



Comments regarding CMS-1807-P

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The Prehospital Blood Transfusion Initiative Coalition (PHBTIC) is a grass roots voluntary initiative composed of over 200 professional organizations, associations, industrial partners and individuals. These individuals include national, regional and local blood collectors and suppliers, trauma physicians, emergency and EMS physicians, nurses, paramedics and EMS administrators. The Coalition's mission is to promote and facilitate the use of approved blood products in the prehospital environment for the treatment of hemorrhagic shock, regardless of the etiology, patient, age, sex, race or location.

The Coalition appreciates CMS' recognition in the proposed rule that blood products are an effective treatment provided by ground and air-based ambulance services in the pre-hospital setting. However, we are concerned that the proposed rule will not achieve the goals of the Coalition or the Administration and, thus, request three critical modifications before the rule is finalized. **First, we recommend that CMS expand the blood products that may be reimbursed under the ambulance fee schedule (AFS) to include all FDA cleared blood and blood components, in addition to Low Titer O+ Whole Blood (LTO+WB). Second, and as described in detail below, we urge CMS to add reimbursement dollars for blood products beyond the existing funding available today. Third, the reimbursement for these products should be available to both ground and air ambulance providers and suppliers.**

All FDA-approved blood and blood components should be considered reimbursable under the AFS.

Recent research has identified that 60% of current prehospital programs with transfusion programs use LTO+WB. They also transfuse Low Titer O Negative Whole Blood (LTO-WB), red blood cells (RBCs), plasma or platelets. In those situations, other blood components are critical interventions that have shown significantly improved clinical outcomes compared to crystalloid. During times of blood shortages, mass casualty incidents, and disaster response, prehospital agencies should remain flexible by utilizing all approved blood products, as this is paramount to reducing patient mortality.

Members of the Coalition are working to address some of the limitations in blood product availability which currently exist. Many prehospital programs have initiated and conduct regular blood donation drives with their local blood collectors to increase the available supply. There are also local, regional and national initiatives examining blood supply needs for catastrophic national events. Therefore, including all blood and approved blood components can ensure availability and access for patients.

The current AFS reimbursement is inadequate to support adding whole blood and blood products without also adding additional funding to cover the cost of providing such services. Lack of adequate reimbursement is a limiting factor in this proven lifesaving intervention.

CMS proposes to add the transfusion of only LTO+WB as one of the treatment options that would support an ambulance services billing for an ALS2 payment. Its rationale is that “many ground ambulance transports providing WBT already qualify for ALS2 payment”¹ although it recognizes that “not all ground ambulance transports providing WBT may already qualify for ALS2 payment.”² Thus, under the proposed rule, the agency is recognizing that pre-hospital transfusions are supported by high quality clinical evidence and that beneficiaries could experience improved outcomes when transfusions are clinically indicated but has decided not to assess the cost of these services so as to establish an appropriate reimbursement amount. Without sufficient reimbursement provided, beneficiaries may not have real access to this treatment option because the vast majority of ambulance services will not have funding to carry these products. In addition, the inability to utilize other approved FDA blood products, when and if LTO+WB is unavailable due to shortages or regional restrictions, could also have the same negative impact on beneficiaries.

The current AFS reimbursement rates are inadequate to cover the cost of items and services covered under it today. The Government Accountability Office (GAO) has issued two reports to Congress finding that the Medicare rates for ground ambulance services do not cover the cost of providing services and result in negative Medicare margins.³ As a result, Congress established the ground ambulance add-ons, which have been extended for more than a decade. It also established the Ground Ambulance Data Collection System to require CMS to collect cost data to support a reform of the AFS to protect access to ambulance services across America.⁴ The chronic underfunding has led to hundreds of ambulance services closing their doors and communities across America losing access to EMS. In May 2023, the Rural Health Research Gateway released a chart book that analyzed 41 States between 2021 and 2022 to identify places and people that are more than 25 minutes from an ambulance station. It dubbed these locations as “ambulance deserts.”⁵

Our Coalition members estimate that securing a single unit of whole blood is extremely costly, as a recent study demonstrated.

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

¹ Display Copy at 1,166.

² Display Copy at 1,167.

³ GAO. “Costs and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased.” (October 2012).

⁴ The add-on payments were originally implemented under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,²¹ temporarily extended by subsequent acts,²² and most recently extended through the end of 2012 by the Middle-Class Tax Relief and Job Creation Act of 2012.

⁵ Yvonne Jonk, Carly Milkowski, Zachariah Croll, Karen Pearson. “Ambulance Deserts: Geographic Disparities in the Provision of Ambulance Services. (May 2023) available at <https://www.ruralhealthresearch.org/publications/1596> (accessed August 25, 2023).

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.⁶

Additionally, another publication indicated 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.⁷ Yet, the median ALS-2 base rate ranges from ~\$600-850, although this rate varies around the country. Adding an expensive treatment, such as pre-hospital transfusions, to an already unstable reimbursement system will only exacerbate the problem and result in even more communities losing access to EMS services.

The Coalition acknowledges that cost data that we have is still limited and while the above information provides some context, it should not be taken as the exact amount required for all services as costs will vary based on region, volume and other factors.

Many in the trauma and EMS communities are lauding prehospital blood administration as the most significant and life-saving clinical intervention in EMS in decades. As noted in the proposed rule, there are studies illustrating that prehospital blood transfusions have improved patient outcomes in both the military and civilian environments. Previously, these patients would have succumbed to their injury or illness with resulting hemorrhagic shock.

Currently, the Coalition is tracking over 175 EMS ground programs in the country which have established prehospital transfusion programs. However, only 2% of all EMS agencies currently carry blood. The Coalition is in the process of surveying national air medical programs as well. Air Medical programs that carry blood products frequently respond to scene calls and provide prehospital blood to ground EMS agencies currently lacking transfusion capabilities. Air Medical programs serve as an essential piece in the chain of survival.

In summary, establishing and supporting EMS transfusion programs (and ultimately allowing for reimbursement of those programs) further supports the improvement of prehospital patient care, overall chain of survival and improved national health care preparedness and defense.

The undersigned individuals, associations and organizations are extremely pleased that CMS recognizes the clinical importance of prehospital blood transfusions. To increase patient access to these products and improve outcomes in patients suffering hemorrhagic shock, CMS should also (1) include all approved blood products in addition to LTO+WB; (2) provide additional funding to support the addition of these products to the AFS; and (3) include air ambulances in the proposal.

Sincerely,

⁶ Levy, M. J., Garfinkel, E. M., May, R., Cohn, E., Tillett, Z., Wend, C., Sikorksi, R. A., Troncoso, R., Jr, Jenkins, J. L., Chizmar, T. P., & Margolis, A. M. (2024). Implementation of a prehospital whole blood program: Lessons learned. *Journal of the American College of Emergency Physicians open*, 5(2), e13142. <https://doi.org/10.1002/emp2.13142>

⁷ 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>

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America's Blood Center (ABC)

American Ambulance Association (AAA)

American College of Emergency Physicians (ACEP)

American College of Surgeons (ACS)

Association for the Advancement of Blood and Biotherapies (AABB).

Blood Centers of America (BCA)

Colorado Springs Fire Department (CO)

Community Volunteer Fire Department (Houston, TX)

Cullman EMS (AL)

Digitech

Florida Association of Critical Care Transport Specialists (FACTS)

Florida chapter of the NAEMSP

Gulf Coast Regional Blood Center

The International Association of Fire Fighters (IAFF)

KaloCyte, Inc.

LifeMed Alaska

National Association of Emergency Medical Technicians (NAEMT)

Plains to Peaks RETAC (CO)

REVA, Inc

Sarnova, Inc.

Terumo BCT

Texas Chapter - NAEMSP

The American Red Cross (ARC)

Thompson Valley EMS (CO)

Tidewater EMS Council (VA)

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Trauma Hemostasis and Oxygenation Research (THOR) Network

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