September 26, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, Maryland 21244-8016

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations (CMS-1715-P)

Administrator Verma,

The American Society of Hematology (ASH) is pleased to offer comments on the proposed rule outlining revisions to the Medicare Physician Fee Schedule (PFS) for 2020.

ASH represents over 17,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell disease, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients in diverse settings including teaching and community hospitals, as well as private practice.

ASH offers comments on the following areas of the proposed rule, which are of particular importance to the Society’s members:

1. Evaluation & Management Visits
   a. Prolonged Service Add-On Code
   b. Complexity Add-On Code
   c. Request for Comment on Revaluing Outpatient E/M Visits within Transitional Care Management (TCM), Cognitive Impairment Assessment/Care Planning and Similar Services

2. Principal Care Management Services

3. E-Visits
4. Merit-Based Incentive Payment System (MIPS)
   a. Value Pathways RFI
   b. Oncology/Hematology MIPS Measures Group

**Evaluation & Management Visits**

ASH thanks the Centers for Medicare and Medicaid Services (CMS) for proposing to retain separate payment for the individual evaluation and management (E/M) services. ASH also supports the agency’s proposal to adopt the outpatient E/M code set as revised by the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel and valuations recommended by the AMA RVS Update Committee (RUC). The Society strongly recommends these policies be finalized; ASH had expressed strong opposition to the policy finalized in the 2019 PFS rule to create a single payment for level 2-4 E/M codes as we believed it could limit patient access to the complex office visits hematologists provide.

Specifically, ASH appreciates the meaningful increase for both level 4 and level 5 visits, as this is significant for specialties, such as hematology, that frequently bill higher-level codes because of the complexity of the diseases and disorders treated. Patients with hematologic diseases and disorders frequently have a complex history and require extensive counseling, emotional support, and lengthy discussions on goals of care. These diseases and disorders are often rare, such as porphyria, which affects many organ systems, and treatment may be unique to each patient. Additionally, many visits incorporate high-level interpretation and explanation to patients of associated lab and radiographic data as hematology is closely aligned with lab results.

ASH supports the documentation changes that accompany the revised outpatient E/M codes allowing providers to choose to select the visit level and bill these services by medical decision making (MDM) or time in accordance with the documentation requirements as revised by CPT. ASH is confident that these changes will meaningfully reduce the administrative burden of documenting these office visit services and appreciates CMS’ efforts to work with the physician community to reduce burden without reducing reimbursement for complex office visit services.

**Prolonged Service Add-On Code**

ASH supports the creation of the prolonged service add-on code and believes it will especially be useful for hematologists, who treat complex and rare diseases. For example, a new lymphoma diagnosis can easily take between 40 to 90 minutes. Additionally, non-malignant hematologic diagnoses, such as acquired or congenital hemophilia, thrombotic thrombocytopenic purpura, and antiphospholipid antibody syndrome, require lengthy, detailed conversations with the patient. These conversations include discussions of underlying diseases, complex medical treatments and adverse effects, counseling, family discussions, and goals of care discussions. ASH believes there is clear value for the implementation of the prolonged service add-on for providers who choose to document their E/M visits by time.

**Complexity Add-On Code**

ASH appreciates CMS’ revision of the complexity add-on code, GPCX1, from what was finalized last year – the creation of two separate complexity add-on codes, one for primary care and one for certain types of specialty care. The revision of this code to be tied to the patient’s condition rather than certain types of specialty care is a significant improvement and will help ensure the outpatient E/M services accurately reflect the cognitive work provided. The Society is concerned, however, about the lack of detail provided on how this code should be used. ASH requests clarification on the circumstances for which this code should be billed.
and specifically, the Society requests guidance on what documentation needs to be included in the medical record when this code is used.

Based on the description provided, ASH interprets the code to be billable in the following situations:

- When primary care services are provided by hematologists; for example, when hematologists provide primary health care to patients with sickle cell disease, hemophilia, thrombophilia, or cytopenia.
- When hematologists provide pain management or referrals to specialists.
- When hematologists plan/coordinate end-of-life care or pre-transplant planning.

It is unclear, however, whether this code could be used when “usual care” is provided by a hematologist (unless the patient does not also see a primary care provider). ASH requests confirmation on use of this code for the examples provided as well as further clarification regarding the statement on usual care. The Society welcomes the opportunity to work with CMS to further refine this code and establish appropriate documentation requirements.

Request for Comment on Revaluing Outpatient E/M Visits within Transitional Care Management (TCM), Cognitive Impairment Assessment/Care Planning and Similar Services

CMS requested comment on how to address other codes that incorporate the value of an outpatient E/M and the other E/M code families. ASH encourages CMS to develop a schedule to address the valuation of these services.

Principal Care Management (PCM) Services

ASH appreciates that the agency is creating an opportunity to recognize non-face-to-face care management services for patients with only one chronic condition. There is confusion, however, among ASH members on how to appropriately implement these codes. Many of our members have expressed frustration that the logistics involved to make use of these codes (e.g. buying new software to implement them) is not worth it for the small reimbursement that comes from the codes. ASH requests that the documentation requirements for this service be less burdensome than those for chronic care management (CCM) and transitional care management (TCM), as burdensome documentation disincentivizes use of these codes. For instance, the CCM codes currently require the development of a lengthy care plan, 24/7 patient access to care and health information, and that the practices’ electronic health records meet certain certification requirements. Adopting requirements similar to those for CCM will only confirm our members’ view that the additional investment and burden required is not offset by the value of the services. The Society acknowledges that CMS is trying to simplify the requirements for the other care management codes – specifically for the care plan requirement for CCM – and hopes the PCM codes documentation is handled in a similar manner. If it would be useful, ASH welcomes the opportunity to serve as a resource to CMS as the agency works to develop the service’s requirements.

E-Visits

ASH appreciates that CMS is acknowledging the non-face-to-face work that is done routinely by physicians. In a 2017 survey of ASH membership, practicing hematologists reported that nearly one-third of their time, on average, is spent on patient-care related issues for which they are not able to bill. The Society does request clarification on what exactly is included in “online, digital assessments.” For example, our members have indicated that a great deal of time is spent corresponding with patients via email and/or electronic health
record (EHR) portals, such as EPIC. Will both email and EHR portals be considered “online, digital assessments?” ASH also requests clarification on whether these codes can be billed more than once in a 7-day period if the time requirements are met.

Additionally, the Society asks that the agency provide template language for institutions to provide to patients informing them that they will now be charged for these types of communications. Our members strongly believe in transparency and that it should be made clear to patients that physician communication is billable time.

ASH is concerned that the low proposed values for these services will limit their documentation and requests that CMS consider increasing the work values for these services so that they are more reflective of the complex clinical decision-making hematologists provide to patients using these digital forms of communication.

**Merit-Based Incentive Payment System**

*MIPS Value Pathway Request for Information*

ASH appreciates that CMS continues to increase the flexibility of the Merit-Based Incentive Payment System (MIPS) and recognizes that the proposal of the new MIPS Value Pathways (MVP) framework for 2021 would connect measures and activities across the four MIPS performance categories (Quality, Cost, Improvement Activities and Promoting Interoperability) in order to create a more coherent program rather what currently feels like four separate programs. ASH thanks the agency for proposing to reduce the reporting burden and supports the goal of more meaningful reporting that would be comparable across physicians. The Society’s specific concerns and suggestions on the MVP Framework are outlined below:

- If this framework is successfully implemented, we recommend it be voluntary pathway, rather than a mandatory one, within MIPS. Providers should not be attributed to MVPs without their consent to participate. CMS should recognize that MIPS is only four years old, and providers have invested time and resources to comply with the current program and may not be ready to invest more to transition to MVPs at this time.

- The Society asks that CMS clarify the timeline for implementation of this framework. While ASH understands that the MVP for certain providers will launch in 2021, it is likely that many specialties, including hematology, will not be ready to launch any MVPs by that time.
  - There are very few hematology-specific quality measures, which require time and expertise to develop. ASH recognizes that CMS is reducing the number of measures currently in MIPS so that the remaining measures will be meaningful. CMS will need to invest significant resources to ensure hematologists and other specialists have outcomes and high-priority measures that will provide the type of quality information the agency hopes to get from MVPs.
  - For a specialty as complex and unique as hematology, multiple MVPs would be needed for hematologists to participate in a manner that would be meaningful for patient care and comparable across providers. Hematology is not a one-size fits all specialty. Many hematologists focus only on non-malignant hematology, such as hemophilia or sickle cell disease, and others focus on malignant hematology, such as leukemia or lymphoma. Many are even more specialized; for example, a physician who specializes in hemophilia may not have the expertise needed to treat an individual with sickle cell disease, and physicians who treat
acute leukemia often focus only on that particular subset of the disease. ASH urges the agency to recognize that it will take time for providers to transition from traditional MIPS to a MVP, if they choose to do so.

Oncoology/Hematology MIPS Measures Group

Lastly, ASH would like to thank CMS for the proposed addition of the oncology/hematology specialty measure set for the 2022 MIPS payment year. ASH encourages finalization of this measure set.

Thank you for the opportunity to provide comments on the proposed rule for revisions to payment policies under the Physician Fee Schedule for 2020. We welcome the opportunity to discuss these comments with you and your team at any time. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

Roy L. Silverstein, MD
President