



September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1786-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program: CY 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS-1786-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 Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems proposed rule for calendar year 2024. 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 potential payment under IPPS and OPSS 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 a 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.

Finally, we are concerned that CMS’ proposed payment rates for most blood and blood products for CY 2024 are lower than the reimbursement rates for 2023 and are inadequate. As highlighted earlier, in late 2021 and early 2022 the country experienced a significant blood shortage, which may be affecting the proposed reimbursement rates for blood and blood products. We urge CMS to collaborate with the blood community to ensure that the reimbursement rates for these vital medical resources are sufficient.

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), Kate Fry (202) 654-2911, (kfry@americasblood.org), or Julie Manes (202-417-5147, julie.manes@redcross.org).

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>.

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Sincerely,



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Chief Executive Officer
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America's Blood Centers



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