Advancing Transfusion and
Cellular Therapies Worldwide

June 28, 2021

The Honorable 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 21244-8013

Submitted Electronically Via 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; (CMS-1752-P)

Dear Administrator Brooks-LaSure:

AABB appreciates the opportunity to submit comments in response to Centers for Medicare & Medicaid Services' (CMS) 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 Proposed Rule (proposed rule) for fiscal year 2022. AABB's comments focus on the proposals related to: (1) the pre-MDC MS-DRG 018 chimeric antigen receptor (CAR) T-cell therapy name revision; (2) cost categories for blood and blood products; and (3) the new technology add-on payment application for pathogen reduced cryoprecipitated fibrinogen complex.

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. The association is committed to "improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide." AABB works toward this vision by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

I. Pre-MDC MS-DRG 018 Chimeric Antigen Receptor (CAR) T-Cell Immunotherapy

AABB continues to encourage CMS to clarify that there must be appropriate reimbursement policies in IPPS for all items and services required throughout a CAR T-cell and related cellular immunotherapy treatment protocol. We commend CMS for recognizing that CAR T-cell treatment protocols involve several essential steps, which the Agency summarizes as: (1) lymphocyte harvesting from the patient with cancer; (2) creation of cancer-targeting lymphocytes in vitro using various immune modulators; (3) selection of lymphocytes with reactivity to cancer antigens using enzyme-linked immune-assay; (4) depletion of the patient's remaining lymphocytes using immunosuppressive agents; and (5) transfusion of the cancer-targeting lymphocytes back into the patient with cancer-this transfusion

represents one treatment. Each of these steps is resource intensive and can take place at different institutions. For example, lymphocytes can be harvested at blood collection establishments, manipulated in a different laboratory, and then administered to a hospital inpatient.

AABB appreciates that CMS established MS-DRG 018 as a pre-MDC due to the extensive resources, steps, and processes required of a CAR T-cell administration consistent with the policy of pre-MDCs that group items or services primarily on resource utilization. However, AABB continues to urge CMS to recognize that appropriate coverage and reimbursement is necessary for all items and services furnished throughout the continuum of CAR T-cell and related cellular immunotherapy treatments.

Additionally, AABB requests that CMS clarify the term "immunotherapies" in its proposal to rename pre-MDC MS-DRG 018. The proposed language, "Other Immunotherapies," may be too broad. AABB urges CMS to utilize a naming convention, such as cellular immunotherapies, which would capture similar resource-intensive procedures for the DRG. Cellular immunotherapies utilize active immune cells that have been enhanced to fight cancer in patients. These therapies include tumor-infiltrating lymphocyte (TIL) therapy, engineered T- Cell receptor (TCR) therapy, CAR T-cell therapy and natural killer (NK) cell therapy. While AABB appreciates that CMS wants to include non-CAR T-cell therapies in order to increase access to new cellular therapies as requested in previous comments, using the term "other immunotherapies" can include many immunotherapies, such as antibody-based targeted therapies and oncolytic virus therapy, which are not cellular therapies and have very different clinical and resource utilization. Thus, AABB urges CMS to use more specific language in the naming of MS-DRG 018 that would more accurately reflect the pre-MDC logic and ICD-10-PCS codes that are mapped to MS-DRG 018.

II. Cost Categories – Blood and Blood Products

AABB supports CMS's proposal to derive costs for blood and blood products for the 2018-based IPPS market basket from the CMS Medicare cost reports. However, we encourage CMS to develop and release additional educational materials that instruct hospitals on how to appropriately report blood products and services on the CMS Medicare cost reports. AABB recognizes that blood products and services are captured in a wide variety of MS-DRGs, and providers may inadvertently exclude them from their cost reports. The Association is committed to working with CMS to educate hospitals on appropriate billing for blood products.

III. New Technology Add-On Payments Application for Pathogen Reduced Cryoprecipitated Fibrinogen Complex

AABB supports the new technology add on payment application for pathogen reduced cryoprecipitated fibrinogen complex (PRCFC). We appreciate that the Food and Drug Administration (FDA) awarded "Breakthrough Device" designation for this product. We urge CMS to finalize the NTAP status for the cases associated with the newly assigned ICD-10-PCS procedure codes 30233D1 or 30243D1.

Conclusion

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions or need additional information, please contact Susan N. Leppke at 301.547.3962 or sleppke@aabb.org.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB