AMERICAN SOCIETY OF HEMATOLOGY
2021 L Street, NW, Suite 900, Washington, DC 20036-4929 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

September 11, 2023

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 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1784-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) 2024.

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 and the patients we serve.

- Conversion Factor Updates
- Evaluation and Management Services
- Payment for Telehealth Services
- Payment for Dental Services
- Dental Services and Sickle Cell Disease
- Drugs and Biological Products Paid Under Medicare Part B
- Practice Expense Data Collection and Methodology
- Potentially Misvalued CPT® Codes 36514, 36516, and 36522
- Services Addressing Health-Related Social Needs
- Payment for Caregiver Training Services

Conversion Factor Update

For CY 2024, the conversion factor is set to decrease by 3.36 percent due to a statutory 0 percent update, a negative 2.17 percent relative value unit budget neutrality adjustment, and the expiration of additional funds Congress added to the conversion factor for 2023. We understand that an act of Congress is required to increase the conversion factor. However, 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, thirty years later, the conversion factor is only two dollars higher. If the conversion factor had been adjusted for inflation the current conversion factor would be approximately $67.00.[1]

The lack of updates to the conversion factor puts physicians in an untenable position, and ASH believes that it is time for the conversion factor to be updated annually to, at the very least, keep pace with inflation. 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 Medicare beneficiary access to care and reimburse physicians fairly for the care they provide. We will continue our efforts to encourage legislators to fix this issue, and urge CMS to do the same.

Evaluation and Management (E/M) Services

Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

ASH is pleased that CMS is seeking comments on ways for the agency to improve the accuracy of the services' valuations and how E/M services might be evaluated with greater specificity, more regularly and comprehensively. ASH members frequently bill E/M codes, particularly levels 3, 4, and 5, due to the complexity of patients with hematologic diseases and disorders. For these reasons, properly valuing and defining E/M services has been a longstanding ASH priority.

ASH has been supportive of CMS' efforts to update the E/M code families beginning with the outpatient services and then the inpatient and observation services. These revisions were the first substantive changes to the definition and valuation of these services since the implementation of the Resource-based Relative Value Scale (RBRVS). The practice of medicine has undergone significant transformations, changing how patients are treated with the introduction of new drugs, therapies, and technologies. This is particularly true for the practice of hematology as new therapies, including gene therapy and Chimeric Antigen Receptor T-cell therapy (CAR-T), have been approved for hematologic conditions. ASH agrees with CMS in recognizing that the revised outpatient E/M codes did not fully account for the resource costs and expertise required to provide longitudinal care to complex patients. More must be done to account for the work, expertise, and resources associated with the delivery of longitudinal, patient-centered care for complex patients.

ASH participates in the CPT® Editorial Panel and the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) processes and has seen how those processes function when defining and valuing E/M and procedural care. The RUC survey process captures quantifiable data about procedures; however, the cognitive, non-procedural care provided by ASH members is more

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

difficult to quantify in a RUC survey as there are components of this work beyond time and intensity, including physician expertise which is an extremely important factor in the care we provide to our patients. The pace of medical knowledge that the hematologist must incorporate into the patient's care has become extraordinary rapid. What was a standard of care only a month or two before is often no longer the care that needs to be delivered. Additionally, the patients our members treat are often seen on a longitudinal basis, and our practitioners form long standing, trusted relationships with their patients that are not measured or captured by a RUC survey. Therefore, ASH is of the opinion that the E/M codes cannot be accurately defined by these existing processes.

Additionally, it is important to note that while ASH participates in the RUC process, we choose not to have our members serve on the RUC when an internal rotating seat is available, and instead remain as specialty society advisors to the committee. When someone serves on the RUC, they are not representing their specialty and cannot participate in the valuation process for services performed by their specialty. RUC members and specialty society advisors invest significant amounts of their time to understand the intricacies of and participate in the process. Not all physicians are able or willing to make this investment, and it is difficult to find members willing to serve. Hematology-specific services—procedures and E/M care—are surveyed and valued so infrequently that we believe it is more important to have our most knowledgeable members available when opportunities for valuation arise to present to the panel. ASH doubts that we are the only specialty to make this calculation, which ultimately limits the RUC's understanding of certain forms of care when survey data is presented.

With this considered, ASH has previously supported the creation of an expert panel to define and value E/M services and we continue to believe that a panel composed of individuals with expertise in healthcare policy, such as physicians, patients, health economists, coders, health informaticists, and other stakeholders with expertise in payment policy, will be able to review E/M payment comprehensively to ensure these codes reflect the complex E/M work of our members. Specifically, an expert panel should be charged with using an evidence-based, data-driven approach to assess the current definitions and documentation expectations and ensure that the valuations of E/M services are accurate, reliable, and reflect the value of the care delivered to Medicare beneficiaries. Following an analysis of data, research, methodologies, and knowledge gaps, an expert panel would be well-suited to develop a set of recommended changes to address inadequacies of E/M service code definitions and valuations.

Moreover, ASH would be remiss not to point out that budget neutrality remains a major challenge to the proper valuation of E/M services, particularly in an environment when overall physician payment has failed to keep pace with inflation over the last 20 years. We recognize that CMS does not have the statutory authority to address budget neutrality on its own and we remain committed to working with Congress to address this issue.

Office/Outpatient E/M Visit Complexity Add-on Implementation

ASH thanks CMS for proposing to reimburse providers for the complexity add-on code G2211 after its implementation was delayed by Congress for three years. We agree with CMS that the complexity add-on code "reflects the time, intensity, and practice expense (PE) resources involved when practitioners furnish the kinds of office/outpatient E/M office visit services that enable them to build longitudinal relationships with all patients (not only those patients who have a chronic condition or

single high-risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time." As discussed, the revised outpatient E/M family still does not fully capture the work of ASH members who deliver care and develop longitudinal relationships with Medicare beneficiaries. G2211 will undoubtedly help to capture the cognitive expertise and complexity of work involved in managing complex, longitudinal care for patients with single or multiple complex conditions, such as chronic lymphocytic leukemia and sickle cell disease (SCD).

Based on the detail provided in the rule, ASH members believe that this code may be billed for visits to follow up with every cancer patient and for all care delivered to transplantation and cellular therapy patients if modifier 25 is not applied. In discussion with our members, we believe these clinical scenarios are excellent examples of the complexity of care this code was intended to address:

- A patient with SCD visits the clinic to see her hematologist and has clearly deteriorated cognitively. The physician needs to understand if this is dementia or SCD-related. Most of the time during the patient's visit is spent ordering neurocognitive testing and consulting with psychiatry.
- A patient with SCD needs to be prescribed oxycontin for their chronic pain. The provider also spends time during the patient's visit managing other medications and then seeking the appropriate pre-approval and prior authorization for oxycontin.

Split/Shared Services

ASH supports the agency's proposal to maintain the current definition of "substantive portion" when determining which practitioner should bill for a split/shared service. This definition would allow for the use of either of the components – history, exam, or medical decision making, or more than 50 percent of total time spent with the patient. ASH appreciates that CMS continues to delay using time as the determinative factor as to which provider will bill the service. The continued delay supports physician-led, team-based patient care and represents usual practice patterns which will reduce burden on physicians and be more consistent with the rest of the E/M code families. These factors combined will benefit patients and improve outcomes.

Payment for Telehealth Services

Implementation of Provisions in the Consolidated Appropriations Act, 2023

ASH supports CMS' implementation of the telehealth provisions in the Consolidated Appropriations Act, 2023. The telehealth flexibilities implemented by CMS since the start of the COVID-19 pandemic have transformed ASH members' practice, improving patient access to care and reducing health care disparities. Patients with hematologic conditions may not have access to hematologists in their communities, and telehealth can help them receive the required specialized care, including follow up care, review of medication options, and review of lab results, regardless of their geographic location. Therefore, we are pleased that Medicare beneficiaries will continue to receive telehealth services in their homes without traveling to an originating site and audio-only services through December 31, 2024. ASH recognizes that CMS lacks the authority to extend these flexibilities permanently, and we will continue in our efforts to urge Congress to grant CMS the authority to ensure that patients have access to these services on a permanent basis.

Reimbursing Telehealth Services at the Non-Facility Rate

ASH urges CMS to finalize the proposal to reimburse telehealth services provided to patients in their homes using POS 10 at the non-facility rate. Our members have made significant investments in their practices to continue offering telehealth services to their patients. Sufficient reimbursement is necessary to recognize the value and effort put forth by providers in delivering high-quality telehealth services, including the significant resources that are required to offer these visits. We are pleased that CMS recognizes this, and we look forward to continuing to work with the agency and Congress to ensure that these services remain available to Medicare beneficiaries on a permanent basis.

Payment for Dental Services Inextricably Linked to Specific Covered Medical Services

In the CY 2023 MPFS final rule, the agency identified clinical scenarios where payment for certain dental services is permitted under Parts A and B, if the services are not considered routine dental services, as defined by the statute. The clinical scenarios covered under Medicare include dental services that are inextricably linked to, and substantially related to the clinical success of, certain other covered services. Beginning in 2024, the agency has proposed additional clinical scenarios whereby the provision of certain dental services should be covered for the success of those clinical scenarios. These include chemotherapy, CAR T-Cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy), all when used in the treatment of cancer.

We are extremely pleased and thank the agency for proposing coverage and payment for dental services for the clinical scenarios noted above. ASH submitted comments on last year's proposed rule where we supported coverage of dental services for those undergoing CAR T-cell therapy and other treatments for cancer, as well as for those with non-malignant blood diseases and disorders including hemophilia and sickle cell disease (SCD). In February of this year, we also submitted comments in response to CMS's Dental Recommendations for CY2024 Review. We encourage the agency to finalize coverage for the dental services included in this rule, and strongly encourage CMS to consider dental coverage for SCD in response to this year's proposal, as outlined below.

Request for Comment on Dental Services Integral to Treatment of Sickle Cell Disease

ASH would like to thank the agency for considering and including our comments on the MPFS 2023 proposed rule on dental services for patients with SCD in this year's proposal, as well as our comments related to the Dental Recommendations CY2024 Review. We appreciate that the agency reads every comment letter, and in our case, has included specific language from last year's letter to request comments from stakeholders on the coverage of dental services for people with SCD.

In both comment letters, we describe that there are "increased dental caries and periodontal disease in people with SCD, many of whom lose a number of teeth, which greatly limits nutrition, general well-being, and overall quality of life."

While we understand that the agency has proposed to cover specific dental services (tooth extractions for example) that are integral for specific conditions, we believe that covered dental services in this specific case should include regular check-ups (prophylactic services) and treatment of dental caries and periodontal disease. We believe that prevention of oral disease and tooth decay are vital components of the overall health and well-being of people with SCD. Our previous comment letter noted that when a patient experiencing a SCD crisis also has a dental infection, they are 72 percent

more likely to be admitted to a hospital compared to those without dental infections. We refer you to our comments from last year for a list of journal articles that support our position. We urge the agency to add SCD as a covered indication for treatment of dental services that are integral to the overall health, wellbeing, and outcomes for Medicare beneficiaries with SCD.

Drugs and Biological Products Paid Under Medicare Part B

CMS is soliciting comments on payment for non-chemotherapeutic complex drug administration services, in response to concerns that non-chemotherapeutic complex drug administration payment is inadequate due to existing coding and Medicare billing guidelines.

ASH believes that the current definitions and coding structure for the administration of complex and non-complex chemotherapy administration services is appropriate and does not need to be revised. Currently, the codes to describe these services are divided into three sections in the CPT code book: Hydration (CPT codes 96360-96361), Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (CPT codes 96365-96379), and Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration (CPT codes 96401-96549). ASH believes that this coding construct is sufficient to capture the drugs and services associated with diseases our members treat.

The CPT code book provides explicit instructions and information on how to bill for these services and notes that the nature of the substance or drug administered, the route of drug administration, and the primary reason for the patient encounter all play a role in the selection of the codes for description of a given outpatient drug administration service. We believe that drugs should not be deemed complex simply based on the type of patient that is receiving the drug. For example, a drug should not be deemed complex simply because it is being administered to a cancer patient but not complex when administered to a non-cancer patient. We refer you to the February 2009 CPT Assistant article "coverage determinations for specific drugs and agents are made by each third-party payer, as are drug/agent classifications."

We understand that discrepancies may occur between the code or service that a physician bills and whether a payer will reimburse for that service. The current coding structure is sufficient to bill physician administered drugs, whether complex or not, and payers need to better implement current coverage policy and reimburse clinicians appropriately when they bill complex drug administration services. Payers should cover and reimburse complex drug administration codes when used with non-chemotherapy drugs if the clinician appropriately documents medical necessity.

Strategies to Update Practice Expense Data Collection and Methodology

ASH would like to thank the agency for requesting comments on the all-important task of maintaining and updating the practice expense (PE) inputs of the physician payment equation. We know that PE data is a key component of the MPFS, encompassing approximately 45% of total payment for a service. As such, PE data needs to be complete and current for each procedure priced under the MPFS.

We are encouraged that the AMA has undertaken the enormous task of updating the Physician Practice Information Survey (PPIS) and we are supporting those efforts. Through ASH's Practice Update e-newsletter, with a distribution of more than 17,000 practitioners, we have encouraged our

members to participate in the survey when it crosses their desk. ASH recommends using the results of this survey before implementing any policy changes or updating PE inputs.

Understanding the significant redistributive effects that new PE data will have on the MPFS, we also suggest that if CMS accepts the results of the PPIS, that this data be phased in over a four-year period. The phase-in will allow physicians and their practices to adjust to the changes without a large redistribution in RVUs, which impacts payment.

ASH recommends that PE data be updated on a regular basis and suggests conducting PE reviews and updates every five years to account for the inevitable changes in technology, practice patterns, clinical labor rates, and other factors that influence these inputs. Updating the data more regularly will provide greater stability within the payment system.

Potentially Misvalued CPT Codes 36514, 36516, and 36522

Every year CMS collects public nominations for potentially misvalued services paid under the MPFS. In this proposed rule, CMS addresses a public nomination stating that services for apheresis, represented by codes 36514, 36516, and 36522 are misvalued. The nominator of these services as misvalued is requesting that the agency create a new labor type of apheresis nurse and use this labor input instead of the RN/LPN labor type. At this time, we do not agree that these codes are misvalued, and would suggest the agency wait to review the results of the PPIS before making any changes since the nominator's concerns relate to practice expense. There is a real possibility that the information needed to either create a new labor type, revise the labor type, or confirm the labor type for these services will be reflected in the survey results. Therefore, we reiterate our position and recommend that the agency wait for the PPIS to be complete before making any changes.

Services Addressing Health-Related Social Needs

CMS has proposed new services that are intended to meet the goals of the Administration to provide fair and equitable care to all, including Medicare beneficiaries. The agency has created services, reported by a new HCPCS G code for the provision of a social determinants of health (SDOH) risk assessment. This new service was created to capture the work and resources related to providing care and assistance that is outside of, but related to, the scope of care and resources captured in E/M services.

We do seek clarification on the frequency of the administration for the SDOH risk assessment. The proposed rule states the service is billable once every six months. We are unclear if this means the service is billed once every six months per physician or once every six months per patient. For example, we can envision a scenario whereby a hematologist may provide the SDOH risk assessment to assist in formulating a treatment plan for lymphoma, while the patient's general practitioner may wish to perform the SDOH risk assessment to help in treating depression within the same six-month period. If the code is finalized for CY 2024, we suggest that the agency clarify this issue in the final rule.

Again, we support the creation of the services described by the new SDOH risk assessment code since it is complimentary to the care and treatment our members provide for their patients. We encourage CMS to finalize the proposed service.

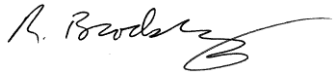
Payment for Caregiver Training Services

We thank the agency for recognizing the value of caregiver training services by proposing payment under the MPFS. The AMA CPT® Editorial Panel recently approved codes that describe caregiver training services used to provide training to improve functional performance for patients. Those services are described CPT codes 9X015, 9X016, and 9X017. Additionally, CMS has proposed to provide payment for caregiver training services in a group setting. The codes associated with these services (CPT codes 96202 and 96203) were previously not payable under Medicare.

We support payment for caregiver training services as we believe caregivers are an important component of any successful course of treatment or assisting with long-term, chronic illness associated with hematologic diseases and disorders. Many caregivers can provide emotional and practical support to family members in most circumstances, but caregiver training services when taught by specialists will improve the care provided by those family members. We encourage the agency to finalize the codes and payment for caregiver training services.

ASH thanks you for considering our comments and recommendations on the MPFS proposed rule. Should you have any questions or require additional expertise, please contact ASH Chief Policy Officer, Suzanne Leous at sleous@hematology.org.

Sincerely,



Robert A. Brodsky, MD
President