



Advancing Transfusion and
Cellular Therapies Worldwide

July 10, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1735-P
Mail Stop C4-26-05
7500 Security Boulevard
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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals; (CMS-1735-P)

Dear Administrator Verma:

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 2021 Rates Proposed Rule (proposed rule) for fiscal year 2021. AABB's comments focus on the proposals related to payment policies for market-based MS-DRG relative weight proposed data collection and methodology, Chimeric Antigen Receptor (CAR) T-cell therapies, and proposed changes to reimbursement for allogeneic hematopoietic stem cell acquisition costs.

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.

Market-Based MS-DRG Relative Weight Methodology: AABB urges CMS not to move forward with its proposed policy to use Medicare Advantage (MA) and third-party payer rates to calculate MS-DRG relative weights because this change may fail to produce reimbursement rates that accurately reflect the cost of delivering care. AABB shares the concerns expressed by the College of American Pathologists (CAP) that MA and third-party payer rates may not account for the same services as the Medicare hospital inpatient rates, which would result in flawed reimbursement rates. For example, the professional component of clinical pathology services is reimbursable under Medicare Part A but may be paid separately by MA and third-party payers. Thus, using the MA and third-party payment rates to calculate the MS-DRG relative weights may result in payment rates that exclude the costs associated with these important services. We encourage CMS to ensure that any revised reimbursement policy results in payment rates that reflect all costs associated with delivering care.

CAR T-Cell Therapies: AABB commends CMS for recognizing that appropriate coverage and reimbursement is necessary to cover all items and services furnished throughout the continuum of CAR T-cell therapies. We join the American Society of Hematology (ASH), the American Society for Transplantation and Cellular Therapy (ASTCT) and the National Marrow Donor Program (NMDP) in supporting CMS's approach to establishing a new MS-DRG for CAR T-cell therapy. We urge CMS to assign complications or comorbidities (CC) and major complications or comorbidities (MCC) status to the new cytokine release syndrome (CRS) ICD-10 diagnosis codes that will go into effect October 1, 2020.

Additionally, AABB agrees with CMS's proposal to use an adjustment formula when paying for CAR-T clinical trial cases, thereby making a reduced payment for clinical trial cases. However, we urge CMS to allow for flexibility due to the differences in clinical trial designs. AABB supports the recommendation made by other medical societies to use value code 90 (previously 86), which would allow CMS to see actual acquisition costs for current CAR T-cell therapy products used in clinical trials where the therapeutic under investigation is not the CAR T-cell therapy product itself. This will provide CMS with insight as to the actual acquisition costs for the CAR-T products.

Reimbursement for Allogeneic Hematopoietic Stem Cell Acquisition Costs: AABB supports the proposed changes to reimbursement for allogeneic hematopoietic stem cell acquisition costs. However, we share the concerns raised by ASH, ASTCT, and NMDP that if the proposal is finalized as written, hospitals would no longer be able to report their actual donor and cell acquisition charges, potentially forcing them to report an average acquisition charge for all patients, regardless of payer. This could significantly impact how transplant centers bill commercial insurance for donor search and cell acquisition services. We encourage CMS to continue allowing providers to report their actual charges.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions or need additional information, please contact Leah Stone at 301-215-6554 or lmstone@aabb.org.

Sincerely,



Debra BenAvram
Chief Executive Officer
AABB