquisition costs attributable to Medicare patients.

V. The Proposed Cost Apportionment Rule Would Impose Administrative Burdens on Transplant Centers and on Medicare Contractors that Ignore the Complexity of Medicare Eligibility Rules and Commercial Payer Contracting Practices.

The proposed Cost Apportionment Proposal would impose administrative responsibilities on Transplant Hospitals and on Medicare contractors that would be virtually impossible to fulfill. Under the proposal, Transplant Hospitals would be required to provide–and Medicare contractors would be required to audit–evidence of the Medicare status of each deceased organ recipient transplanted at another Transplant Hospital, and implementation of the new rules would entail substantial new administrative expenditures both for Transplant Hospitals and the Medicare Administrative Contractors that audit them.

In fact, it is unclear whether Transplant Hospitals could obtain the information required under the Cost Apportionment Proposal and whether that information could be obtained in time to be accurately included in Medicare cost reports–regardless of the administrative costs expended. Under the proposal, a Donor Transplant Hospital would need to obtain a copy of the Recipient Transplant Hospital's contract

[4] If the Cost Apportionment Proposal is adopted, revenues received from the OPO for organs transplanted into non-Medicare patients presumably will not be offset against otherwise allowable costs, since such an offset would reduce OAC payment below the reasonable costs of procuring organs transplanted into Medicare recipients. See Section V of these comments.

with each non-Medicare recipient's primary payer, to determine whether amounts not paid by that primary payer could be billed to Medicare as a secondary payer; however, commercial payers universally preclude Transplant Centers from disclosing contract terms. Since Medicare serves as a secondary payer for a significant proportion of kidney transplant patients[5], these impossible-to-fulfill administrative requirements have the potential to result in significant underpayment of Medicare's portion of kidney acquisition costs. And even when Medicare serves as a recipient's primary payer, eligibility may be (and often is) determined retroactively–outside the time period covered by the cost report—which, again has the potential to result in underpayment of Medicare's portion of kidney acquisition costs.

These administrative problems are exacerbated by new organ allocation policies recently adopted by the Organ Procurement and Transplantation Network, which significantly broaden the geographic distribution of organs. For example, the new deceased kidney allocation system changes the definition of "local allocation" from the Donation Service Area to 250 nautical mile circles originating from the Donor Hospital. While other solid organs have adopted a similar approach, the larger number of both kidney Transplant Hospitals and transplant candidates is likely to result in an extraordinary increase in the number of kidneys transplanted outside of the immediate area where they were procured. Most centers work primarily with their single affiliated OPO under the current system, but now are going to be directly linked to donor hospitals that span as many as 18 different OPOs—and a median of nine OPOs. Conversely, the median number of "local" transplant centers that an OPO currently works with is three, but under the new system OPOs will be responsible for placing locally allocated kidneys at a median of 34 (20–55) different Recipient Transplant Centers.[6]

We strongly believe that the Cost Apportionment Proposal should not be finalized and that CMS should conduct a further study of the potential impact of this Proposal on organ availability, access to transplantation, and long term costs. However, if CMS does decide to modify the current cost apportionment rules, we believe that a number of alternatives should be considered including, for example, using the national or state average Medicare percentage for all organs sold to an OPO or to another Transplant Center or assuming that the Medicare percentage for organs transplanted elsewhere is the same as the Donor Hospital's own Medicare percentage. Either alternative would eliminate the extraordinary administrative burden imposed on both OPOs, Transplant Hospitals, and MACs under the Cost Apportionment Proposal.

For all of these reasons, we respectfully request that CMS conduct a comprehensive study of the potential impact of the transplant-related provisions of the Proposed Rule on organ availability, access to transplantation and refrain from finalizing the Proposed Rule pending completion of the study and consultation with stakeholders. We would also appreciate the opportunity to meet with you regarding the potential impact of these proposals. If you have any questions regarding ASTS' position on the Proposed Rule, please do not hesitate to contact Jennifer Nelson-Dowdy at Jennifer.Nelson-Dowdy@asts.org or by calling (703) 414-7870.

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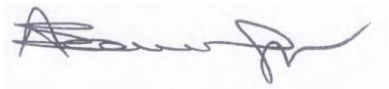
[5] According to the 2020 USRDS Annual report, approximately 27.5% of kidney transplant recipients in 2018 had Medicare as a Secondary Payer.

[6] Adler, J.T., Husain, S.A., King, K.L. and Mohan, S. (2021), Greater complexity and monitoring of the new Kidney Allocation System: Implications and unintended consequences of concentric circle kidney allocation on network complexity. Am J Transplant, 21: 2007-2013. https://doi.org/10.1111/ajt.16441

Respectfully,



A. Osama Gaber, MD, FACS
President
American Society of Transplant Surgeons

Attachment A

ASTS Response to Proposed Rule Request for Information on Updating Surgeon Fees for Kidney Acquisition

The Proposed Rule solicits comments on the physician effort and resources required to procure a cadaveric kidney for transplantation. Specifically, CMS is soliciting data or other information on surgical time, dry runs (number and percentage of retrievals in which an organ is not recovered), travel and wait times, as well as the incremental time required for extended criteria donors and donors after cardiac death. Additionally, CMS is soliciting resource information to determine the difference in procuring one kidney or a pair of kidneys from a single donor.

There have been significant changes in organ procurement since 1987, when the current surgeons' fee of $1250 was established. First, over the years, deceased donor organs have become increasingly marginal; kidneys from deceased donors with advanced age and comorbidities are being utilized more than in previous decades. This has the effect of increasing the complexity of organ recovery and the frequency of intra-operative findings that result in the abandonment of the effort. [An increasing number of organs were recovered from donors who, in past years, may not have been considered suitable based on age or medical history. For the second straight year, the most common age range of deceased donors was 50 to 64. The 3,726 donors in this category increased by 7.9 percent over 2019. According to 2020 UNOS data, donation also increased significantly among individuals who died of cardiorespiratory failure as opposed to brain death; the 3,223 donors after cardiorespiratory death (DCD donors) increased by 18.6 percent over the total in 2019.

Second, increasing DCD donors to the donor pool has required surgeons to learn newer skills. UNOS only has data on DCD donation starting in 1993, and the number of DCD donors continues to increase. Per UNOS data, there have been over 2000 DCD donors/year in the US over the past 3 years—so the numbers are significant. DCD procurements add complexity to the procurement process. Surgeons must travel to community hospitals, wait for cardiac death after withdrawal of care for one hour (up to 2 hours in certain OPOs), all of which utilizes valuable surgeon time. Not infrequently, donor transition to cardiac death is unpredictable and may be slow, resulting in abandonment of the effort. Reported rates of futile DCD runs occur at least 10-12% of the time.

When procuring deceased donor organ kidneys, it is customary to allow the aorta and vena cava (or portions of these) to be part of the organ vasculature. In addition, about 20% of the time, there is anomalous vascular anatomy to the kidneys. For this reason, the entire vasculature (including the aorta and vena cava) and en-bloc kidneys are dissected out and removed from the donor body, and then separated outside, giving consideration to the vasculature. The kidneys are thus not removed singly in most cases.

Attachment B

Living Donor Follow Up

The Proposed Rule states:

> *The OPTN policy provides for follow-up visits, which occur at 6 months, 12 months, and 24 months post-donation. These follow-up visits are not allowable nor reportable as organ acquisition costs on the MCR and cannot be billed to Medicare. These follow-up visits are for collecting longer term data on the effects of living donation on the donor rather than for meeting medical needs of the donor.*

Proposed Rule at 1520:

The Proposed Rule cites OPTN guidance procedures for data collection for this assertion.[7] In fact, the OPTN guidance document cited does not support the assertion that follow up visits are conducted for data collection purposes only. The document states, among other things,

> *Follow-up of living kidney and liver donors is crucial for understanding and minimizing the risks that donors face.*

It is well-accepted that living donor follow up is clinically necessary.

Long-term living kidney donor follow-up visits were mandated specifically to ensure the long-term safety of living kidney donors. These protocols were established primarily to ensure that prior living kidney donors are monitored for the occult development of chronic kidney disease, which is an incompletely understood, but inevitable possible sequela of donating a kidney. Living kidney donors may lack insurance or insurability at the time of donation, and may go on to lose insurance coverage, economic stability and social networks after donation. In this, they are similar to all persons, but the fact of their altruistic living kidney donation, which both saves lives and money for payers (including for Medicare), ethically mandates that they receive long-term follow-up. Given that maintenance hemodialysis is up to 2.6 times as expensive as transplantation, protection of living kidney donors is pragmatic for payers, as well as ethically sound.[8] When a prior living kidney donor follows up with a transplant center, they do so with the explicit and implicit understanding that they are receiving medical follow-up.

Living kidney donors do not return for such follow-up with the expectation that they are doing so for the purpose of providing data collection, nor should they. Transplant surgeons and nephrologists do not see those living donors in follow-up for the purpose of collecting their data, but instead for the purpose of screening this vulnerable population for hypertension, chronic kidney disease, frailty, mood disorders, lack of coping skills, financial resources and social support. In short, living kidney donors follow-up with transplant centers for medical care, and transplant centers encourage their follow-up so that they can deliver such care. This critical follow-up should be allowed under the Medicare Cost Report (MCR).

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[7] https://optn.transplant.hrsa.gov/resources/guidance/procedures-to-collect-post-donation-follow-up-data-from-living-donors/ accessed on March 16, 2021.

[8] USRDS ESRD Database. Total Medicare costs from claims data for period prevalent ESRD Patients.

The follow-up needed requires basic medical surveillance (for example, blood pressure, serum creatinine and urine protein assessment) as well as social follow-up (emotional, social, and economic resources) that transplant program staff are both most incentivized and most equipped by experience and training to accurately and sensitively obtain. The requirement for data collection was, and remains, a secondary reason for such follow-up and is of important, but theoretical, benefit to the transplant community and to future living kidney donors. The immediate and pressing reason for providing follow-up of this vulnerable and potentially underserved population is to ensure that they have a minimum amount of medical surveillance. Without this follow-up, they would be at elevated risk of adverse outcomes and would, in effect, represent an altruistic group that is effectively abandoned after the incredible, lifesaving act of donation. The act of living kidney donation has an enormously beneficial effect on the economics of ESRD, and ripple effects throughout the transplant ecosystem as living donation directly impacts the supply/demand mismatch between organ supply and need.[9] The lifetime cost savings of a single living donor kidney transplant range from $1.3-1.45 million per recipient.[10] The salutary effects of living kidney donation on Medicare finances and the history of provision of a needed subsidy via the MCR provide both economic and ethical rationales for ongoing support of this critical clinical service via the MCR.

[9] U.S. Renal Data System 2013 Annual Report. End-Stage Renal Disease in the United States.
[10] Held P, McCormick F, et al. A cost-benefit analysis of government compensation of kidney donors. Am J Transplant. 2016;16:877-885. PMID 26474298.

Attachment C

Counting Medicare Recipients Transplanted under Research Protocol

The Proposed Rule states:

> *For organ acquisition cost allocation purposes, a "research organ" is an organ procured and used for research regardless of whether it is transplanted as part of clinical care (with the exception of pancreata [procured for certain islet transplant research].*

It is our understanding that, under the policy as proposed, organs transplanted into a Medicare patient as part of a research protocol approved by an IRB would not be counted as Medicare organs. ASTS strongly objects to this proposal.

This proposal would cast a pall over transplants performed as part of (Institutional Review Board) IRB-approved research protocols. This would serve to limit not only innovation and the effect of such innovation on future patients but would also limit access and equity for current transplant candidates by creating uncertainty as to the fiscal feasibility of IRB-approved transplant protocols in general. It is important to note that IRB-approved research protocols are often utilized to provide care to the most vulnerable patient populations and allow use of organs at highest risk of discard without such protocols. We believe that the proposed policy, if adopted, would thus be a detriment to ongoing efforts to increase the number of transplants performed, decrease the number of useable deceased donor organs discarded, maximize the equity of the care provided within the transplant ecosystem, and improve access to care for our vulnerable patients. These issues of increasing transplant access and equity are, quite literally, a matter of life or death for current and future transplant candidates and provide powerful rationales for modifying the proposed policy.

Specific populations that would immediately be put at risk if the proposed policy were enacted include transplant candidates with Human Immunodeficiency Virus infection (HIV) and candidates without Hepatitis C Virus (HCV) infection. Specific deceased donor organs at risk for discard would include all organs from HIV positive donors and those from Hepatitis C Virus (HCV) positive donors. HIV positive organ donation occurs only under IRB-approved research protocols, and the proposed policy would potentially eliminate these organs from use by disallowing cost reporting via the MCR associated with their use.

For those with HIV, HIV infected donor to HIV infected recipient transplants provide a life-saving option that increases access and equity. This was made possible by the passage of the HOPE act (HIV Organ Policy Equity Act), which was an example of visionary bipartisan leadership in the Legislative and Executive branches of the Federal government and which took effect in November 2015 for kidney and liver transplants and was expanded in May 2020 to include organs of all types.[11] Such transplants are uniformly conducted under research protocols (developed in conjunction with the National Institute of Health (NIH), and would not be counted as Medicare organs under the proposed policy.

Likewise, recent modifications of CDC guidelines on the use of HCV positive organs for HCV negative recipients have paved the way for significantly expanded (and generally clinically successful) use of HCV

[11] HHS notice, 11/25/2015 on Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV. H.R. 7809 – HOPE Act of 2020.

positive organs, thus helping decrease organ discards, increase the number of transplants performed, and increase access for a vulnerable population.[12] The transplantation of HCV positive organs into HCV negative recipients is conducted under clinical trial protocols and must be approved by an Institutional Review Board (IRB). Based on the definition of a research organ defined in the proposed policy, these transplants would not be counted as Medicare organs if they are transplanted into Medicare beneficiaries, thus essentially denying Medicare payment for such transplants. This policy would almost certainly have the practical effect of making HCV infected organs unavailable to HCV negative Medicare beneficiaries and would likely result in the discard of a significant number of useable HCV positive organs while denying or limiting access for HCV negative MC beneficiaries.

Significant advances are being made in the field of organ rehabilitation utilizing ex vivo perfusion and other techniques to make organs at risk of discard (so called "marginal" organs) suitable for transplantation. Studies of new techniques for organ rehabilitation are generally conducted as part of IRB-approved research protocols. It is our understanding that, under the Proposed Rule, organs that are rehabilitated under a research protocol and subsequently transplanted into a Medicare beneficiaries would not be counted as Medicare organs.

We believe that the proposed exclusion of Medicare coverage for organs transplanted in conjunction with a qualified clinical trial is inconsistent with CMS' clinical trials policy. Under this policy, codified as **National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1):**

> *Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials…*

Organ acquisition costs qualify as "routine costs" for a transplant recipient enrolled in a qualified clinical trial, since organ acquisition costs are "Items or services that are typically provided absent a clinical trial (e.g., conventional care)" for transplant recipients. Such costs therefore should be covered as they would be in the absence of the clinical trial, i.e., they should be "counted" as Medicare organs for the purpose of determining the OAC payable by Medicare.

The proposed policy would deter ongoing efforts to increase the number of transplants performed, would increase deceased donor organ discards, would deny transplantation to MC beneficiaries, and limit access to care for our most vulnerable populations. Enacting this proposal has the potential to stop efforts to improve access, equity and innovation in their tracks. These are powerful rationales for modifying the proposed policy.

For these reasons, we strongly oppose this proposed rule change and respectfully request that CMS conduct a comprehensive study of the potential impact of the transplant-related provisions of the Proposed Rule and refrain from finalizing the Proposed Rule pending completion of the study and consultation with transplant ecosystem stakeholders. We would also appreciate the opportunity to meet with you regarding the potential impact of these proposals.

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[12] Levitsky J, Formica RN, Bloom RD, et al. The American Society of Transplantation Consensus Conference on the Use of Hepatitis C Viremic Donors in Solid Organ Transplantation. Am J Transplant, 2017;17:2790-2802.

Attachment D

Estimated Impact of Cost Apportionment Proposal on Organ Acquisition Costs by Organ

Analysis of FY 2019 Medicare Cost Report Organ Acquisition Data

	Total Organ Acquisition Costs Reported	Current Medicare Share	Organs Sold (Count as Medicare Organs Currently)	Organs Transplanted Reported	Medicare Transplants (Medicare Usable Organs - Organs Sold)	Estimated Medicare Share Under Proposed Rule	Decreased Medicare Reimbursement Estimate Under Proposed Rule
Heart	$ 530,767,937	41%	1,143	3,484	772	22%	$ (74,089,233)
Intestinal	$ 13,312,938	19%	3	76	12	15%	$ (330,860)
Kidney	$ 2,303,094,763	67%	7,861	23,498	13,393	58%	$ (161,685,140)
Liver	$ 967,443,042	38%	2,203	8,705	1,958	22%	$ (106,130,235)
Lung	$ 401,333,680	46%	758	3,471	1,221	35%	$ (34,585,199)
Pancreas	$ 78,882,078	59%	325	968	448	46%	$ (6,217,185)

Analysis of FY 2019 Medicare Cost Report Organ Acquisition Data

Medicare Cost Report (MCR) data is publicly available to download from the CMS website by Fiscal Year (https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year). The files of hospital cost reports submitted in Fiscal Year 2019 (downloaded on 5/25/2021) were utilized to conduct this analysis.

Hospitals that perform solid organ transplants are permitted to complete a D4 Worksheet for each Medicare-certified organ transplant program. For example, if a hospital has Medicare approved kidney and heart transplant programs, it files a D4 worksheet for kidney and a D4 worksheet for heart with the MCR. The D4 worksheets were extracted from the dataset and the key rows and columns containing the organ acquisition costs and organs reported by the hospitals were identified.

The instructions for completing the D4 worksheet are in the CMS Provider Reimbursement Manual – Part 2, Chapter 40-(T16) — Hospital & Hospital Health Care (Form CMS-2552-10), Section 4028. Based on these instructions, the total organ acquisition costs, revenue from organs sold, organs excised, transplanted, and discarded were extracted. The total organs transplanted reported in the MCR were compared with the total organs transplanted in the OPTN data for calendar year 2019, and matched within 1%, indicating that the MCR dataset was reasonably aligned with annual volume data.

The count of organs that were transplanted into Medicare recipients is not specifically reported on the D4 and may include both Medicare primary and Medicare secondary beneficiaries. Therefore, the number Medicare organs transplanted was deduced by subtracting the organs excised and the organs discarded from the reported Medicare usable organs (per the MCR instructions). The Medicare ratio of organs transplanted at the hospital was calculated as this Medicare transplant number divided by the total number of transplants reported.

To estimate the number of organs excised at the hospital that would ultimately be transplanted into Medicare beneficiaries (the major change in the proposed IPPS rule), this same percentage of Medicare transplants was applied to the excised organs. This estimated number of organs excised at the hospital and transplanted into Medicare beneficiaries (where transplant occurred at any hospital) were then counted as Medicare usable organs that would be reported under the proposed rule (the revised Medicare usable organs count). The calculated number of reported organs transplanted at the hospital into Medicare beneficiaries was also included in the revised Medicare usable organ count, and the percentage of Medicare transplanted organs was applied to the revenue received for excised organs (revenue for organs sold) to adjust the revenue share to account for organs ultimately transplanted into non-Medicare beneficiaries (even though the proposed rule does not include revisions to adjust this revenue).

A new Medicare share was calculated using the revised Medicare usable organs divided by the total usable organs. This new share was applied to total reported organ acquisition costs and the adjusted revenue for organs sold was subtracted to arrive at the new Medicare Reimbursement Amount that each hospital and organ program would expect based on what was reported on the MCR. This was done for each D4 Worksheet, and then summarized by hospital, state, and organ type.

Attachment E

Deceased Donor Kidneys Potentially Lost as a Result of Adoption of Cost Apportionment Proposal
(Excerpted from Analysis Prepared by Brigitte Sullivan, Independent Transplant Consultant)

Source of Transplanted Organs	Donors in CY20	Kidneys in CY20	Kidneys TPD in CY20	Conservative		Moderate		Significant	
				Decr	Organs Lost	Decr	Organs Lost	Decr	Organs Lost
Donation after Cardiac Death (DCD) Donors <65 at non-Transplant Center Hospitals (decreased transfers to facilitate donation)	1,993	2,970	1.49	5%	(149)	10%	(297)	20%	(594)
Brain Dead Donors <65 (decreased OTPD rate due to hospital reimbursement disincentives and diminished donor center hospitals)	8,609	13,491	1.57	5%	(675)	10%	(1,349)	20%	(2,698)
Total	**10,602**	**16,461**			**(824)**		**(1,646)**		**(3,292)**