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September 9, 2024

Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via http://www.regulations.gov

RE: CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (CMS-1807-P)

Dear Administrator Brooks-LaSure:

The American Society of Hematology (ASH) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Medicare Physician Fee Schedule (MPFS) proposed rule for calendar year (CY) 2025.

ASH represents more than 18,000 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 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. Our mission is to foster high-quality, equitable care, transformative research and innovative education to improve the lives of patients with blood and bone marrow disorders. With these goals in mind, we provide comments on the following policies of importance to ASH members who care for patients in private, community practices, hospital practices, and academic settings.

- Conversion Factor Updates
- Development of Strategies for Updates to Practice Expense Data Collection and Methodology
- Payment for Telehealth Services
- Valuation of Specific Codes
- Non-Chemotherapeutic Complex Drug Administration
- Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Diseases (HCPCS code GIDXX)
- Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services

**Conversion Factor Update**

For CY 2025, the conversion factor is set to decrease by 2.80 percent, primarily driven by the expiration of the conversation factor update that Congress approved in March. We understand that an act of Congress is required to increase the conversion factor. Therefore, we encourage the agency to work with Congress to develop a permanent solution that allows for regular inflationary updates for the MPFS. The conversion factor was $31.0010 in 1992 and yet, 32 years later, the conversion factor is only two dollars higher. If the1992 conversion factor is adjusted for inflation, that adjusted conversion factor would be $70.61.[1] Other Medicare payment systems receive regular updates, including the Inpatient Prospective Payment System and the Outpatient Prospective Payment System. We believe that the MPFS should be treated similarly to ensure access to care for Medicare beneficiaries and to reimburse physicians fairly for the services they provide.

We can think of no other profession that would provide its services based on a conversion factor that does not reflect cost-of-living adjustments, and yet physicians continue to do just that while absorbing the increasing costs for clinical staff, supplies, and equipment. This continues to be an untenable situation. As such, we encourage the agency to work with Congress to fix the Medicare physician payment system to implement sustainable and long-term payment solutions.

**Development of Strategies for Updates to Practice Expense Data Collection and Methodology**

The agency continues to examine ways to regularly update practice expense (PE) inputs and examine the types of data used to make these changes. In this year's proposed rule, CMS has asked for comments on how the agency can improve the stability and predictability of future updates to the PE inputs.

The Society would like to reaffirm our position in support of the use of the Physician Practice Information Survey (PPIS) data currently being collected by the American Medical Association (AMA). The data collected through this survey will be the most up-to-date information available that captures the costs of operating a medical practice. The use of this data will at least level-set the PE inputs and provide an updated underlying framework for payment systems.

Understanding the significant redistributive effects that any PE updates have on the MPFS, the Society supports phasing in the new data over a four-year period. The agency has used this methodology in the past, and many stakeholders are familiar with this approach. A phase-in of updated data allows physicians and their practices to adjust to changes more easily when there are significant redistributive effects. This is particularly important given the downward pressure physicians are experiencing from the conversion factor and MPFS payments.

ASH also reaffirms our previous comments on the frequency of updates to the PE data. We believe that PE data needs to be updated on a regular basis (every five years) to account for changes in practice patterns as well as to account for the inevitable changes in technology, clinical labor rates, and other factors that influence practice expense inputs.

**Payment for Telehealth Services**

*Frequency Limitations of Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations*

The agency proposes to permanently remove frequency limitations for E/M services when provided via telemedicine for the following CPT and HCPCS codes; subsequent inpatient visits (99231, 99232, and 99233), subsequent nursing facility visits (CPT codes 99307, 99308, 99309, and 99310), and critical care consultation

[1] US. Bureau of Labor Statistics, CPI Inflation Calculator. https://www.bls.gov/data/inflation_calculator.htm

services (HCPCS G codes, G0508 and G0509). Prior to the COVID pandemic, there were frequency limitations (i.e., the number of times a provider may bill for a service during a given time frame) for these services. However, during the public health emergency, CMS lifted the frequency restrictions to allow greater access to care.

Our Society supports permanently removing the frequency limitations for these services. The members of our society and the patients they treat greatly benefited from the telehealth flexibilities, including the removal of frequency limitations, enacted during the COVID pandemic. Allowing physicians the capability to care for patients via telemedicine when it is medically most appropriate allows greater flexibility for both the physician and the patient and increases access to care.

*Audio-only Communication Technology to Meet the Definition of "Telecommunications Systems"*
CMS proposes to revise the definition of an interactive telecommunications system to include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician is technically capable of using an audio/video system, but the patient is not capable of, or does not consent to, the use of video technology.

The Society supports this change in definition, allowing audio-only as a type of communication technology that may be used to deliver covered telehealth services under the Medicare program. Many patients suffering from hematologic conditions and diseases are often the most vulnerable, including the elderly and underserved populations including those in rural areas. Many elderly people prefer the use of the telephone, and others simply do not have access to video or know how to use the video capabilities of various telecommunication devices, while others may not have access to the internet services needed to support the use of video technologies. Therefore, the use of audio-only communication greatly expands access to care by giving a patient the flexibility to communicate with their physician in a manner that is available and best suits them.

However, the change in definition will be moot unless Congress extends the Medicare telehealth flexibilities that are set to expire at the end of 2024. Telehealth flexibilities offer greater access to care as they eliminate the need for transportation, which can be a barrier for underserved populations, including those in rural areas. We encourage CMS to work with Congress to implement permanent changes to payment for audio-only services. Additionally, our Society will continue its efforts to encourage Congress to grant CMS the authority to make these changes permanent.

**Valuation of Specific Codes**
*Therapeutic Apheresis and Photopheresis (CPT Codes 36514, 36516, 36522)*
CPT codes 36514 (*Therapeutic apheresis; for plasma pheresis*), 36516 (*Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion*), and 36522 (*Photopheresis, extracorporeal*) were identified as misvalued in the 2024 MPFS final rule. The misvaluation was driven by the inclusion of an inappropriate clinical labor type in the PE.

At the January 2024 American Medical Association (AMA) RVS Update Committee (RUC) meeting, it was determined that an oncology nurse is the most appropriate labor type to include in the PE calculation of these services, given there is no clinical staff code for "apheresis nurse specialist." Using "oncology nurse" as the clinical staff type for these services would "more accurately reflect the work of an apheresis nurse," and as such CMS proposes to accept the RUC recommendation to use the oncology nurse clinical staff in the PE valuation of these codes. ASH participated in the process to reexamine and revalue the clinical labor inputs for these services at the January 2024 RUC meeting and as such supported the RUC recommendation.

Therefore, we support the proposal as outlined in the rule, and request that CMS finalize it without modification.

*CAR T-cell Therapy Services (CPT Codes 3X018, 3X019, 3X020, and 3X021)*
At the May 2023 Current Procedural Terminology (CPT) Editorial Panel meeting, four CPT III codes representing CAR T-cell services were converted to CPT Category I codes (3X018, 3X019, 3X020, and 3X021). The Category I codes were surveyed by stakeholders, including ASH, and PE and work relative value units (wRVUs) were recommended to the AMA RUC. The wRVUs for all four services, which include cell collection (3X018), cell preparation (3X019), cell receipt and preparation for administration (3X020), and cell administration (3X021), were accepted by the RUC. The RUC accepted PE inputs for CPT code 3X021 for cell administration, but not for CPT codes 3X018, 3X019, 3X020. The RUC recommended contractor pricing for PE for those three services only and submitted that recommendation to CMS. In the proposed rule, CMS stated that contractor pricing can only be applied at the whole code level, and not a single component of a code, in this case the PE for 30X18, 30X19, and 30X20. The agency is now seeking comments on PE inputs for these services.

First, we would like to thank the agency for accepting the PE recommendations for CAR T-cell administration services (CPT code 3X021) and the work values for the entire code family. ASH participated in the process, and we are grateful to the agency for supporting the RUC recommendation for this service, which is the component of CAR T-cell therapy primarily performed by hematologists. We believe that accurate valuation of this service supports ASH and CMS' shared goal of ensuring Medicare beneficiaries have access to new technology and innovative treatments.

However, we recommend that the agency implement, with the assistance of the specialty society stakeholders who participated in the RUC process, PE inputs for the services associated with 3X018, 3X019, and 3X020. CAR T-cell therapy is an innovative, and complex treatment that requires specialized expertise and care, which includes very specific clinical labor, supplies, and equipment for the cell collection, processing, and receipt and processing to prepare the cells for administration. Without PE values for each of these steps in the treatment process, it is unlikely that practitioners will be able to support the delivery of CAR T-cell therapy in the physician office setting. Currently, the non-facility setting is an appropriate place of service for CAR T-cell therapy, as stated by CMS in *Transmittal 11774, National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy*. Transmittal 11774 updates places of service (POS) to include POS 11 (office) and 49 (independent clinic) as valid POS for CAR T-cell claims. Additionally, while N/A is indicated for these services for the non-facility setting in the RVU file released with the proposed rule, the N/A does not prohibit Medicare Administrative Contractors from making payment in non-facility. However, what the N/A does do is limit the non-facility payment amount to the facility amount, which would be insufficient to cover the resources needed to perform the services, threatening patient access to CAR T-cell therapy in non-facility settings.

Additionally, ASH believes that the establishment of PE values for 3X018, 3X019, and 3X020 will support the delivery of this service in the most medically appropriate setting as determined by a physician in consultation with a patient, rather than having site selection unduly influenced by cost. The provision of CAR T-cell therapy is life-changing for many Medicare beneficiaries, and access to this care is vitally important. Many patients who may need this therapy live in rural areas without access to large academic medical centers or large hospital systems. The establishment of PE inputs will ensure access to care in settings like the office or independent clinic. Uncertain or inconsistent pricing across health care settings and Medicare Administrative Contractor jurisdictions will lead to confusion among physicians and potentially stifle access to these life-saving treatments.

Finally, given that CAR T-cell therapy services are considered new technology under the rules of the AMA RUC, the services will be reevaluated by the RUC in three years. In that time, there may be more experience with the provision of CAR T-cell therapy in the non-facility setting, and new recommended PE inputs will be more robust. ASH recommends that CMS accept the PE inputs submitted through this comment period, on an interim basis, rather than contractor pricing the entire family of codes. This will allow access to care while stakeholders gather the necessary data and gain valuable experience in determining the appropriate PE input information.

*Telemedicine Evaluation and Management (E/M) Services (CPT codes 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090, and 9X091)*
As a part of its work in a nearly complete overhaul of the E/M section of the CPT code book, the CPT Editorial Panel created, and the RUC subsequently valued, 17 new codes to describe services for the provision of telemedicine E/M. The agency states that the new codes for telemedicine E/M mirror, nearly identically, the current codes used to report new and established office E/M services, and that the RUC recommended RVUs are also nearly identical to the office visit E/M services.[2]

Noting that there are already services on the Medicare telehealth services list (office/outpatient E/M code set) that describe E/M services when furnished via telemedicine and that the agency is required by section 1834(m)(2)(A) to "pay an equal amount for a service furnished using a "telecommunications system" as for a service furnished in person, the agency shared that there is not a programmatic need to recognize and provide payment for the newly established telemedicine E/M codes. The new codes 9X075-9X090, will be assigned a procedure status indicator of "I", indicating that there is a more specific code that should be used in the Medicare program, in this instance the existing office E/M codes.

While ASH appreciates the work of the AMA CPT Editorial Panel and the AMA RUC to create and value the new E/M telemedicine codes, we support CMS's proposed policy not to pay for these services under the MPFS. The new code family is duplicative of current office visit E/M services and will create confusion for providers, coders, and others that interact with the CPT code set. For years, practitioners have been using modifiers and POS codes to indicate when a telemedicine service has been provided, and we believe that this should continue. Additionally, during the COVID pandemic, practitioners became even more adept at correctly billing for telemedicine services without the need for a separate telemedicine E/M code family.

If commercial payers start requiring use of the new codes to report telemedicine services, this will create additional confusion, as practitioners and other stakeholders will have two coding structures to report identical services. ASH therefore suggests that CMS provide sub-regulatory guidance specifically outlining how to document, code, and bill for telemedicine E/M services. We realize that this may be duplicative to guidance released in the past but encourage the agency to continue to educate stakeholders on this issue and ensure that Medicare providers are clear on how to bill for telemedicine E/M services for Medicare beneficiaries.

**Non-Chemotherapeutic Complex Drug Administration**
Last year, CMS requested comment on payment for non-chemotherapeutic complex drug administration services to address stakeholder concerns that non-chemotherapeutic complex drug administration payment is inadequate due to the existing code structure and Medicare billing guidelines. Specifically, the agency asked if there were instances of "down coding or denials for the administration of non-chemotherapeutic infusion drugs." Commenters, including ASH, recommended the agency follow the existing coding guidelines and

[2] Medicare Physician Fee Schedule, 2025 proposed rule, pg. 163/164 display copy.

constructs outlined in the CPT code book. ASH believes that CPT coding guidelines are sufficient to describe the services associated with the administration of drugs and biologics.

Based on comments received, CMS proposes to update the Medicare Claims Processing Manual, chapter 12, section 30.5, to modify the coding language to match the CPT code definitions for complex non-chemotherapy infusion code series stating that the administration for particular kinds of drugs and biologics may be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401-96549.

The Society supports the policy as outlined in the rule. We are pleased to see that the agency has taken our comments, and those of other stakeholders under advisement.

**Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Diseases (HCPCS code GIDXX)**

In response to stakeholder engagement, CMS created and proposed payment for HCPCS add-on code GIDXX to report services associated with visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant. The code was created by CMS to "describe the intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease performed by a physician with specialized training in infectious diseases."

The Society supports policies that reimburse physicians for the additional time, effort, and expertise associated with the non-procedural care of Medicare beneficiaries. We have advocated for payment system changes that would appropriately value E/M services and have long held the belief that the payment system is skewed towards valuing procedural care at higher levels when compared to E/M services. The agency has noticed this issue as well as evidenced by the creation and valuation of HCPCS G2211 to account for the additional work associated with complex patient care in the office setting. ASH supported CMS in this effort and is appreciative for the recognition of the complex work and expertise our members provide to beneficiaries.

However, the Society does not support the creation of a specialty specific HCPCS code to account for certain inpatient services provided by an infectious disease physician. While we certainly appreciate the complexity of this type of care and the value of an infectious disease physician's expertise, particularly during the COVID pandemic, the development of this code creates an imbalance in the fee schedule by creating one code which favors the expertise of one specialty at a higher level than other specialties.

We also point out that in the proposed rule, CMS states "*we recognize that historically, the CPT Editorial Panel has frequently created CPT codes describing services that we originally established using G codes and adopted them through the CPT Editorial Panel process. We note that we would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking.*"[3] ASH finds this problematic, as CPT codes are not meant to be specialty specific, and any code in the CPT code set may be reported by any qualified physician or qualified healthcare provider, regardless of specialty. CMS endorsing the creation of specialty specific codes within the CPT code set goes against this long-standing convention and has the potential to cause additional imbalances.

The Society expects that many physician specialties will begin requesting HCPCS codes to account for the expert, complex, time consuming, and valuable care that their specialty members provide. For example, hematologists are called upon to manage perioperative care for patients with coagulation disorders. This is

[3] Medicare Physician Fee Schedule, 2025 proposed rule, pg. 201 display copy.

extraordinarily complex care and requires the expertise and skill of a hematologist for successful surgical outcomes. Other examples of diagnosis and management of hematologic malignancies that would benefit from a HCPCS code include the management of complications associated with hematologic malignancies such as hyperleukocytosis or leukostasis, tumor lysis syndrome, disseminated intravascular coagulation (DIC), thrombotic thrombocytopenic purpura (TTP), cord compression, and neutropenic fever. We could make the argument that this too may require the creation of a HCPCS G code to ensure that hematologists are compensated appropriately. Hematologists often manage issues of infectious disease in their patients and need to interpret complex polymerase chain reaction (PCR) and next generation sequencing tests; hematology patients who have received chemotherapy or those who have post bone marrow transplantation (BMT) complications may require frequent monitoring by their hematologists- without necessarily involving the infectious disease specialists- for complications such as cytomegalovirus viremia (CMV).

ASH recommends that the agency create a general HCPCS G code for complex inpatient non-procedural care (i.e., E/M services) that all specialties could use, akin to G2211 used for office E/M, which would capture complex patient care in the inpatient setting. This will avoid the issues that we expect will develop if the agency finalizes the code for infectious disease care.

**Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services**

ASH thanks CMS for thoroughly reviewing our request to consider coverage for dental services linked to Medicare services for the treatment of sickle cell disease (SCD). We understand that the agency did not feel that the data and other evidence submitted met the threshold of the dental services being inextricably linked to other Medicare covered services. In our member's experience caring for individuals living with SCD, we find that dental health is indeed inextricably linked to their overall health and treatment. We will be following up with the agency outside of the rulemaking period to discuss this issue further.

Thank you for the opportunity to provide these comments. We look forward to our continued collaboration with CMS to ensure Medicare beneficiary access to physician services. Should you have any questions or wish to discuss these issues further, please contact Carina Smith at casmith@hematology.org.

Sincerely,

Mohandas Narla, DSc
President

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Chair, Committee on Practice