



September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

RE: 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 of Hematology (ASH) is pleased to offer comments on the calendar year (CY) 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. We appreciate the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the provisions of interest to our members.

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.

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

1. CY 2022 Conversion Factor
2. Proposed Practice Expense Changes - Impact on Hematology/Oncology
3. Telehealth
4. Closing the Health Equity Gap in CMS Clinical Quality Programs
5. MIPS Value Pathways

CY 2022 Conversation Factor

ASH is concerned about the proposed payment cuts to the CY 2022 conversion factor resulting from budget neutrality requirements. The cuts are a major problem at any time but particularly when physicians continue to face financial distress due to the COVID-19 pandemic. To mitigate the budget neutrality cuts, we strongly urge CMS and the Department

2021

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of Health and Human Services (HHS) to utilize its authority under the public health emergency declaration to waive the reduction to the conversion factor. ASH will join the American Medical Association (AMA) and other medical societies to advocate with Congress to prevent the 3.75% reduction in the conversion factor from occurring in 2022.

Proposed Practice Expense Changes - Impact on Hematology/Oncology

CMS is proposing significant reductions in practice expense values for office-based hematology and hematology/oncology services, such as chemotherapy, apheresis, and photopheresis services. While we recognize the need for the update in labor rates across all services, the impact on these services will be significant. ASH joins the American Society of Clinical Oncology (ASCO) in supporting the update in clinical labor prices but wants to express our concerns on the accuracy of the data and methodology being used to determine labor rates for hematology/oncology services. ASH joins ASCO in asking CMS to work with our Societies to establish accurate labor price inputs and methodology to set clinical labor rates for the coming years. The Society asks that if CMS moves forward with this proposal, that the agency phase in the reductions to delay the impact during these challenging times.

Telehealth

Physicians and patients alike have greatly benefited from the expanded telehealth services as a result of the declared Public Health Emergency (PHE) for the Covid-19 pandemic. Permanent expansion of many of these services, however, will provide benefits beyond the PHE, especially for individuals living with chronic disease. ASH is pleased to see that the agency is proposing to make permanent audio-only telehealth services for the diagnosis, evaluation, and treatment of a patient with a mental health disorder but urges CMS to go further and to work with Congress to make the flexibilities allowed under the PHE permanent for all patients and physician services. Specifically, ASH supports permanent removal of the geographic and site of service originating site restrictions to allow Medicare beneficiaries to utilize telehealth from their homes rather than require them to travel to specific sites. Additionally, the Society urges CMS to continue to cover and pay for the audio-only codes at the reimbursement levels set in the April 30, 2020, Interim Final Rule.

Many hematologic diseases are rare and complex to manage. Patients may not have access to medical experts in their communities, and telehealth can help them receive appropriate care regardless of where they live. Furthermore, many patients travel great distances to see specialists, such as hematologists, particularly for follow-up visits to review lab tests or to discuss medication options, such as oral chemotherapies. Permanently expanding telehealth services would ease the burden on patients and allow them to continue care management remotely, in a more efficient and safe manner.

Virtual Check-in

ASH appreciates that CMS created and is now proposing to permanently adopt coding and payment for HCPCS code G2252 as described in the CY 2021 PFS final rule. The Society, however, continues to urge CMS to continue to cover and pay for the audio-only codes at the reimbursement levels set in the April 30, 2020, Interim Final Rule. Video is not always an option – technology fails, bandwidth is not strong enough, and some elderly patients do not know how to access/utilize it. While ASH appreciates CMS' offer to create new coding and payment similar to that of the virtual check-in, the

Society strongly feels that the current audio-only codes are better suited for physicians and patients, have been widely utilized since coverage/payment was approved early in the PHE, and reflect the appropriate lengths of time and reimbursement (at the current rates).

Closing the Health Equity Gap in CMS Clinical Quality Programs

ASH recognizes that persistent inequities in health care exist in the United States and has been a leader in its commitment to combatting inequities in hematology, supporting scientists and clinicians from backgrounds underrepresented in medicine, and embracing diverse voices across the patient and health care communities. As such, the Society applauds CMS for pursuing proposals intended to improve health equity in CMS quality programs. ASH agrees with CMS's priority to enhance data collection efforts in order to better measure and analyze disparities across programs and policies. ASH supports stratification of quality metrics based on social risk factors and race and ethnicity as an important step for giving hospitals, providers, and patients more comprehensive and actionable information on health disparities.

As the agency's health equity work progresses, ASH encourages CMS to give special consideration to rare disease populations which may be disproportionately impacted by health inequity. For example, sickle cell disease (SCD) is an inherited blood disorder that affects an estimated 100,000 Americans, primarily African American and Latino populations. Sickle cell trait (SCT) is even more prevalent and occurs in 1-3 million Americans and 8-10 percent of African Americans in the United States. When compared to other genetic disorders, such as cystic fibrosis, SCD has received relatively little attention and few resources from the scientific, clinical, and public health communities. In its report titled *Addressing Sickle Cell Disease: A Strategic Plan and Blueprint for Action*, the National Academies of Sciences, Engineering, and Medicine identified the affected population being primarily composed of racial and ethnic minorities, which must contend with persistent discrimination in the health care system and racism in society at large, as a contributing factor to the lack of awareness and resources for SCD.ⁱ

ASH is working to improve SCD care, treatment, research, and data in the U.S. and in 2015, established a transformative, patient-centric, multifaceted Sickle Cell Disease Initiative to improve outcomes for individuals with the disease. As part of this work, the Society created the ASH Research Collaborative including a Sickle Cell Disease Clinical Trials Network (SCD CTN), Data Hub, and the Sickle Cell Disease Learning Community. The Data Hub is a technology platform that facilitates the exchange of information by aggregating data in one place, and making available for inquiry, research-grade data on hematologic diseases. Using the Data Hub, the SCD CTN can collect key information and identify gaps that will help advance SCD research and treatment options. The Sickle Cell Disease Learning Community aims to promote the implementation of evidence-based practice to improve SCD care. The Learning Community was made possible through a grant from the Department of Health and Human Services Office of Minority Health. ASH stands ready to work with CMS to enhance data collection efforts with the ultimate goal of improving health equity for individuals with SCD as well as with other hematologic diseases and disorders.

MIPS Value Pathways

ASH appreciates the agency's efforts to further develop and improve the Merit-based Incentive Payment System (MIPS), including the creation of MIPS Value Pathways (MVPs). The Society, however, is concerned about the limited ability for certain specialties, including hematology, to

participate in an MVP. The creation of an MVP requires sufficient and meaningful measures. There are very few hematology-specific quality measures, which require time and expertise to develop. ASH is currently working on creating hematology-specific measures – in sickle cell disease and diagnosis of venous thromboembolism – and will work with CMS to continue to improve the program. ASH would be happy to meet with you to discuss the progress and challenges related to developing these quality measures.

Thank you for the opportunity to provide comments on the Physician Fee Schedule proposed rule for CY 2022. The Society welcomes 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 716-361-2764 (cell).

Sincerely,



Martin S. Tallman, MD
President

¹ National Academies of Sciences, Engineering, and Medicine. 2020. Addressing sickle cell disease: A strategic plan and blueprint for action. Washington, DC: The National Academies Press. <http://doi.org/10.17226/25632>.