TO: ASTS Members
FROM: Diane Millman, JD
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RE: 2027 Inpatient Prospective Payment System (IPPS) Final Rule

CMS Issues Final Rule That Effectively Precludes OPOs from Generating an Operating Margin on Solid Organ Procurement and Reduces Allocation of G&A Costs to Transplant Program Organ Acquisition Cost Center

On July 31, 2026, CMS released the 2027 Inpatient Prospective Payment System Final Rule (the "Final Rule"). The Final Rule includes an overhaul of Medicare payment for extra-renal organs, new rules reducing Medicare payment for General and Administrative Costs allocated to Organ Acquisition Cost (OAC) Centers, and new "reasonable cost" restrictions for both OPOs and Transplant Centers.

Medicare Payment for Non-Renal Organs

Under the Final Rule, effective for cost reporting periods beginning on and after October 1, 2028, CMS will extend to extra-renal organs the payment methodology currently used for deceased donor kidneys. Under the new system, OPOs will submit to Medicare's OPO contractor (Palmetto) historical and projected cost information, and Palmetto will establish (and will make public) the SACs for extra-renal organs for all OPOs. OPOs are required to charge transplant programs based on the contractor-approved SAC for organs procured for both Medicare and non-Medicare recipients.

Costs associated with extra-renal organ procurement will be included on OPOs' cost reports, and Palmetto will reconcile OPO cost reports for each year, based on Medicare "reasonable cost" principles. This process may result in either an overpayment or underpayment determination. Adverse determinations are subject to appeal by the OPO. However, the Final Rule specifically provides that any financial liability resulting from reconciliation of OPO costs remains with the OPO and may not be passed on to transplant programs retroactively.

Because Medicare rules do not allow reimbursement for amounts in excess of costs (e.g. profit), OPOs will need to rely on other lines of business (e.g. tissue recovery), foundation funding, and loans/lines of credit to fund new initiatives whose costs are not built into their solid organ SACs. It is anticipated that the new rules will upend OPOs' financial planning, and OPOs have expressed serious concerns that delays in reconciliation of their cost reports are likely to result in significant cash flow issues. It is possible that these changes may increase OPOs' reluctance to pay for surgical fees for kidney procurement, which OPOs will no longer be able to subsidize through revenues obtained from the procurement of extra-renal organs.

In addition, it is concerning that the new system will go into effect at or around the time that the new OPO performance metrics are likely to result in the transition of a number of DSAs to new

OPOs. The Final Rule explicitly states that the costs of preparing bids to take over a new DSA are not reimbursable costs under Medicare cost reporting principles. The SACs for expansion DSAs are to be based on the new OPO's projected costs; however, SAC revenues may not cover unanticipated expenses or organ acquisition volumes that are lower than anticipated.

Elimination of Administrative & General (A&G) Cost Allocation for Organs Purchased from OPOs

The Final Rule includes two significant provisions impacting transplant program organ acquisition costs. First, the Final Rule precludes transplant programs from including organs purchased from an OPO in the accumulated cost statistic used to allocate A&G costs. Second, the Final Rule includes provisions that specify the methodologies that may be used to adjust the allocation statistic to prevent an improper allocation of overhead to purchased items and services (including the costs of organs purchased from an OPO) on the Medicare Cost Report. The Final Rule also adds new provisions specifying the process a provider may use to change its allocation method.

Because the amounts paid to purchase deceased donor organs from OPOs may be substantial, this regulatory change has the potential to significantly reduce payment for G&A organ acquisition costs. ASTS members are advised to consult with their hospitals' cost reporting teams to determine whether changing the hospital's cost finding methods would minimize the impact of the change.

Modification and Codification of Reasonable Cost Principles

The Final Rule also includes several provisions that modify or codify the "reasonable cost" rules that are used by Medicare to determine allowable costs for both OPOs and transplant programs.

Codification of the Prudent Buyer Standard and Its Application to Organ Acquisition Costs

The Final Rule codifies the application of the prudent buyer principle to providers (including but not limited to transplant programs and OPOs) to specify that providers and OPOs are expected to economize by "not paying more than the going price for an item or service and seeking to minimize their costs, so that their actual costs will not exceed what a prudent and cost-conscious buyer would pay for a given item or service." If costs are determined to exceed the level that prudent buyers incur, the excess costs are not reimbursable in the absence of clear evidence that the higher costs were unavoidable.

The Final Rule sets forth special factors to be considered when applying the prudent buyer standard to OPOs, and the same factors may be relevant when applying the prudent buyer standard to a transplant program's organ acquisition activities. These factors include, but are not limited to, time constraints for procurement; geographic availability of alternative vendors or service providers; efforts made to negotiate pricing; clinical rationale for vendor selection; pre-negotiated contracts with perfusion vendors, transport providers, and procurement teams; periodic market analyses to ensure contract rates remain competitive; and documented cost

justifications for high-cost procurement. The Final Rule also cautions that OPOs and Medicare contractors "should consider the clinical necessity of the service or technology (for example, normothermic regional perfusion or machine perfusion to improve organ viability) when applying the prudent buyer principle."

In light of the codification of the prudent buyer standard, ASTS members are advised to put in place processes that document their programs' efforts to minimize costs such as, efforts to research alternatives to high price vendors, negotiate prices, and conduct periodic market analyses. In addition, care should be taken to document the clinical rationale for major expenditures (e.g. for perfusion), to minimize the likelihood of the contractor's second guessing financial and clinical decisions down the line.

Bereavement and Aftercare

The Final Rule makes it clear that CMS does not consider bereavement support or other "aftercare" provided to donor families (e.g. assistance in communicating with organ recipients and their families) to be allowable organ acquisition costs, since these services are provided after the organ procurement process is complete. This determination is likely to result in the termination of OPO programs to provide donor family support.

Travel and Meal Costs

CMS codified in regulation the requirements that must be met for travel and meal costs to be allowable. Under the new regulations:

Travel

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

Meals

- Costs incurred by providers for meals sold to visitors, meals for their employees and staff (including executives and management) and non-personnel (including attending physicians) are not allowable costs;

- Costs incurred by providers for de minimis refreshments provided to attendees at educational events are allowable costs;
- Costs incurred by providers for meals for employees and contracted staff, whose role is essential to the provider's objectives, when an employee or contracted staff is required to travel away from their primary work location and an overnight stay is required, such as when completing trainings or education, provided such trainings are patient care related are allowable costs.
- Costs incurred by providers for drugs sold to other than patients, for fines or penalties, and for operation of a gift shop are not allowable costs.