ASTCT
American Society for
Transplantation and Cellular Therapy

September 13, 2021

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

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-1751-P; Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the provisions in the Calendar Year (CY 2022) Revisions to Payment Policies under the Physician Fee Schedule and other changes to payment policies.

ASTCT is a professional membership association of more than 2,600 physicians, scientists and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. The clinical teams in our society have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current FDA approvals for chimeric antigen receptor T-cell (CAR-T) therapy.

Proposed Changes Impacting Evaluation and Management (E/M) Services

We appreciate that CMS has continued to propose clarifications for E/M policies. We also appreciate that for CY 2021, CMS adopted the American Medical Association's (AMA's) CPT changes for office/outpatient E/M services and for these codes, retired the 1995/1997 documentation guidelines. With these changes, CMS continues to uphold the intent of the Administrative Simplification Act (ASA) to reduce administrative burden by applying standard code sets and definitions to all providers and payers.

The ASTCT asks that CMS continue releasing E/M policies that use AMA/CPT codes and the AMA guidelines for reporting the codes on claims, because it significantly reduces administrative burden since *all* HIPAA-covered entities must follow the code set authorities' guidelines for reporting services.

We believe that CMS should go further and continue with the changes it initiated in CY 2021, by fully retiring the 1995/1997 documentation guidelines for the remaining E/M services beyond the office/outpatient E/M codes. We ask that CMS make this change as soon as possible, because

our members submit codes and claims for the other E/M services like inpatient and observation care. It is burdensome for providers to maintain two documentation standards: Medicare's 1995/1997 documentation guidelines, and the AMA/CPT guidelines for these other E/M services. If CMS adopts AMA/CPT guidance for these services, it will result in reduced administrative burden for our members, because it will allow all providers to uniformly follow and apply AMA/CPT documentation guidelines when reporting any E/M service on claims, regardless of setting or payer.

In this rule, CMS has proposed policies regarding when, how and who can bill for split or shared E/M visits, for critical care services, and for E/M services furnished by teaching physicians, involving residents. The ASTCT provides the following comments concerning these policies.

Shared/Split Services

In this rule, CMS clarified that the concept of shared/split outpatient E/M services is applicable in the facility setting only and proposes to define a shared/split visit in a new section at 42 CFR § 415.140. Included in this definition is a specification that a shared/split E/M visit is one that is "[b]illed by the clinician who furnished more than half of the total visit time (the distinct time spent by each physician and Non-Physician Provider (NPP) would be summed to determine total time)."

CMS further clarified this definition by stating that the clinician providing the "substantive portion" of the visit based on time could still select the level for the visit based on medical decision making (MDM). CMS proposed that the clinician who did perform the substantive portion and bills for it would have to sign the medical record and affix a new modifier that would indicate a shared/split visit, and that the medical documentation must specify the specific clinicians who performed the visit.

The ASTCT believes that if MDM is involved in the shared/split visit, then by definition the physician should be considered to be the clinician who furnished the "substantial portion" of the visit. Since MDM involves work such as modifications to the plan of care for the patient, or evaluating risk, the physician is contributing to a level of work that goes beyond simply the time furnished during the visit. Specialists such as hematologists have background knowledge and experience and thus will contribute more overall to the medical decision making involved in a visit than an NPP.

Therefore, we recommend that when medical decision-making is used to select the E/M level for a shared/split visit, and the physician documentation supports physician contribution to medical decision making, then the physician should be considered as the one having furnished the substantial portion and will be the one to bill for the visit. We believe this will appropriately recognize the physician effort involved in MDM as part of a shared/split visit.

Critical Care Services

CMS also provided clarifications on critical shared services in the proposed rule. One important proposal would be to formalize that when more than one physician or NPP furnishes critical care services to the same patient on the same day, then the critical care services would be covered when each clinician's services are medically necessary, and if they are not duplicative, and the clinicians represent more than one specialty. CMS also proposed that critical care services can be furnished as shared/split visits.

We appreciate CMS providing further clarification relating to critical care services. Additional clarity on these matters is very helpful for clinicians. The ASTCT supports CMS' proposal to cover critical care services provided to the same patient on the same day by more than one clinician. However, an important part of covering these services is that the clinicians must represent more than one specialty. This could mean that if it is unable to be determined if an NPP and a physician providing critical care services are from different specialties, then it is a possibility that the services would be denied. Currently, not all Medicare Administrative Contractors (MACs) recognize when NPPs add the specialty code in the remarks field on physician claims.

We recommend that if CMS finalizes this proposal, that it requires all MACs to recognize the specialty codes submitted by NPPs on physician claims, so that claims are not denied for concurrent critical care services. We also support CMS' proposal that critical care services can be furnished as shared/split visits.

However, CMS also proposed that critical care services and an E/M visit cannot be billed on the same day for the same patient by a clinician, or clinicians within the same specialty within the same group. **The ASTCT disagrees with this proposal and asks the agency to reconsider**. It is our belief that this is contrary to current AMA/CPT coding guidelines.

For CPT codes, critical care services have a particular definition—that is, it involves services for a patient with an illness or injury that "acutely impairs one or more vital organ such that there is a high probability of imminent or life-threatening deterioration in the patient's condition." Because AMA/CPT defines critical care services in this way, it means that it is only the time during which that patient is critically ill or injured, and for which the clinician is directly furnishing care to the patient, which may be counted as critical care time for the purpose of billing for these services. That also means it is possible for a patient to, within the course of a day, not be critically ill or injured, and be seen by a clinician for a typical E/M visit, and then be provided with critical care services by that same clinician or a clinician within the same specialty if their condition changes.

Current practice is that the same provider (or provider within the same specialty and group) may bill critical care services and an E/M visit on the same date of service, as long as the time for each service does not overlap. **We recommend that CMS should not finalize its proposal, and instead should continue with current practice**. In the view of the ASTCT, the time will not

overlap, because patient acuity must be documented in the medical record. Time that is documented for E/M services cannot be attributed to critical care services because the acuity of the patient at the time of the E/M services is not critical.

We also want to stress that for critical care services, as well as for other services such as E/M, we believe it is important CMS is consistent with the AMA/CPT coding definitions and guidelines for reporting of services. This is a major tenant of the Administrative Simplification Act, and we ask that CMS adheres to it in its coding policies whenever possible. Consistency greatly reduces administrative burden on providers and ensures more consistent reporting and coding. We note that CMS and other payers adjudicate the codes submitted on claims via their respective coverage and payment policies, but that consistency of reporting services and codes on claims results in important public health data to enable evaluation of evidence-based medicine and services being rendered for similar conditions.

Billing for Teaching Physicians

CMS proposes to modify its current rules for billing for E/M services for teaching physicians. At present, CMS rules state that the teaching physician must be present during the key portion of the E/M visit that determines the level of service that is billed. CMS proposes that when time, instead of MDM, is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. **The ASTCT agrees with and supports this proposal.**

Telehealth Services Under the Physician Fee Schedule

During the ongoing Public Health Emergency (PHE), telehealth services have been important to physicians and patients. We are grateful to CMS for considering how to handle telehealth services going forward, as the PHE begins to wind down. In the CY 2021 MPFS Final Rule, CMS created three categories of telehealth services. In this proposed rule, CMS has proposed to allow services that are designated as Category 3 to remain on its list until the end of CY 2023. The intent of this proposal is to provide a pathway to evaluate whether or not these Category 3 services should be permanently added to the telehealth list after the end of the PHE.

The ASTCT supports this proposal. It is important to continue to collect data on which services should remain permanently on the list. **In recognition of CMS' intentions, we would recommend that CMS consider implementing a similar pathway for telehealth services that are furnished by hospital outpatient departments (HOPDs).** We support a similar policy for HOPDs for the same reasons that we support it for physicians. We would also ask that when CMS considers this, that it should include the patient's home as an originating site for Category 3 codes, also until the end of CY 2023, and ask that CMS clarify this in the final rule.

The ASTCT's membership serves many patients who are immunocompromised, such as those who have undergone stem cell transplantation. For these patients, being able to utilize telehealth services from their homes will help reduce their risks of being exposed to COVID-19 or other

potentially deadly infections. Even beyond the pandemic, the exposure these patients face due to their compromised status could be reduced if they were able to access care in this manner for issues not requiring in-person contact with a clinician. **The ASTCT recommends that CMS consider permanently allowing HOPD telehealth services with "home" as an originating site.**

We make this request in this letter since the matter was not addressed in the CY 2022 Outpatient Prospective Payment System Proposed (OPPS) Rule, and it is relevant to MPFS in that it relates to who incurs the practice expenses that are associated with these telehealth services. It would be ideal if CMS could address this issue in both the OPPS and MPFS Final Rules.

Physician Assistant (PA) Services

CMS has proposed that Physician Assistants (PAs) would be able to bill Medicare directly for their services, starting CY 2022. This proposal as a welcome change, and the ASTCT is appreciative that CMS has put this forward and encourages the agency to finalize this as proposed.

Changes to Beneficiary Coinsurance for Procedures Furnished During the Colorectal Cancer Screening Encounter

ASTCT members are providers who treat patients with hematological malignancies. We understand the issues and barriers that co-insurance for screenings and diagnostics can present to patients. Therefore, any change that helps reduce those barriers for patients is one that we fully support.

In the proposed rule, CMS has put forward a special coinsurance rule for procedures which are planned as colorectal cancer screening tests but become diagnostic tests when the provider identifies the need for additional services, such as the removal of polyps. Beginning in CY 2022, the coinsurance payment that Medicare beneficiaries are required to pay will be for planned colorectal cancer screenings that result in additional procedures that are furnished in the same clinical encounter, will be gradually reduced. As of the beginning of CY 2030, that amount will decrease to 0%.

We understand that this proposal is linked to changes in the statute. We are grateful both that Congress addressed this issue, and for this proposal from CMS to implement it. We ask that CMS consider whether it is possible to give providers the flexibility to reduce the co-insurance amounts to zero prior to 2030 since this will likely reduce patient complaints.

Thank you for the opportunity to provide these comments on the CY 2022 Medicare Physician Fee Schedule Proposed Rule. The ASTCT welcomes the opportunity to discuss these recommendations in more detail or to answer any questions you may have. Please contact Alycia

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Maloney, ASTCT Director of Government Relations at amaloney@astct.org for any follow up issues.

Sincerely,

Stella M Davies, MBBS, PhD, MRCP
President, ASTCT