Association for the Advancement of Blood & Biotherapies

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September 3, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Ms. Brooks-LaSure:

The Association for the Advancement of Blood & Biotherapies (AABB), America's Blood Centers (ABC), the American Red Cross (ARC), and the Blood Centers of America (BCA) appreciate the opportunity to submit comments in response to the policy included in the proposed rule updating Medicare part B payment and coverage policies for CY 2025. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals.

Our comments relate to CMS' proposal to add the administration of low titer O+ whole blood transfusion to the current list of advanced life support, level 2 (ALS2) procedures. We commend CMS for recognizing that pre-hospital blood transfusions are lifesaving interventions. However, we are concerned that CMS' proposed policy will not achieve the intended outcome of ensuring that patients have access to pre-hospital blood transfusions.

The proposed policy is flawed because (1) it does not apply to all FDA-approved blood and blood components that are critical for patients requiring prehospital hemostatic resuscitation; and (2) the current payment rate for ALS2 is far too low to accommodate the cost of providing pre-hospital blood transfusions. We encourage CMS to add funding beyond existing reimbursement to capture the costs associated with pre-hospital blood transfusions. CMS, through the CMS Innovation Center, can develop and implement a payment and service delivery model that incorporates pre-hospital blood transfusions into the emergency medical system.

1. **CMS should provide coverage for all FDA-approved blood and blood components that are provided in the pre-hospital setting of care.**

There is evidence that pre-hospital blood transfusions, whether in the form of low-titer O whole blood or component blood therapy, are lifesaving interventions. Currently, there are different perspectives among subject matter experts regarding the comparative benefits and harms of low-titer group O whole blood transfusion versus component blood therapy transfusion for patients requiring prehospital hemostatic resuscitation however, there is generally agreement both therapies are superior to the current standard of care. CMS should not limit access to approved blood components; rather, CMS should cover all FDA-approved blood and blood components that are provided in the pre-hospital setting of care.

Component blood therapy and whole blood transfusions are both generally more effective than isotonic fluid resuscitation alone. Isotonic fluids can dilute blood components, potentially leading to coagulopathy and worsening outcomes. Whole blood transfusions may provide better hemostatic resuscitation by preserving clotting factors and oxygen-carrying capacity. Component therapy, by providing targeted transfusion of red blood cells, plasma, and platelets, may better support hemostasis and oxygen delivery. Additionally, on a practical level, component therapy is substantially more readily available as all blood centers produce these products, versus low-titer O whole blood which is only produced by a smaller subset of centers and in much lower quantities. Ongoing studies are investigating these therapies.

The Agency for Healthcare Research and Quality (AHRQ) is currently conducting a systematic review on the feasibility, effectiveness, and safety of blood and blood product transfusions in the prehospital setting and will be comparing the benefits and harms of low-titer O whole blood transfusion, component blood therapy transfusion, and fluid resuscitation. AHRQ indicates that the results of the systematic review "will inform future prehospital care evidence-based guidelines, protocols, and state and local EMS agency decision-making."[1]

In addition to the ongoing studies and systematic review, more research and comprehensive data are needed to evaluate these critical interventions, including the risks and benefits of the therapy options to different patient populations and to the continued availability of the blood supply. A comprehensive gap analysis is also needed to (1) identify research questions, (2) assess EMS capabilities and operational limitations; (3) define the scope of training needed for EMS personnel to safely administer blood in pre-hospital settings, (4) understand blood collectors' operational limitations that may impact the availability of different interventions; (5) evaluate the potential impact of pre-hospital transfusion programs on the hospitals' inventories, which are essential to patient care; and (6) study blood wastage and methods to limit it.

For example, blood collectors need to be positioned to support pre-hospital blood transfusion programs. Some operational challenges may include: (1) donor recruitment; (2) manufacturing; (3) supply chain; and (3) the ability to meet demand. These considerations may impact EMS providers' ability to provide low-titer group O whole blood or component blood therapy. For instance,

[1] Agency for Healthcare Research and Quality, Effective Health Care Program, Prehospital EMS Blood Transfusion, Key Questions (May 28, 2024), *available at* https://effectivehealthcare.ahrq.gov/products/ems-blood-transfusion.

- **Donor Support:** Challenging trends related to blood donor recruitment and retention will impact blood collectors' ability to support pre-hospital blood transfusion programs. For example, over the past 10 years, there has been a 39% decline in younger donors under 30. Blood collectors will need to successfully recruit new Group O donors, who are critical to ensuring that whole blood or red blood cell units are available for pre-hospital transfusion programs. Demand for group O universal type blood by hospitals already outpaces supply most of the time, the need for low-titer further draws from a smaller potential pool of donors. Thus, blood collectors will incur donor recruitment and operational costs to support pre-hospital blood transfusion programs.

- **Manufacturing:** Manufacturing leukoreduced low titer group O whole blood must be done within 8 hours of collection, which significantly limits the pool of group O donors from which the product can be manufactured. The donors have other restrictions, such as aspirin free, low titer and transfusion-related acute lung injury (TRALI)-safe, placing further constraints on eligible group O donors.

- **Supply Chain:** Blood collection establishments currently rely on a limited number of blood bags to support whole blood collections. There is limited availability of these bags, which restricts the number of potential whole blood collections.

- **Demand:** Blood collection establishments are concerned about being able to meet the increased demand for low-titer group O whole blood - which has the potential to impact blood availability for hospitals. A successful pre-hospital blood transfusion program will require collaboration between blood collectors, hospitals, and local emergency management services providers. Additionally, it will require robust community engagement to support donor recruitment and retention.

Despite CMS recognizing that EMS systems are beginning to implement prehospital blood transfusion programs that provide patients with whole blood or component blood therapy, CMS' proposed policy would only cover low-titer O whole blood. We encourage CMS to avoid finalizing a coverage policy that does not capture all available and approved blood and blood component therapy options for patients requiring prehospital hemostatic resuscitation. Rather, CMS should cover all FDA-approved blood and blood component therapies provided in the pre-hospital setting of care.

2. **The payment rates for the existing service levels, including ALS2, are far too low to accommodate the cost of providing blood transfusions.**

Flawed reimbursement policies and inadequate payment rates will limit the widespread availability of pre-hospital blood transfusions. A paper published in April 2024 discusses lessons learned from the implementation of a prehospital whole blood program in Maryland. As this is only a single example, we want to emphasize that the costs associated with each aspect of individual pre-hospital blood transfusion programs will vary due to factors such as location, supplier contracts, labor expenses, and volume of blood utilized. The below description on the

budget and finance considerations for the Maryland program illustrates that the current ALS2 reimbursement rate is insufficient to cover pre-hospital blood transfusions:

> The initial cost to equip each EMS supervisor vehicle and station was approximately $6500 in 2023. Each unit of blood used costs $550, and administration equipment was approximately $375. The fluid warmers cost $4600, and each disposable circuit costs $87.50. Training costs, including salary support, were funded through existing budget lines and were estimated to be approximately $225 per each of the 12 EMS supervisors assigned to the field. No salary support was needed for the six EMS supervisors on a daywork schedule, totaling approximately $2700. Budget reallocations and grant funding enabled blood storage and administration equipment purchase and additional costs, including salaries for personnel training, training supplies, reserve equipment, and ongoing effort support for program administration. Estimated annual program costs are between $46,250 and $69,375 (50–75 patients/year × $925/patient) and depend on blood utilization.[2]

Another study indicates that the average cost of LTO+WB can range from $500 to $600 and a midsized EMS program reported blood product costs of $80,000 per year.[3] Due to reimbursement concerns, only a few (approximately 1%) well-funded prehospital agencies have implemented this proven lifesaving intervention. Reimbursement policies must be aligned with coverage for EMS providers to be able to implement pre-hospital blood transfusion programs.

3. **We encourage CMS, through the CMS Innovation Center, to develop and implement a payment and service delivery model that incorporates pre-hospital blood transfusions into the emergency medical system.**

CMS cites a lack of authority as a reason for not providing an additional payment to support pre-hospital blood transfusions. However, the CMS Innovation Center was established for precisely the reason of "developing and testing health care payment and service delivery models to improve patient care, lower costs, and align payment systems to promote patient-centered practices."

Thus, CMS, through the CMS Innovation Center, can facilitate the implementation of effective pre-hospital blood transfusion programs by establishing a service delivery and reimbursement model that incorporates pre-hospital blood transfusions into the emergency medical system. Expanding patients' access to pre-hospital blood transfusions will enable ambulance care teams to better address emergency health care needs in a timely manner, which will improve patients' outcomes and reduce costs to the medical system.

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[2] Levy MJ, Garfinkel EM, May R, Cohn E, Tillett Z, Wend C, Sikorksi RA, Troncoso R Jr, Jenkins JL, Chizmar TP, Margolis AM. Implementation of a prehospital whole blood program: Lessons learned. J Am Coll Emerg Physicians Open. 2024 Mar 21;5(2):e13142. doi: 10.1002/emp2.13142. PMID: 38524357; PMCID: PMC10958095.

[3] Schaefer, R. M., Bank, E. A., Krohmer, J. R., Haskell, A., Taylor, A. L., Jenkins, D. H., & Holcomb, J. B. (2024). Removing the barriers to prehospital blood: A roadmap to success. The Journal of Trauma and Acute Care Surgery, 97(2S Suppl 1), S138–S144. https://doi.org/10.1097/TA.0000000000004378

CMS should consider a model that includes a pre-hospital blood product add-on payment that incorporates the costs associated with procuring, storing, and administering blood transfusions. Activities may include, but are not limited to, procuring blood products from entities such as blood collection establishments and hospitals, storing blood products in accordance with safety standards, and transfusing the blood safely and effectively.

Comprehensive reimbursement policies and sufficient payment rates may improve health care quality and lower costs to the Medicare system by reducing hemorrhagic deaths and long-term hospitalizations following ambulance transport. The model can enhance the quality of care provided to Medicare beneficiaries by ensuring that they receive the appropriate level of care that is delivered safely at the right time and place.

Our organizations are committed to working with the EMS community and CMS to advance policies that increase access to pre-hospital blood transfusions.

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,

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