

To: Daniel Garrett

Jennifer Nelson Dowdy

CC. Diane Mossholder Laurie Kulikosky Peggy Tighe

From: Diane Millman

Re: 2020 Hospital Outpatient Prospective Payment System (HOPPS) and Physician Fee

Schedule (PFS) Proposed Rules

Yesterday, CMS released the 2020 HOPPS and PFS Proposed Rules. While there are a number of policy and payment changes of general applicability that may impact transplantation, this memo focuses on those transplant-specific issues that we believe will warrant comment by ASTS. Comments are due on September 27.

Physician Fee Schedule Proposed Rule

As you know, national average Medicare payment rates are computed by multiplying RVUs for a procedure by the conversion factor. The proposed RVUs for transplant procedures will remain relatively unchanged under the PFS Proposed Rule (See spreadsheet transmitted contemporaneously with this memo) and the conversion factor will increase only slightly, from \$36.0391 to \$36.0896. Therefore it is not anticipated that the payment rates applicable to the transplantation procedures performed by ASTS will change significantly in 2020.

The only other transplant-specific issues noted in the PFS Proposed Rule relate to Hematopoietic Cell Transplantation and Cellular Therapy, which we understand is not an issue of primary concern to ASTS, and the ability of Managed Care Plans that exclude transplantation (and certain other services) from capitation to qualify as an Advanced Alternative Payment System under the Quality Payment Program. Please let us know if you believe either of these issues warrant comment by ASTS.

There are issues of more general applicability that have the potential to substantially impact Medicare payment for ASTS members' professional fees in future years. These issues primarily include proposed modifications of Medicare payment for evaluation and management services (scheduled to take effect in 2021) and potential changes in Medicare payment and policy for global surgery codes (which include all transplant procedure codes). We would strongly advise

coordinating closely with the American College of Surgery with respect to both of these policy issues.

We note, too, that the PFS Proposed Rule signals that CMS is "committed to the transformation of MIPS, which will allow for: more streamlined and cohesive reporting; enhanced and timely feedback; and the creation of MIPS Value Pathways (MVPs) of integrated measures and activities that are meaningful to all clinicians from specialists to primary care clinicians and patients Pathways (MVPs) of integrated measures and activities that are meaningful to all clinicians from specialists to primary care clinicians and patients." The new MVPs framework would apply beginning with the 2021 MIPS Performance Year/2023 Payment Year. The PFS Proposed Rule includes a Request for Information on how to implement a new value oriented approach to the Quality Payment Program. Again, we recommend that, if ASTS decides to submit comments on the MVP framework, it coordinate its comments closely with those submitted by the ACS.

Hospital Outpatient Prospective Payment System Proposed Rule

While the PFS Proposed Rule does not include significant transplant-specific provisions, the HOPPS Proposed Rule includes a number of transplant-specific provisions that warrant ASTS comment.

First, CMS is proposing to revise the definition of "expected donation rate" that is included in the second outcome measure to match the Scientific Registry of Transplant Recipients (SRTR) definition. The CFCs for OPOs regulations at 42 CFR 486.318(a) and (b) require that an OPO must meet two of three outcome measures, which are measured based on an SRTR definition of "donation rate" as follows:

"[t]he expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. This rate is adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.

Due to an oversight, CMS failed to incorporate this change into the OPO Conditions for coverage (CfCs), and the HOPPS Proposed Rule would correct this oversight.

Second, and more importantly, the HOPPS Proposed Rule includes a solicitation of public comments for proposed revisions to the OPO CfCs and the Transplant Conditions of Participation (CoPs). CMS indicates that it is seeking input on the TC CoPs because they are inextricably intertwined with the OPO CfCs. Accordingly, in addition to requesting comment on a number of specific OPO outcomes measures, 1 CMS specifically requests information on the following question:

¹ These questions are:

[•] Do the current OPO outcome measures that are set forth at 42 CFR 486.318 accurately and reliably reflect an OPO's performance? If not, please explain.

[•] What are the impacts or consequences of the current outcome measures on: (1) an OPO's performance; and (2) the availability of transplantable organs?

"Are there any transplant center CoPs that conflict with or should be harmonized with the OPOs CfCs? If yes, identify the specific requirements and how they would harmonize?"

Thus, the HOPPS Rule provides the opportunity for ASTS to achieve its longstanding objective of harmonizing OPO CfC and Transplant Center CoP outcome requirements. We strongly urge ASTS to respond to this solicitation of comments and, if possible, coordinate a united response with AST and possibly others in the transplant community.

[•] What impact, if any, do the certification and decertification processes for OPOs have on organ procurement and transplantation?

[•] Are there any potential, empirically based outcome measures, other than those currently at § 486.318, that could be used either in addition to, or instead of, the current outcome measures for OPOs? If recommending another outcome measure, what is the empirical evidence for that recommended measure?