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September 11, 2017

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
200 Independence Avenue, SW
Washington, DC 20201

Re: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Medicare Part B for CY 2018 (CMS-1676-P)

Dear 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 2018.

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 anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists were pioneers in demonstrating the potential of treating various hematologic diseases; and we 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 who are providing care to patients in diverse settings including teaching and community hospitals, as well as private practices.

ASH looks forward to working closely with the Centers for Medicare and Medicaid Services (CMS) as the agency implements this proposed rule and offers the following comments which focus on areas of particular importance to our members:

1. Proposed Payment Rates for Non-excepted Items and Services Furnished by Non-excepted Off-Campus Provider-Based Departments of a Hospital
2. Proposed Valuation of Specific Codes
    a. Therapeutic Apheresis (CPT Codes 36511, 36512, 36513, 36514, 36516, 36522)
    b. Bone Marrow Aspiration (CPT Codes 38220, 38221, 382X3, 2093X)
    c. Chemotherapy Administration (CPT Codes 96401, 96402, 94409, 96411)
    d. Hydration (CPT Codes 96360,96361, 96372, 96374, 96375, 96377)
3. Evaluation & Management (E/M) Guidelines and Care Management Services

<u>Proposed Payment Rates for Non-excepted Items and Services Furnished by Non-excepted Off-Campus Provider-Based Departments of a Hospital</u>

CMS was directed by the Bipartisan Budget Act of 2015 to implement a site neutral payment policy, paying for certain items and services in off-campus Provider-Based Departments (PBDs) under the PFS rather than the Hospital Outpatient Prospective Payment System (HOPPS). CY 2017 marks the first year that the agency has adjusted payments, reducing reimbursement to these PBDs by 50 percent of the HOPPS payment rate. The agency is proposing to reduce reimbursement to 25 percent of the HOPPS payment rate in CY 2018 because of the concern that the CY 2017 adjusted amount was generally resulting in greater overall payments to these PBDs than they would otherwise be paid under the PFS.

ASH recommends that CMS not implement this further reduction in reimbursement to these PBDs as proposed. Instead, ASH suggests that the agency implement the alternative raised in the proposed rule to reimburse these PBDs at 40 percent of the HOPPS rate in CY 2018. We believe that this more measured approach will allow CMS to review a full year of claims data on the mix of services reported in these settings before making another significant change in reimbursement in a two year period. If CMS chooses to cut reimbursement to 25 percent of the HOPPS rate in 2018, these PBDs would see a 75 percent decrease in reimbursement in a two year period. A cut of this magnitude in this period of time could have serious repercussions for patient access to care and should be based on actual data.

Proposed Valuations of Specific Services

Therapeutic Apheresis (CPT Codes 36511, 36512, 36513, 36514, 36516, 36522)

CPT code 36516 was identified as potentially misvalued in the CY 2016 PFS proposed rule. For CY 2018, CMS is proposing the RUC-recommended work RVU for all six codes in the family and is also proposing to use the RUC-recommended PE inputs without refinement. ASH supports the agency's proposal to accept the RUC-recommended values for both work and PE. We do not believe that CMS should make any reductions in clinical labor time for this family of services as compelling evidence to increase these times was presented to and accepted by the RUC during its review of this family.

CMS is also seeking comment on whether these procedures are creating a new point of venous access or utilizing a previously placed access. Based on the vignettes for these services and descriptions of work presented during the recent RUC review, the Society concludes it is typical for a patient to have a previously placed venous access utilized for this service. While in some cases a revision to the access site may need to be made, or initial access achieved, this is not representative of the typical patient scenario.

Bone Marrow Aspiration (CPT Codes 38220, 38221, 382X3, 2093X)

The family of bone marrow aspiration codes noted above was reviewed as a result of CPT code 38221 being identified as part of a high expenditure screen for services with Medicare allowed charges of $10 million or more that had not been recently reviewed. Before being surveyed and reviewed by the RUC, the descriptors for CPT codes 38220 and 38221 were revised to reflect changes in practice patterns and two new CPT codes, 382X3 and 2093X, were added to the family. ASH supports the revisions made to this code family and the elimination of G0364, as these services are now covered by the new code 382X3.

ASH also supports CMS' proposal to accept the RUC-recommended work values for these services. We have serious concerns, however, about the RUC's recommendation to change the global period for these services from XXX to 000. Maintaining these codes as XXX globals is consistent with

both medical practice and the survey methodology used to determine the RUC-recommended values. As we understand it, XXX codes are generally for E/M, imaging & diagnostic services, therapeutic services, radiation oncology and pathology. These services are part of a diagnostic service, and there is no compelling reason to change them to a 0-day global.

Also, these codes are billed less than 25 percent of the time with an E/M service. Since an E/M service being performed on the same day is not typical, this is not a compelling reason to change the global period. In the instance when an E/M service is billed on the same day, the patient has a condition such as acute leukemia or aplastic anemia for example, where there is urgency in the decision making about the patient's care and any delay in treatment could increase the risk of a negative outcome. By changing the global designation, the Society is concerned that this will increase the risk of an audit. The Medicare reimbursement for these services does not cover an institution's cost of providing them in many instances and cannot support a change that may cause our members to down code or not bill for the E/M service to reduce the risk of an audit.

ASH does not support the agency's proposal to reduce the "Lab Tech activities" from 12 to nine minutes. The technician must be present for the entire procedure. Immediately after the physician inserts the aspiration and biopsy needle, the medical technician takes the aspiration and biopsy material to make slides. The physician performing the aspiration and biopsy needs to know - while still in the procedure room – whether the slides show that quality material was collected. If the material in the specimen is not of the appropriate quality, the technician informs the physician so the bone marrow aspiration needle can be reinserted to collect a new sample. Because the most common indication for this procedure is unspecified anemia, multiple aspirations are needed to obtain marrow aspirate for studies on bone marrow material in addition to making slides. The technician at the bedside is responsible for transferring aspirate to appropriate lab tubes for this additional diagnostic testing such as flow cytometry, cytogenetics and molecular diagnostics. These diagnostic samples are critical to make the correct diagnosis. Twelve minutes of time is required for completion of these clinical needs and duties.

Chemotherapy Administration (CPT Codes 96401, 96402, 94409, 96411)

CMS is proposing the RUC-recommended work values for the chemotherapy administration services that were identified through a high expenditure services screen with Medicare allowed charges over $10 million. ASH supports the agency's proposal to finalize these RUC-recommended values.

For CPT code 96402, CMS is proposing the RUC-recommended equipment times with refinements for the biohazard hood and exam table from 31 to 34 minutes to reflect the service period time associated with the code. ASH supports this proposed refinement, as well as the agency's proposal to finalize the RUC-recommended PE inputs for the other three services in the family without refinement.

IV Hydration and Application of On-body Injector with Subcutaneous Injection (CPT Codes 96360, 96361, 96372, 96374, 96375, 96377)

CMS is proposing to accept the RUC-recommended work and PE RVUs for the IV hydration services, the new code for the application of the on-body injector, and other therapeutic injection services. ASH supports the agency's intention to finalize these values.

Evaluation & Management (E/M) Guidelines and Care Management Services

ASH thanks CMS for the proposal to review and revise the E/M documentation requirements. Our members have long advocated that these requirements are outdated and create unnecessary administrative burden. Physicians must be paid for the care they deliver to their patients, and the current documentation requirements force our members to spend time and energy meeting extensive documentation requirements to warrant a higher level visit, time and energy that would be better used to deliver care to the complex patients we treat.

The Society agrees that the requirements for history and physical exam are the most vulnerable to EHR manipulation and that most of these "inputs" can be incorporated with the medical decision making (MDM) itself. By simplifying these requirements, physicians will be allowed to focus on MDM, the prioritization of care, careful resource allocation, and result in an improved, more efficient healthcare system.

However, ASH does not accept the premise that the existing criteria for assessing MDM are adequate. For hematologists, there are many aspects of our practice that do not fit within the MDM criteria currently in place. The complexity of the care delivered to patients with acute leukemia or sickle cell disease, for example, cannot be captured by the current documentation requirements for MDM.

Additionally, ASH strongly disagrees with CMS' assessment because the retention of existing auditing requirements for MDM for 99214 and 99215 implies that the current auditing criteria for outpatient E/M activity are accurate. These criteria, which have become the standard, are based on the 1995/97 CMS guidelines developed during a different era. Over the last 25 years, there have been enormous changes in medical practice as EHR utilization has increased. Furthermore, the "complexity density" of cognitive work has profoundly changed with the advent of more ambitious expectations for disease prevention and health promotion, the evolution of increasingly complex therapeutic strategies that require multiple interacting medications, and the emergence of an entirely new category of biologic therapies. Biologics themselves are profoundly expensive and their judicious application requires the highest levels of MDM.

Despite this critical first step in addressing the issue of documentation guidelines, the focus on changing just the guidelines for the history and physical exam fail to fully account for the challenges facing those who deliver E/M services. The proposed rule states that MDM and time are the more significant factors in distinguishing E/M visit levels. While these factors are certainly important, the failure of existing E/M codes to fully capture all of the work conducted by hematologists and other cognitive physicians when delivering these services creates the more significant burden on cognitive physicians than the documentation requirements. Our members spend a significant time on pre- and post-visit work that is currently uncompensated despite the agency's best efforts to address this by creating the transitional care management (TCM) and chronic care management (CCM) services. As a member of the Cognitive Care Alliance, ASH has advocated for the creation of new codes so that cognitive work is accurately described and valued, as well as revising the documentation requirements.

As long as the agency is focused on the documentation requirements, we remain concerned that there is no accurate accounting for the interactivity and the complexity of office visits with highly complex patients. Additionally, there is no recognition of the clinical expertise achieved with years of training and experience that creates the ability to instantly recognize a pattern and make a diagnosis

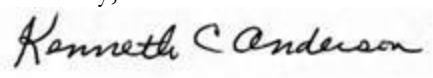
of enormous clinical value in a matter of moments. We agree that MDM is key to determining the level of an E/M service. However, we believe that it is not only the critical documentation requirement, but is also the critical piece to properly define and value E/M services.

In order for reformed documentation expectations for E/M services to have the intended effect, they must be linked to correcting the deficiencies in both the definition and valuation of these services. CMS cannot afford to continue to delay a thorough re-examination of the E/M codes. Despite the vastly expanded therapeutic and diagnostic choices, the increasingly complex interactions among treatments and concurrent conditions, and the conversation requirements of an increasingly health literate public, there has been no adjustment in the definitions of E/M services, and only incremental changes in their valuations, since the development of the Resource-Based Relative Value Scale (RBRVS).

Work values in the fee schedule must be evidence-based and the development of a reliable and representative knowledge-base for the definition and pricing of physician services will ensure the accuracy and reliability of physician payment for all E/M services. If the necessary research on what the full range of E/M services entail is conducted and used to develop new service codes that accurately capture the care delivered by physicians, as well as the establishment of appropriate documentation guidelines for these new codes, both the unnecessary administrative burden currently faced by cognitive physicians and the misvaluation of E/M services as a whole can be properly addressed and corrected. We urge CMS to correct the longstanding deficiencies of the PFS in order to understand fully what occurs during all E/M services. This will allow for service codes to be properly redefined and revalued. In addition, the documentation expectations for auditing and analytics can then be revised to improve communication and reduce administrative burden.

Thank you for the opportunity to provide these comments. We welcome the opportunity to discuss these proposals and others being considered with you and your team. If you have questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager, at lbrady@hematology.org or 202-292-0264.

Sincerely,



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