ASTS
American Society of Transplant Surgeons

September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Delivered Electronically

Re: RIN 0938-AV33; Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule

Dear Administrator Brooks-LaSure:

As President of the American Society of Transplant Surgeons, I am writing to you to provide the ASTS's comments on the 2025 Physician Fee Schedule (PFS) Proposed Rule ("Proposed Rule"). ASTS is a medical specialty society representing approximately 2,000 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.

Our comments on the Proposed Rule focus on six issues: The proposed 2.8 perfect reduction of the conversion factor; proposed telemedicine policies; the proposed use of modifiers to reflect transfers of care of global surgical procedures; the proposed coverage of dental services integral to the treatment of End Stage Renal Disease (ESRD); the expansion of Medicare coverage for certain immunosuppressive drugs; and the proposed inclusion of a Kidney Transplant Management Measure under the Cost Component of MIPS.

The Proposed Conversion Factor Reduction

Under the Proposed Rule, the CY 2025 Medicare conversion factor (CF) would decrease for the by approximately 2.80 percent from $33.2875 to $32.3562. If this reduction is adopted in the 2025 PFS Final Rule, 2025 will be the fifth straight year of CF reductions. We understand that this reduction is in large measure the result of the expiration of a 2.93 percent temporary update to the CF at the end of 2024 and a zero percent baseline update for 2025 under the Medicare Access and CHIP Reauthorization Act (MACRA). We also recognize that this cut is required to comply with governing legislation provisions related to budget neutrality. Nonetheless, such continued and significant payment reductions for critical procedures, such as transplant surgery, are simply unsustainable.

ASTS is a strong supporter of H.R. 2474, the "Strengthening Medicare for Patients and Providers Act," which would provide a permanent, annual update equal to the increase in the Medicare Economic Index, thereby easing the cost crunch impacting physicians and surgeons throughout the country.

> ***Recommendation:*** *We urge the Administration to urge Congress to enact H.R. 2474, to ensure continued access to high quality medical and surgical care for Medicare beneficiaries.*

Proposed Telemedicine Policies

The expansion of telemedicine resulting from the COVID epidemic has proven critical to ensuring access to medical care for millions of Americans, and we appreciate CMS' recognition that access to telemedicine services cannot and should continue to expand.

> ***Recommendation****: ASTS strongly supports CMS' proposals to authorize remote supervision of services incident to physicians' services for another year; to authorize Medicare payment for audio-only services when a Medicare beneficiary is unable to access video telecommunications capability; and to authorize teaching physician remote supervision of residents under certain circumstances; and lifting frequency limits on telehealth for subsequent inpatient and nursing facility visits and critical care consultations, which may be particularly important*

Global Surgical Packages Care Transitions

For procedures that include a 90-day global surgical package, including transplantation, CMS proposes to require the use of the appropriate transfer of care modifier (modifier -54, -55, or -56) when a physician plans to furnish only a portion of the global package, including not only when there is a formal, documented transfer of care (as under current CMS policy) but also when there is an informal, non-documented but expected transfer of care. CMS believes this proposal would prevent duplicative Medicare payment for postoperative care" by reducing payment for the global surgical package to subtract the portion of the service provided by another physician. CMS seeks comment from interested parties, including the RUC, about how best to determine the appropriate payment proportions for the pre-operative, surgical, and post-operative portions of the global package.

Instead of concentrating on the postoperative visits provided by the surgeon, CMS is seeking data on visits provided by practitioners other than the practitioner who performed the surgery. While theoretically this new focus could generate some data about practitioners who are providing evaluation and management (E/M) services to patients who are in a global period after a surgery, it will not result in data on the number of postoperative visits provided by the operating surgeon, nor confirm that the other practitioner was providing care related to the surgery. Because these proposed policies will not produce data on the visits that the surgeon is providing, they will not result in complete and actionable data and will therefore not be a step toward improving the valuation of global codes.

Recommendation: *Ultimately, we continue to support the RUC process as the most efficient way to value global codes using magnitude estimation, which has been the process since the Harvard study and development of the first MPFS. As a peer review group, all medical and surgical specialties participate and judge the data as presented. Those data are subjected to inspection, review, and deliberation before the RUC makes recommendations for valuation.*

Expanded Coverage of Dental Services for Beneficiaries with End Stage Renal Disease (ESRD)

Beginning in 2023, CMS began to expand coverage of dental services that are "inextricably linked" to other Medicare covered services. In this year's Proposed Rule, CMS is proposing to expand Medicare coverage of dental services to services to include: (1) dental or oral examination in the inpatient or outpatient setting prior to Medicare-covered dialysis services for beneficiaries with ESRD; and (2) medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, Medicare-covered dialysis services for beneficiaries with ESRD.

Recommendation*: ASTS strongly supports CMS' proposal to provide Medicare coverage for dental or oral examination prior to Medicare-covered dialysis services and diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, Medicare -covered dialysis services for beneficiaries with ESRD. Furthermore, ASTS supports post-transplant dental care since patients are immunocompromised and infections beginning in the oral cavity ultimately may result in rejection and/or severe complications.*

Expanded Coverage of Certain Immunosuppressive Drugs

The Proposed Rule would expand Medicare coverage of certain immunosuppressive drugs. Under current Medicare policy, payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the U.S. Food and Drug Administration (FDA) and meet one of the following conditions:

- The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.
- The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.
- Have been determined by a Part B carrier, in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue.

These requirements have long been a barrier to access to immunosuppressive drugs necessary to prevent organ rejection, many of which are used off-label.

The Proposed Rule would address these barriers by:

- Authorizing coverage of immunosuppressive drugs to include orally and enterally administered compounded formulations that meet the requirements above, even though compounded formulations are not FDA-approved.

- CMS is also proposing to liberalize rules that currently impose barriers to access for transplant recipients and others on long term immunosuppressive regimens. Specifically, CMS is proposing to allow payment of a supplying fee for a prescription of a supply of up to 90 days, rather than 30 days as is the case under current law; and to allow refills for an immunosuppressive drug based on the individual circumstance of the beneficiary in accordance with applicable state laws, rather than prohibiting payment for refills as under current rules.

ASTS Recommendation: *ASTS strongly supports CMS' efforts to remove barriers to access for immunosuppressive drugs that are critical to avoid organ rejection and urges CMS to finalize the proposals on this topic included in the Proposed Rule*.

Transplant Management Cost Measures

CMS is proposing to add six new episode-based measures to the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year:

- Chronic Kidney Disease (CKD), which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for patients who receive care to manage and treat CKD stages 4 and 5;

- End-Stage Renal Disease (ESRD), which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for patients who receive medical care to manage ESRD; and

- Kidney Transplant Management, which assesses MIPS eligible clinicians on the risk adjusted and specialty-adjusted cost to Medicare for ongoing kidney transplant-related care and management starting at least 90 days after transplant surgery.

An ASTS member participated in the measure development process for the Kidney Transplant Management measure and raised significant concerns about the methodology used and the potential impact of this measure on post-transplant care and, in particular, on the potential unanticipated consequences that may result from incentivizing physicians caring for post-transplant patients to reduce the intensity of the care provided to this vulnerable patient population. Our concerns in this respect are set forth in greater detail in the attached comments (Attachment A) submitted to the measure development contractor and follow-up presentation (Attachment B).

Recommendation: *ASTS remains strongly opposed to the adoption of the Kidney Transplant Management measure for the reasons set forth in the attached document and urges CMS to refrain from finalizing this cost measure for the purposes of the MIPS program*.

It is unclear to us whether, and to what extent, the proposed CKD and ESRD cost measures may impact access to transplantation. Specifically, it is unclear to us whether, and to what extent, these measures may incentivize or disincentivize physicians who provide day to day care of CKD and ESRD patients to refer their patients for transplant evaluation. Moreover, it is unclear to us whether the implementation of cost measures in these areas has the potential to disincentivize prescription of potentially game-changing SGLT2 inhibitors, such canagliflozin, dapagliflozin and empagliflozin, that have the potential to significantly slow the progression of CKD, thereby significantly improving health outcomes and reducing Medicare expenditures for ESRD treatment, including dialysis and transplantation.

> ***Recommendation:*** *ASTS urges CMS to closely examine the ESRD and CKD cost measures to ensure that implementation of these measures does not disincentivize referrals of medically appropriate patients for transplant evaluation or the use of breakthrough pharmaceuticals, such as SGLT2 inhibitors or other promising new technologies*.

ASTS appreciates the opportunity to comment on the Proposed Rule. If you have any questions, please do not hesitate to contact Emily Bresser, ASTS Associate Director of Advocacy, at emily.besser@asts.org.

Respectfully submitted,

Ginny Bumgardner, MD, PhD
President

Attachment A
ASTS Comments to CMS Administrator Brooks La-Sure on Kidney Transplant Cost Measure
March 10, 2023

American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

March 10, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

As President of the American Society of Transplant Surgeons (ASTS), I am writing to you to express ASTS' concern about the potential adoption of the Kidney Transplant Management Cost Measures under the Medicare Quality Payment Program (QPP). ASTS is a medical specialty society representing approximately 2,000 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 understand that the Kidney Transplant Management Cost Measures assess the ongoing transplant management care for a patient who has undergone a kidney transplant, beginning at least 90 days post-transplant. The measure includes clinically related costs for ongoing management of a kidney transplant (such as medication) and consequences of care (such as inpatient admissions).

ASTS believes that incorporating into the QPP an incentive for physicians to economize on post-transplant care has the potential for direct negative consequences on kidney transplant recipients, such as decreased recipient patient survival; decreased long-term kidney graft survival; decreased referral of more difficult to transplant patients to transplant centers for fear of being penalized for more expensive post-transplant care; pressure on transplant centers not to use hard-to-place organs due to higher post-transplant costs; and overall decreased medical care by the post-transplant assigned physicians to avoid being allotted additional costs. We believe there is not enough understanding of optimal post-renal transplant patient care to be able to assign appropriate cost measures without the strong possibility of harming patients and decreasing the survival of transplant organs.

Over the past several years, both CMS and HRSA have attempted to promote an increase in renal transplantation. These efforts have included focusing on increasing the use of hard-to-place organs and transplanting more challenging recipients, often from lower socio-economic groups. CMS created an additional DRG to help offset some of the increased costs of using these difficult organs and patients for transplantation that provides higher reimbursement for patients who require hemodialysis during the original transplant admission. There have also been several HRSA-sponsored national clinical projects, such as the COIIN Study, to help transplant centers and Organ Procurement Organizations (OPOs) learn to improve the outcomes of these transplants

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Peer reviewed publications clearly document the increased cost of transplanting these organs and patients, both inpatient and post-transplant. In addition, Congress has recently passed legislation to extend coverage of immunosuppressive medications beyond the prior three-year mark for the explicit purpose of extending the graft life of kidney transplants, a change that is anticipated to both increase the patient's expected life survival and decrease costs to the CMS ESRD system.

At this stage, there is little data addressing the potential post-transplant cost implications of increased use of hard-to-place organs and transplantation of more challenging and complex patients over the long term. As CMS and HRSA (and potentially Congress) increase pressure on transplant centers to increase use of hard-to-place organs and to transplant more complex patients, it may be anticipated that post-transplant cost profiles will shift; however, it is not anticipated that the shift will be uniform. Risk aversity varies significantly among transplant centers, creating significantly different challenges for physicians who manage post-transplant care over the long term in different areas of the country and within the same locality. *In light of the potential impact of these changes on post-transplant costs, we believe that adopting a post-transplant cost measure is inconsistent with other public policy initiatives that strongly encourage transplantation of more complex recipients and increased utilization of hard-to-place kidneys.* We are concerned that focusing on early post-transplant costs may be contradictory to all stated HRSA, patient groups, and medical professional society stated aims in improving the opportunity and long-term success of kidney transplant to all. Simply focusing on lower costs in the first few years after kidney transplant may result in decreased long-term graft survival, decreased patient survival, and actual increased costs to CMS by increasing unnecessary early return to dialysis.

Despite an increasing success in short term outcomes after renal transplant, long term outcomes are still mostly unchanged over the last few decades. The true benefit of renal transplantation comes in long term allograft function as patient's life expectancy is extended for every year of function of the graft, and avoiding the need to restart dialysis or delaying the return to dialysis are the true cost savings of renal transplantation. The goal of post-transplant care is to extend the healthy life of a patient after transplant, which most clearly focuses on extending the survival of the organ transplant. There are no proven 'best practices' for early post-transplant care that result in improved long term kidney transplant graft survival.

One can easily see how forgoing expensive tests or changing to less expensive medications to avoid being deemed a more expensive provider and facing reimbursement penalties may result in missing an avoidable treatable clinical condition, such as low-grade rejection or infection, which will clearly decrease the long-term function of the allograft as well as put the patient's life at risk. If the QPP program rewards providers for saving costs in the early post-transplant setting, which results in lost opportunities for more years of functional graft life, the relatively few dollars saved in the post-transplant outpatient setting will be overwhelmed by the cost of re-transplantation or return to dialysis. The relatively small savings in the MIPS outpatient setting is simply not worth the overall risk in a system which is encouraging the transplant of more difficult (and expensive) organs and the transplantation of more difficult (and expensive) patient recipients.

There are numerous clinical scenarios illustrating the imprudence of incentivizing cost savings in the post-transplant patient population. For example:

- Some more expensive drugs have been proven to provide longer graft survival, such as an intravenously infused immunosuppressive drug Belatacept. Patients receiving this drug have more admissions within the first year of transplant for cellular rejection episodes but decreased antibody mediated rejection and proven longer patient and graft survival with better renal function at seven years after transplant (Vincenti NEJM 2016). With this knowledge, how do we account for the increased inpatient and outpatient first year cost of treating the cellular rejection? How do we account for the cost/time of utilizing a more difficult intravenous medication over traditional, but inferior, oral medications?

- A major development in increased renal transplantation has been the appropriate use of donors with increased risk of infection, particularly Hepatitis C positive donors. The care of these recipients after transplant is also increased in outpatient care by mandatory follow up testing in addition to the early cost of the drugs to treat the Hepatitis C infection.

- The hard-to-place kidney donor graft often has very slow recovery of function. At 90 days post-transplant, these patients still require more costly care, including medications (such as erythropoietin analogues), potentially intermittent dialysis, and need for repeat renal duplex imaging and/or biopsies. Some of these costs may be able to be excluded directly from the MIPS calculation – such as a biopsy – but the other costs of increased resources cannot be easily excluded in this concept of MIPS.

- When there are indications that a patient is beginning to reject a graft, it is often in the best interests of the patient to be hospitalized and observed closely by the transplant team in order to save the graft and avoid a return to dialysis. Graft rejection can happen for a myriad of reasons that are unrelated to the quality of post-transplant patient management, and when it does, there should be no financial incentive for the treating physician to avoid hospitalizing the patient.

Moreover, patient groups with different numbers and severities of co-morbidities demand different levels and expense of post-transplant care, and the ability to fairly allocate this cost to 'post-transplant' versus 'non-post-transplant' appears to us to be virtually impossible. For example, transplanting patients with lower financial resources with diabetes or other complex chronic medical co-morbidities demands resource-intensive care for the patient's direct safety, as well as prolonging graft function. The best care after renal transplantation often involves these recipients receiving medical specialist care for these important chronic conditions for the first time in their lives (e.g., endocrinologist or cardiologist). This will increase the costs in these patient populations for the benefit of longer-term graft and patient survival, but to the detriment of the physician or physician group to whom these patients are assigned.

Finally, we strongly believe that incentivizing treating physicians to be cost conscious in addressing transplant-related issues that may arise during the post-transplant period is 'penny wise and pound foolish' considering the distribution of costs during the transplant journey: pre- transplant, transplant and post-transplant periods. The costs of transplantation are heavily 'frontloaded'. High initial health care costs are associated with the transplant episode, including costs associated with organ procurement, surgery, the pre- and immediate post-operative hospital stay which includes biological induction agents, and the higher doses of maintenance immunosuppression in the early post-transplant period. The extent to which subsequent cost savings offset the initial cost of transplantation depends on the length of graft and patient survival post-transplant. Encouraging post-transplant cost savings that jeopardize the initial investment made to acquire and transplant the organ simply makes no sense.

In light of all of these factors, we request that Acumen and CMS refrain from moving forward with the development of the Kidney Transplant Management Cost Measure of the QPP. We look forward to discussing this matter with you further. If you have any questions, please do not hesitate to contact Emily Besser, ASTS Associate Director, Advocacy, at Emily Besser@ASTS.org.

Sincerely,

William C. Chapman

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

References:

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Attachment B
ASTS Presentation to CMS Regarding Kidney Transplant Cost Measure
May 13, 2023

MIPS: Kidney Transplant Management (Cost Measurement)

AMERICAN SOCIETY OF TRANSPLANT SURGEONS

MEETING WITH THE CENTERS FOR MEDICARE & MEDICAID SERVICES

MAY 9, 2023

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Meeting Agenda

- Introductions
- Procedural Background and ASTS Position
- Kidney Transplantation in Evolution
  - Efforts to increase renal transplantation
  - Unknown cost implications of :
    - Increasing utilization of hard-to-place organs
    - Reducing disparities
  - Technological innovations
- Known Unknowns: Clinical Scenarios impacting post-transplant costs
- Penny-wise/pound foolish: Transplant vs. post-transplant costs
- Concluding Remarks
- Questions?

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Our Involvement

- ASTS was asked to join the Workgroup in July 2022; Dr. Ken Andreoni was selected to represent ASTS
- Both Dr. Andreoni and the ASTS liaison attended all scheduled Workgroup meetings.
- Dr. Andreoni made repeated requests for additional information so ASTS could make more information comments:
  - 3/24/23 (email)
  - 3/24/23 (direct chat during webinar)
  - 4/12/23 (email)
  - 4/20/23 (email): Acumen finally responds that they cannot supply deidentified data to help ASTS make information decisions and recommendations to Acumen/CMS

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ASTS Position

- There is not enough understanding of optimal post-renal transplant patient care to be able to assign appropriate cost measures without the strong possibility of harming patients and decreasing the survival of transplanted organs.

- Current efforts to increase the availability of transplantation, decrease non-use of kidneys procured for transplantation, and reduce disparities are likely to modify the costs of post-transplant care over the coming years in ways that cannot be predicted.

- Adopting a post-transplant cost measure is inconsistent with other public policy initiatives that strongly encourage transplantation of more complex recipients and increased utilization of hard-to-place kidneys

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Kidney Transplantation in Evolution

- Legislative, regulatory and media focus on increasing access to renal transplantation
  - Increasing the use of hard-to-place organs
  - Transplanting more challenging recipients
  - Reducing disparities
- NASEM Report
- A changing regulatory environment
  - Modification of OPO Conditions of Coverage increases pressure on OPOs to procure organs at risk of non-use.
  - Modification of allocation methodology increases cold ischemic time, need for post-transplant dialysis and other post-transplant complications.
  - Modifications of OPTN transplant center performance metrics increases emphasis on organ acceptance

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Cost implications of increasing access and equity

There is a lack of data addressing the potential post-transplant cost implications of increased use of hard-to-place organs and transplantation of more challenging and complex patients over the long term.

- Increased use of hard-to-place organs and transplantation of more complex patients is likely to shift post-transplant cost profiles.
- This shift is unlikely to be uniform.
- Risk aversity varies significantly among transplant centers, creating different challenges for physicians who manage post-transplant care over the long term in different areas of the country and within the same locality.

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Cutting Costs at the Risk of Patient Harm

- **Forgoing expensive tests/changing to less expensive medications and avoiding rehospitalization to avoid MIPS penalties may impact graft and patient survival.**
- Examples:
  - Drugs with expensive initial upfront costs that prove longer graft survival
  - Transplants with Hepatitis C organs
  - Treatment of more costly care required for recipients of hard-to-place kidney donor grafts
  - Hospitalization of a patient who appears to be beginning to reject a graft. (Graft rejection can happen for a myriad of reasons that are unrelated to the quality of post-transplant patient management, and when it does, there should be no financial incentive for the treating physician to avoid hospitalizing the patient.)

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Financial Impact of Improving Equity

- Increasing inclusion of disadvantaged patient populations on transplant waitlist is likely to increase post-transplant cost profiles in ways that are not yet completely understood.
- Financially disadvantaged transplant recipients with diabetes or other complex chronic medical co-morbidities may receive medical specialist care for these important chronic conditions for the first time in their lives (e.g., endocrinologist or cardiologist).
- Addressing disparities in transplantation has the potential to increase the cost of care for transplant recipients in ways that are not easily characterized as “transplant-related” or non-transplant related.

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Penny Wise and Pound Foolish?

- The costs of transplantation are heavily 'frontloaded.'
  - High initial health care costs are associated with the transplant episode, including costs associated with organ procurement, surgery, the pre- and immediate post-operative hospital stay which includes biological induction agents, and the higher doses of maintenance immunosuppression in the early post-transplant period.
- The extent to which subsequent cost savings offset the initial cost of transplantation depends on the length of graft and patient survival post-transplant.
- **Encouraging post-transplant cost savings that jeopardize the initial investment made to acquire and transplant the organ simply makes no sense.**

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Conclusion

ASTS urges Acumen and CMS to carefully consider the potential impact of including a post-transplant cost measure under the Quality Payment Program, in light of the potential impact of such a measure on long term patient and graft survival and in light of current efforts to increase the availability of kidney transplantation.

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Questions / Discussion

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