September 6, 2024

Centers for Medicare and Medicaid Services

U.S. Department of Health and Human Services

Attention: CMS-1807-P

P.O. Box 8016

Baltimore, MD 21244-8016

[To Whom It May Concern:]

On behalf of the nearly 12,000 members of the International Association of Fire Chiefs (IAFC), I express support for the proposal by the Centers for Medicare and Medicaid (CMS) to modify the definition of ALS2 to account for instances where patients are administered whole blood transfusion therapy (WBT), but do not otherwise qualify for ALS2 payment. The IAFC believes that WBT has shown to be effective in the field for saving patients’ lives and we applaud the decision of CMS to reimburse for these treatments. In addition, we associate ourselves with the comments of the Prehospital Blood Transfusion Initiative Coalition (PHBTIC), which makes additional recommendations for a successful WBT effort.

**The Effectiveness of Whole Blood Therapy**

The use of WBT to treat casualties in the recent wars in Afghanistan and Iraq demonstrated the effectiveness of using transfusions in the field to save the lives of military service members. This experience informed efforts in the United States by fire and emergency medical service (EMS) agencies and regional trauma networks to begin WBT programs. The use of WBT provides first responders with access to 1:1:1 component ratio of red blood cells, plasma volume, and clotting factors that can be used to save patients’ lives. As CMS notes, 147 EMS systems now provide whole blood therapy to their patients with an additional 200 or more systems anticipated to provide some form of blood product transfusion by the end of 2024.

The use of WBT provides benefits for both major metropolitan and rural fire departments. Jurisdictions with large or heavily concentrated populations like Washington D.C. or San Antonio, use WBT programs to save lives when transport through congested city streets to a trauma center can take 40 minutes. Meanwhile, air ambulance operations in Maryland, southern Texas, and southern Minnesota can use WBT to save patients’ lives as they are transported to hospitals by air. It is important to highlight the crucial role that WBT can play in mass casualty incidents, where trauma centers can be overwhelmed with patients and treatment in the field can save multiple victims’ lives.

A 2022 study by Kronstedt, Miller, et al. found that “WBTs have an evolving body of evidence to support their use in traumatic hemorrhagic shock.” It found the use of WBT to be safe and effective and even reduce mortality in prehospital trauma, especially in cases where the transport times are more than 30 minutes. The article highlighted a WBT program in Southwest Texas that found WBT to be especially effective for use in rural areas, where access to a trauma center is longer than 60 minutes by ground transportation. The article highlights that the WBT program reduced patient mortality by 36% for adults and 20% for pediatrics.[[1]](#footnote-1)

**The Need to Consider All FDA-Approved Blood Components as Reimbursable**

The CMS proposes modifying the definition of ALS 2 to add the administration of Low Titer O Positive Whole Blood (LTO+WB) to the list of new ALS2 procedures. The IAFC applauds CMS for taking this first step, but strongly recommends broadening the reimbursement for WBT to include Low Titer O Negative Whole Blood (LTO-WB), red blood cells, plasma, and platelets.

Many departments that have WTB programs use LTO-WB, along with LTO+WB. As blood banks recover their stock after the COVID-19 pandemic, fire and EMS departments must have the capability to use all blood products approved by the U.S. Food and Drug Administration (FDA). This flexibility is especially important in mass casualty incidents and major disasters, where there will be a large number of patients and a great need for WTB treatment in a short amount of time to save lives.

**The Need to Provide Additional Funding to Support WBT Programs**

The IAFC notes that CMS is unable to provide additional payments or add-on payments for the administration of WBT. The IAFC recommends that CMS consider how to assess the cost of WTB services and reimburse for that cost or provide add-on payments to help offset the cost of WTB programs.

It can be expensive for an agency to administer a WTB program. For example, the new WTB program by the Washington, D.C. Fire and EMS department is expected to cost $500,000 in the first year, including $550 per unit of blood.[[2]](#footnote-2) These start-up costs can be prohibitive, especially in rural communities. A rural, volunteer fire or EMS department must rely upon fundraisers, such as Bingo Nights or pancake breakfasts, to raise the needed funds. However, their communities will benefit greatly from a WTB program where a trauma center or major hospital may be an hour or more from the incident scene. By providing a more robust reimbursement for WTB programs, this lifesaving practice can be adopted more effectively by agencies across the United States. These programs may also help address the Post-Crash Care portion of the US Department of Transportation’s National Roadway Safety Strategy by improving the ability to save lives after a motor vehicle crash.

**The Need to Allow Reimbursement for WBT to Both Ground and Air Ambulance Providers and Suppliers**

The IAFC also would like to highlight the need for both ground and air ambulance programs to be reimbursed for the use of WBT. While many fire departments provide EMS and ground-based ambulance transport in their communities, it is important to recognize that some fire departments also operate helicopters for providing emergency medical transport. In addition, fire departments on islands or remote locations rely upon state or regional air ambulance operations to transport trauma patients to hospitals. We have an interest in ensuring the survivability of a patient regardless of how they are transported to the hospital. As such, we support the reimbursement of WTB administration by ground and air ambulance operations.

The IAFC thanks CMS for their proposal to modify the definition of ALS2 to reimburse for WTB administration. We think that this proposal will broaden the use of this effective treatment across America. However, the IAFC also would like to recommend that CMS reimburse for the use of all FDA-approved blood components; provide additional funding to support WBT programs; and reimburse both ground and air ambulance programs for WBT programs. By encouraging greater adoption of WBT administration, CMS can help ensure the survivability of patients facing lifesaving crises.

Sincerely,

[Fire Chief Josh Waldo

President

International Association of Fire Chiefs]

1. Kronstedt S, Lee J, Millner D, Mattivi C, LaFrankie H, Paladino L, Siegler J. The Role of Whole Blood Transfusions in Civilian Trauma: A Review of Literature in Military and Civilian Trauma. Cureus. 2022 Apr 18;14(4):e24263. doi: 10.7759/cureus.24263. PMID: 35481238; PMCID: PMC9033529. [↑](#footnote-ref-1)
2. Portnoy, Jenna. D.C. paramedics will start giving blood to trauma patients at the scene. The Washington Post. January 25, 2024. [↑](#footnote-ref-2)