AMERICAN SOCIETY OF HEMATOLOGY
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June 28, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1752–P
P.O. Box 8013
Baltimore, MD 21244–1850

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

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program
(CMS–1752–P)

Dear Administrator Brooks-LaSure,

The American Society of Hematology (ASH) is pleased to offer comments on the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year (FY) 2022 Rates. We appreciate the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the provisions of interest to our members, including MS-DRG 018 Chimeric Antigen Receptor T-cell (CAR-T) Therapies, Graduate Medical Education, and Closing the Health Equity Gap.

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.

The Society's comments on the proposed FY 2022 Medicare IPPS Rule are as follows:

MS-DRG 018 Chimeric Antigen Receptor T-cell (CAR-T) Therapies

ASH supports CMS' efforts to assure Medicare beneficiary access to CAR-T therapies by creating MS-DRG 018 and developing a payment methodology to recognize the high costs associated with treating these very sick patients. ASH's members are at the forefront of this therapy, conducting research and providing this potentially curative treatment to patients with certain types of blood cancers. Patients receiving CAR-T therapy have typically exhausted all other treatments, including chemotherapy, radiation, or stem cell transplant. CAR-T therapy represents a potentially life-saving option to patients whose care needs are currently unmet by existing therapeutics. The Society's main priority is protecting and improving appropriate patient access to this potentially curative therapy.

ASH supports CMS continuing to use the methodology it finalized last year in determining the relative weight for CAR-T MS-DRG 018 in FY 2022, which excludes clinical trial cases and cases with standardized pharmacy charges less than $373,000 and to continue to pay for these cases at an adjusted amount. These steps are critical to recognizing the high cost of caring for these patients. It is difficult to predict what the costs associated with other future CAR-T therapies will be. There will likely be new or different side effects or additional agents that are co-administered with the therapy that may increase toxicity, adding additional yet necessary care costs. The Society urges CMS to take these issues into account as the agency updates the new proposed MS-DRG over time.

Proposed Payments for Indirect and Direct Graduate Medical Education Costs

ASH supports CMS policy proposals to implement provisions of the Consolidated Appropriations Act of 2021 relating payments to hospitals for direct and indirect graduate medical education (GME) costs. Allowing for the funding and distribution of 1,000 new residency positions starting in 2023 (with up to 200 new slots per year), the emphasis on the needs of expansion of residency positions in hospitals in rural and medically underserved areas, and increases for hospitals with lower per resident amounts for direct GME, will strengthen the existing residency training programs in the United States and begin to address the dire need for additional physicians to meet the pressing need for additional health care providers.

Over the past four years, ASH conducted a comprehensive longitudinal workforce study designed to examine the current hematology workforce and the existing pipeline of future hematologists. One of the recommendations from this study was the need to increase the number of fellowship programs that prioritize training in hematology following residency, especially non-malignant hematology, and promote careers in hematology in the United States. ASH felt so strongly about the need that the Society has initiated the Hematology-Focused Fellowship Training Program (HFFTP), which will fund the creation of ten new innovative hematology-focused fellowship tracks within existing U.S. adult hematology-oncology training programs, with the goal of producing 50 new hematologists by 2030. ASH's commitment of $19 million toward this pressing need would be complemented by CMS's effort. Expanding residency slots is an important step towards expanding the physician workforce and we strongly support this proposed CMS policy. The Society would be pleased to brief CMS on our efforts and serve as a resource as needed.

Closing the Health Equity Gap in CMS 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 including proposals in the IPPS proposed rule 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 Americans and Latinos. 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 with 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.[1]

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) and Data Hub. 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. 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.

In closing, the Society thanks CMS for the opportunity to provide input on the proposed FY 2022 Medicare IPPS Rule. Please reach out to ASH Chief Policy Officer, Suzanne Leous (sleous@hematology.org), with any questions or clarifications regarding our comments.

Sincerely,

Martin S. Tallman, MD
President

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[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.