
September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Re: Comments on CMS-1772-P— CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (“HOPPS Proposed Rule” or “Proposed Rule”)

Re: Dear Administrator Brooks-LaSure:

On behalf of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST), we are pleased to have the opportunity to comment on the 2023 HOPPS Proposed Rule (the “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. AST is transplant professional society representing over 4,200 members engaged in patient care and transplant research. We are dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, organ donation, and service to the community through a lens of equity and inclusion.

Preliminarily, we wish to express our support for two provisions of the Proposed Rule:

ASTS/AST Recommendation: ASTS/AST strongly support the Centers for Medicare and Medicaid Administration’s (CMS’) proposal to include as DCD organ acquisition costs the costs for donor management when death is imminent, as set forth in the Proposed Rule.

ASTS/AST Recommendation: ASTS/AST support CMS’ intent in the proposal to allow any surgeon, rather than only the excising surgeon, to determine that an organ is unusable but recommend use of “physician” rather than “surgeon” to account for the role played in these determinations by critical care intensivists, pulmonologists and other medical doctors as designated by many organ procurement organizations (OPOs).

ASTS/AST Recommendation: ASTS/AST support CMS’ proposal to reclassify miscellaneous dental procedures (CPT 41899) into APC 5871, the same APC utilized for other dental procedures. The increased payment resulting from this reclassification

has the potential to reduce financial barriers to the use of hospital outpatient operating rooms for medically necessary dental procedures for potential transplant recipients whose dental treatment requires general anesthesia.¹ We also recommend that CMS include dental procedures on the Ambulatory Surgical Center List of Covered Surgical Procedures, in order to further increase access to operating rooms for dental treatment required as a precondition of transplant surgery.

Our remaining comments focus on two proposals included in the Proposed Rule that significantly and adversely impact transplantation:

- The proposed disallowance of all costs associated with organs that are the subject of a research protocol regardless of whether or not the organ is transplanted as a component of clinical care.
- The proposed disallowance of General and Administrative (G&A costs) associated with organs purchased from an Organ Procurement Organization (OPO), another Transplant Program, or a Non-Transplant Hospital.

Finally, our comments address the CMS' Request for Information (RFI) regarding computation of the Medicare ratio, which is used to determine Medicare's share of organ acquisition costs (OAC).

I. Medicare Payment for Research Organs as OAC

A. Organs Subject to a Research Protocol that are Subsequently Transplanted as a Component of Clinical Care

The Proposed Rule is unclear regarding whether or not an organ that is included in a research study but subsequently transplanted as part of clinical care is reimbursable. On the one hand, certain language in the preamble to the Proposed Rule would appear to disallow Medicare payment for a "research organ" regardless of whether it is transplanted as part of clinical care. Other preamble language, however, suggests that an organ identified as a research organ and subsequently transplanted as part of clinical care is fully allowable, stating:

We expect that when an organ, identified as a research organ, is transplanted into a patient, the organ is counted as a total usable organ and a full SAC is assigned.

If, in fact, CMS' intent is to disallow all Medicare payment for research organs that are subsequently transplanted as part of clinical care, this policy has the potential to strongly dissuade, if not to stop, critical transplant research. For example, this change, which is characterized as a "clarification" of existing policy, may virtually stop HIV to HIV

¹ We note that the 2023 Physician Fee Schedule Proposed Rule would extend Medicare coverage to include dental treatment, as well as dental evaluation of potential transplant recipients.

transplantation in its tracks and to significantly slow to the development of new perfusion and organ preservation technologies that have the potential to help alleviate the organ shortage by increasing the functionality of organs at risk of discard. Moreover, 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.

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-to-HIV transplants are uniformly conducted under research protocols (developed in conjunction with the National Institute of Health (NIH), as required by federal policy.² 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 positive organs, thus helping decrease organ discards, increase the number of transplants performed, and increase access for a vulnerable population. However, the transplantation of HCV positive organs into HCV negative recipients may be conducted under clinical trial protocols that must be approved by an Institutional Review Board (IRB). If “research organ” is defined to include those organs that are transplanted into recipients as part of clinical care, Medicare payment for all organ acquisition costs associated with HIV+ to- HIV+ transplants and with HCV+ to HCV- transplants may be disallowed, seriously jeopardizing the continued financial viability of these transplants and substantially limiting the availability of HCV positive organs, one of the fastest growing sources of transplantable organs.

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. Under the Proposed Rule, it is unclear whether organs that are rehabilitated under a research protocol and subsequently transplanted into a Medicare beneficiaries may be counted as Medicare organs, seriously jeopardizing this research.

Moreover, 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:

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...

² [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](#).

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 Medicare beneficiaries, and would limit access to care for our most vulnerable populations.

Disallowing the costs of organs that are the subject of a research protocol but that are subsequently used as part of clinical care is not only inconsistent with CMS’ otherwise applicable research policy but also inconsistent with Medicare regulations. Specifically, 42 CFR § 413.5(c) (2) provides that:

Costs incurred for research purposes, over and above patient care, will not be included [as reasonable costs for cost reporting purposes. (Emphasis added.)

The Medicare regulation relating specifically to research costs is even more explicit: 42 CFR § 490(b)(2) states:

If research is conducted in conjunction with, and as a part of, the care of patients, the costs of usual patient care and studies, analyses, surveys, and related activities to serve the provider's administrative and program needs are allowable costs in the determination of payment under Medicare.

Thus, disallowing the costs of “research organs” that are subsequently transplanted as a component of clinical care is inconsistent both with Medicare’ research policy and with the governing regulations.

ASTS/AST Recommendation: ASTS/AST recommends that CMS clarify that the OAC attributable to organs that transplanted as part of a research protocol be “counted” in the same manner as other organs in determining the Medicare ratio and that the non-research related costs of such organs be allowable costs for the purposes of determining OAC.

B. Allowable Costs of Research Organs Not Transplanted as a Component of Clinical Care

We are also concerned that finalizing the Proposed Rule without change would incentivize discard of organs that potentially could be used for research. The Proposed Rule confirms longstanding policy that organ discards may be included in the G&A cost center, and the costs thereby spread among usable organs. On the other hand, the Proposed Rule makes it clear that the cost of research organs may not be included in OAC at all. This policy, if adopted in final form, has the potential to incentivize OPOs and transplant programs to discard organs that might otherwise be used for research. Organs are generally used for research only after they have been determined to be unsuitable for transplantation, and the costs of procuring any organ intended for

transplantation should be treated in the same way as the costs of unusable organs for OAC purposes.

ASTS/AST Recommendation: ASTS/AST requests that CMS refrain from adopting a policy that disallows all costs associated with an organ used for research and rather to adopt a policy under which organs that are procured with the intent to transplant, that are subsequently determined to be unusable and that are used for research be treated as unusable organs for the purposes of determining OAC.

ASTS/AST Recommendation: ASTS/AST also requests CMS to confirm its longstanding policy that organs procured with the intent to transplant are included in determining the Medicare ratio for cost allocation purposes and other purposes.

II. “Clarification” of Allocation of Administrative and General (A&G) Costs

The Proposed Rule includes a “clarification” that would disallow a Transplant Hospital (“Recipient Transplant Hospital”) from including the purchase cost of the organs received from an OPO or another Hospital in the accumulated cost statistic by which A&G costs are allocated. The Proposed Rule indicates that this practice is inconsistent with 42 CFR § 413.24(d)(6)³, which is intended to prevent duplication of Medicare payment for costs directly assigned to a provider-based entity or department.

However, 42 CFR § 413.24(d)(6) is plainly inapplicable here. The purchase price paid by a Recipient Transplant Hospital to an OPO (or other Hospital) for an organ includes the OPO’s (or the other Transplant Hospital’s) costs (including that OPO’s (or other Hospital’s) A&G costs) but does NOT include the Recipient Transplant Hospital’s A&G costs. The Recipient Transplant Hospital’s A&G costs are distinct from the A&G or other costs incurred by the OPO (or Transplant Hospital) from which the organ is acquired. While the OPO’s (or other Transplant Hospital’s) A&G and other costs are included in an organ’s purchase price, the Recipient Transplant Hospital’s own A&G costs are not. Therefore, inclusion of the purchase price of an organ does not raise the potential for duplicative payment any more than the inclusion of the cost of any other purchased item or service, and there is no reason to treat the purchase price of an organ differently from the cost of any other purchased service. Singling out the purchase price of

³ This regulation states:

6) Provider-based entities and departments: Preventing duplication of cost. In some situations, the main provider in a provider-based complex may purchase services for a provider-based entity or for a department of the provider through a contract for services (for example, a management contract), directly assigning the costs to the provider-based entity or department and reporting the costs directly in the cost center for that entity or department. In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Where a provider has purchased services for a provider-based entity or for a provider department, like general service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department. If the like costs of the main provider cannot be separately identified, the costs of the services purchased through a contract must be reclassified to the main provider and allocated among the main provider's benefiting cost centers.

an organ and excluding it from the A&G allocation statistic inappropriately treats the organ purchase price differently from the costs incurred by the hospital for other purchased items services.

Preliminary estimates provided by a group of concerned transplant administrators suggests that finalizing this proposal without change has the potential to result in reductions of over \$178 million in Medicare payment reductions for Recipient Transplant Hospitals' OAC.

ASTS/AST Recommendation: ASTS/AST recommends that the 2023 HOPPS Final Rule clarify that the purchase price of an organ that a Recipient Transplant Hospital pays to an OPO or another Hospital may be included in the accumulated cost statistic by which A&G costs are allocated.

III. RFI on Counting Organs for Medicare's Share of Organ Acquisition Costs.

As indicated in the preamble to the Proposed Rule, in the 2022 Inpatient Prospective Payment System (IPPS) Proposed Rule, CMS proposed to modify Medicare's methodology for determining Medicare's share of OAC by allowing Medicare payment only for those organs actually transplanted into Medicare beneficiaries and requiring transplant centers that procure an organ to track the payer source of the recipient. While the 2022 IPPS Final Rule did not finalize this proposal, the Proposed Rule solicits comment on a variation of this concept. Specifically, the Proposed Rule describes for comment an alternative proposal that would not require Transplant Hospitals and OPOs to track payor information associated with transplanted organs but would require Transplant Hospitals and OPOs to report only organs transplanted into Medicare beneficiaries for purposes of calculating Medicare's share of organ acquisition costs.

While this methodology would not impose as significant administrative costs as those that would have resulted from finalizing the 2022 IPPS proposal, the alternative methodology described in the Proposed Rule may still result in extraordinary payment reductions, especially for those transplant programs that have established the most successful hospital-based Organ Procurement Centers. The potential repercussions of such a massive reduction in Medicare payment for organ acquisition costs was set forth at length in our prior comments, which are incorporated by reference.

And while we recognize that the 2022 IPPS Final Rule indicated that CMS would be revisiting the OAC allocation issue, we are concerned that CMS has chosen to address this issue at this time and through an RFI published as part of an unrelated proposed rule. CMS' focus on changing the OAC cost allocation methodology comes at a time of considerable change for the transplant community. The modification of OPO Medicare certification standards and modifications of organ allocation policies are placing considerable pressure on the system as a whole at a time when it is under increasing pressure to increase access to transplantation (especially for underserved minorities). CMS' focus on changing a longstanding feature of the system in a manner that has the potential to substantially reduce Medicare payment for transplantation increases uncertainty at critical time in the transformation of the system.

This initiative is apparently based on the premise that the current system significantly shifts OAC that should be paid by non-Medicare payors to the Medicare program. This understanding of the current system is inconsistent with Congress intent. Since our prior comments were filed, we have had the opportunity to investigate the legislative history relevant to Congress' decision to exclude organ acquisition costs from IPPS payments. The legislative history of the National Organ and Transplantation Act of 1984 indicates that Congress was aware of, and specifically endorsed the current methodology for determining Medicare's share of organ acquisition costs. See House Report 98-1127. Specifically, in a hearing held by the House Committee on Science and Technology; Subcommittee on Investigations and Oversight. Committee on Science and Technology (HRG-1983-TEC-0066, 1983), the CMS (then HCFA) Administrator specifically stated:

...[t]he Medicare program assumes initial liability for all the costs of kidney acquisition. We believe that this is the most administratively feasible approach since Medicare pays for the vast majority of transplants. **We are aware that some kidneys will be transplanted to persons not eligible for Medicare benefits. when this occurs, we seek to recoup those costs through a system of "offsets."** (Emphasis added.)

Therefore, the current system for determining Medicare's share of OAC has been specifically endorsed by Congress and should not be modified in the absence of an amendment of the governing legislation.

Despite the explanation proffered to Congress, CMS now essentially assumes that the current methodology necessarily results in Medicare's paying for organs transplanted into non-Medicare beneficiaries. This seriously mischaracterizes the current system, which is more accurately described by the statement of the HCFA Administrator at the time NOTA was enacted, as quoted above. In fact, while Medicare provides "initial liability" for organs retrieved by a Transplant Hospital and transplanted elsewhere, revenues received from non-Medicare payers are offset against otherwise allowable OAC. The net result of the current methodology is that Medicare contributes to payment for non-Medicare patients' OAC only to the extent that these payers fail to pay the full OAC for their insureds. If, as Proposed Rule and the 2022 IPPS Proposed Rules anticipate, non-Medicare payers paid for the full OAC attributable to their insureds, the amounts paid under the current system would not result in any significant cross-subsidy from Medicare to other third-party payers for OAC.

In any event, the job of quantifying whether and to what extent such a cross-subsidy exists and the job of determining the potential impact of the proposed alternative methodology are not easy ones. We do not believe that the RFI provides sufficient time for the transplant community to address the detailed questions posed by CMS, whose answers are critical to determine whether or how the current policy should be changed. The RFI requests detailed hospital-specific data pertaining to the financial implications of the current methodology for determining the Medicare ratio as well as the financial repercussions of adopting the alternative methodology described in the 2023 HOPPS Proposed Rule. We believe that the responses to these questions are likely to vary significantly among Transplant Hospitals. In addition, because the payer mix for different

types of organ transplants (e.g. kidney, liver, heart, lung) varies widely, the questions need to be answered for each organ type separately to obtain an accurate picture of the implications of the alternative methodology overall. Answers also need to be subdivided for each organ type based on whether the transplant involved a living or deceased donor since, again, the payer mix for living and deceased donor transplants varies significantly. We do not believe that most Transplant Hospitals are in a position to provide accurate data to CMS in response to the RFI within the time allowed.

The need to extend the deadline is even more pressing in light of CMS' decision to publish the RFI as part of the 2023 HOPPS Proposed Rule. While the 2022 IPPS Final Rule alerted the transplant community that modification of the Medicare ratio methodology remained under consideration, it was not anticipated that an RFI related to this issue would be published as part of a proposed rule that addresses Medicare payment for outpatient services, since the Medicare ratio is entirely irrelevant to hospital outpatient payment. While ASTS/AST and other affected stakeholders are alerting members of the community about the RFI and its potential implications, that educational process takes time to reach and engage most transplant hospitals, further impeding individual transplant hospitals' efforts to respond by the deadline.

Moreover, a number of the questions posed in the RFI and not sufficiently specific to be answered in a way that would provide a sound basis for policymaking. For example:

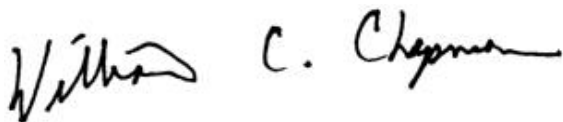
- The RFI requests hospital-specific data on what percentage of transplant recipients over the past five years were Medicare beneficiaries; b) Medicaid patients; c) private pay patients; and d) patients who receive financial assistance for services provided at a free or reduced rate. This question does not specify whether or not the responses should break down payer mix for each type of organ transplant involved (e.g. renal, lung, heart, etc.); the type of donor involved (living or deceased); or how dual eligible recipients should be listed.
- The RFI requests information on how Transplant Hospitals currently “support” OAC costs financially. This question does not specify whether, or how Transplant Hospitals are to account for revenues received for organs “sold” to an OPO (which may or may not be offset by the costs associated with acquiring the organs).
- The RFI requests each commenter to describe the impact of the revenue reduction resulting from an alternate organ counting methodology, both in absolute terms and relative to the transplant program and hospital as a whole. This question does not make it clear whether recipients for whom Medicare is a Secondary Payer should be treated as Medicare beneficiaries or whether the answers are to be broken down based on whether the organ type (kidney, heart, lung, etc.) or donor type (living or deceased) involved. Nor is it clear what how the “relative” impact of the loss is to be computed (percentage of net revenues; percentage of gross revenue; or some other measure) or whether the relative impact is to be determined based on pre-COVID financials or more recent financial statements.

We do not believe that individual hospital responses that are based on widely varying interpretations of the RFI questions will provide a sound basis for future policymaking. Extension of the deadline for response would provide an opportunity for CMS to clarify the questions and for us to convey these clarifications to the transplant community.

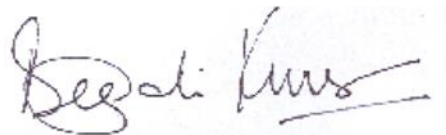
ASTS/AST Recommendation: We urge CMS to extend the deadline for responses to the RFI, to ensure more informed responses and to engage in a collaborative effort with transplant community to gather the information necessary to formulate any potential change in the Medicare ratio methodology.

We appreciate the opportunity to comment on these important issues. If you have any questions regarding the position of ASTS and AST on the policies proposed or the RFI included in the Proposed Rule, please do not hesitate to contact Emily Besser (Emily.Bessert@ASTS.org) or Shandie Covington (scovington@myast.org).

Regards,



William C. Chapman, MD
President
American Society of Transplant Surgeons



Deepali Kumar, MD, MSc, FRCPC, FAST
President
American Society of Transplantation