



June 10, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1808-P
P.O. Box 8013
Baltimore, MD 21244-8013

**RE: Medicare and Medicaid Programs and the Children's Health Insurance Program;
Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the
Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal
Year 2025 Rates (CMS-1808-P)**

Dear Ms. Brooks-LaSure:

The Association for the Advancement of Blood & Biotherapies, America's Blood Centers and the American Red Cross appreciate the opportunity to submit comments in response to Centers for Medicare & Medicaid Services' (CMS) Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals proposed rule for fiscal year 2025. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals. Our comments focus on the request for public comment on the separate payment under IPPS for establishing and maintaining access to essential medicines.

We appreciate CMS's commitment to ensuring access to essential medicines as part of supply chain resiliency and public health preparedness. By recognizing the importance of essential medicines, CMS is taking a proactive approach to safeguarding public health during emergencies and crises. Nevertheless, we have reservations about the proposed policy's effectiveness in achieving its intended goals, as it excludes blood and blood products from the category of essential medicines. We encourage CMS to revise the proposed policy to (1) include blood and blood products, and (2) ensure that the payments are sufficient to cover all costs associated with procuring and maintaining essential medicines, including a "buffer stock" of blood and blood products.

The proposed rule defines "essential medicines" as the 86 essential medicines prioritized in the "Essential Medicines Supply Chain and Manufacturing Resilience Assessment" report, developed by the Assistant Secretary for Preparedness and Response (ASPR). This report exclusively focuses on small molecules and therapeutic biologics and explicitly omits blood and blood products from its analysis and scope "due to differences in their supply chains."¹ These differences should not result in blood and blood products being omitted from CMS' proposed payment policies for establishing and maintaining access to essential medicines.

Conversely, blood and blood products are explicitly classified as essential medicines on the U.S. Food and Drug Administration (FDA) Executive Order 13944 "List of Essential Medicines,

¹ Essential Medicines Supply Chain and Manufacturing Resilience Assessment, (May 2022), footnote 3, available at https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

Medical Countermeasures, and Critical Inputs”.² As highlighted in the FDA Executive Order 13944 List, blood and blood products items are essential for addressing various medical conditions, including trauma, surgeries, cancer treatments, and other life-saving interventions. The blood supply is a critical aspect of emergency preparedness and unlike other pharmaceuticals and biologics, blood cannot be manufactured to meet demand. Therefore, we strongly urge CMS to include blood and blood products within the scope of the proposed payment policy for ensuring access to essential medicines.

By including blood and blood products in the proposed payment policy, CMS would further enhance its emergency preparedness efforts, contributing to the resilience of the health care system and the well-being of patients. The COVID-19 pandemic exposed vulnerabilities in the blood supply chain, underscoring the critical need for a steady and accessible reservoir of these vital medical resources. Hospitals and healthcare providers faced significant challenges in ensuring an adequate supply of blood and blood products for patient care during the pandemic.^{3,4,5} Thus, recognizing blood and blood products as essential medicines in the payment policy would be a proactive step toward safeguarding public health and enhancing the overall resilience of the health care system.

Our organizations also request that CMS ensure that payments are sufficient to cover the costs of maintaining a “buffer stock” of blood and blood products. Unlike other essential medicines, blood must be constantly and regularly collected from donors in the community. Furthermore, blood has a limited shelf life, with red blood cells lasting up to 42 days and platelets for only five days. During disasters and emergencies, it is the blood on the shelf that saves lives. Hence, establishing a payment policy for creating and storing a “buffer stock” of blood and blood products would contribute to a more holistic framework that addresses routine and emergency health care needs.

We appreciate the opportunity to comment on the proposed rule and look forward to continued discussion. If you have any questions or require additional information, please contact Susan Leppke (301-547-3962, sleppke@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org), or Julie Manes (202-417-5147, julie.manes@redcross.org).

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

Kate Fry
Chief Executive Officer
America’s Blood Centers

J. Chris Hrouda
President, Biomedical Services
American Red Cross

² FDA Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs, (October 2020), available at <https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs>.

³ Young, M, US Faces Worst Blood Shortage in Over a Decade Amid Pandemic, *The Guardian*, (January 2022), <https://www.theguardian.com/us-news/2022/jan/13/blood-donation-crisis-us-red-cross>.

⁴ Rosen, N, Severe National Blood Shortage May Force Doctors to Augment Patient Care, Officials Say, *ABC News* (June 2021), <https://abcnews.go.com/Health/severe-national-blood-shortage-force-doctors-augment-patient/story?id=78354725>.

⁵ U.S. Department of Health and Human Services, HHS Announces New Campaign to Increase U.S. Blood and Plasma Donations, (August 2022), <https://www.hhs.gov/about/news/2022/08/04/hhs-announces-new-campaign-increase-us-blood-plasma-donations.html>.