

Elisabeth Daniel, (667) 290-8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Genevieve Kehoe, Ambulatoryspecialtycare@cms.hhs.gov, or 1-844-711-2664 (Option 4) for issues related to the Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care.

Kimberly Long, (410) 786-5702, for issues related to expanding colorectal cancer screening.

Rachel Katonak, (410) 786-8564, for issues related to expanding Hepatitis B vaccine coverage.

Mei Zhang, (410) 786-7837, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA-PD plan (section 2003 of the SUPPORT Act).

Katie Parker, (410) 786-0537, for issues related to Parts A and B overpayment provisions of the Affordable Care Act.

Alissa Stoneking, (410)786-1120, for issues related to Parts C and D overpayment provisions of the Affordable Care Act.

Amy Gruber, (410) 786-1542, for issues related to low titer O+ whole blood transfusion therapy during ground ambulance transport.

Renee O’Neill, (410) 786-8821, for inquiries related to Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program.

Danielle Drayer, (516) 965-6630, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

- Provisions on Medicare Parts A and B Payment for Dental Services Inextricably

Linked to Other Covered Services (section II.J.)

- Payment for Skin Substitutes (section II.K.)
- Strategies for Improving Global Surgery Payment Accuracy (section II.L.)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

(section III.B.)

● Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Conditions for Certification and Conditions for Coverage (CfCs) (section III.C.)

● Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (section III.D.)

- Medicare Diabetes Prevention Program (MDPP) (section III.E.)

● Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)

- Medicare Shared Savings Program (section III.G.)

● Medicare Part B Payment for Preventive Services (§§ 410.10, 410.57, 410.64, 410.152) (section III.H.)

- Medicare Prescription Drug Inflation Rebate Program (section III.I.)

● Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care (section III.J.)

- Modifications to Coverage of Colorectal Cancer Screening (section III.K.)

● Requirements for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section III.L.)

- Expand Hepatitis B Vaccine Coverage (section III.M.)

● Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport (section III.N.)

N. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

1. Ambulance Fee Schedule Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Our regulations relating to coverage for ambulance services are set forth at 42 CFR part 410, subpart B. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414, subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments in § 414.610(c)(5)(i) and three temporary add-on payments in § 414.610(c)(1)(ii) and (c)(5)(ii) to the base rate and/or mileage rate.

2. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

Under the AFS, Medicare Part B covers seven levels of service for ground (including water) ambulance transports and two levels of service for air ambulance transports. The levels of service for ground ambulance transports include basic life support (emergency); basic life support (non-emergency); advanced life support, level 1 (ALS1) (emergency); ALS1 (non-emergency); advanced life support, level 2 (ALS2); paramedic intercept; and specialty care transport (§410.40(c)). Definitions for the levels of service can be found at § 414.605 and in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services.

At § 414.605, ALS2 is defined as either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures: (1) Manual defibrillation/cardioversion; (2) Endotracheal intubation; (3) Central venous line; (4) Cardiac pacing; (5) Chest decompression; (6) Surgical airway; (7) Intraosseous line. These procedures must be performed by ALS personnel trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic (§ 414.605).

According to the 2020 National Association of State Emergency Medical Services Organizations Assessment (NASEMSO), there are approximately 11,450 ground EMS agencies that provide 9-1-1 response with transport to an acute care hospital.⁷⁶³ The administration of low titer O+ whole blood transfusions, otherwise referred to as whole blood transfusion therapy (WBT), began in 2017 when two Emergency Medical Services (EMS) systems in Texas began providing WBT to patients in hemorrhagic shock during ambulance transports. Prior to this, use of blood products in the treatment of hemorrhagic shock in the form of blood component therapy was available only in the hospital setting and by one EMS system. Low titer O+ whole blood contains low levels of antibodies that patients of any blood type can receive, and is provided in EMS settings to significantly increase these patients' chances of survival.

By September 2023, more than 121 EMS systems in the United States were using blood products in the form of either WBT, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma.⁷⁶⁴ Seventy percent of these systems were using WBT.⁷⁶⁵ As of March 2024, 147 EMS systems (1.2 percent of the EMS systems in the United States) carry whole blood

⁷⁶³ National Association of State EMS Officials. 2020 National Emergency Medical Services Assessment 2020. Table 3, p 27. Available from: [www./https://nasemso.org/](https://nasemso.org/). Accessed May 1, 2024.

⁷⁶⁴ Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

⁷⁶⁵ Levy MJ, Garfinkel EM, May R, et al. Implementation of a prehospital whole blood program: Lessons. *J Am Coll Emerg Physicians Open.* 2024;5: e13142. <https://doi.org/10.1002/emp2.13142>.

products, with 200 or more systems anticipated to provide some form of blood product transfusion by the end of 2024.⁷⁶⁶ Today, nearly 60 percent of those 147 EMS systems carry low titer O+ whole blood, with the remainder utilizing other blood products.⁷⁶⁷

EMS systems that administer WBT and other blood products (PRBCs and plasma) generally utilize it for patients suffering hemorrhagic shock stemming from traumatic injury, though it may also be indicated in certain non-traumatic medical conditions such as hemorrhagic shock from a gastrointestinal bleed.⁷⁶⁸ Traditional EMS resuscitation protocol for massive hemorrhage from trauma and other medical conditions such as gastrointestinal bleeding consists of crystalloid fluids and blood component transfusions, which consist of a balanced portion of PRBCs, platelets, and fresh frozen plasma.⁷⁶⁹

During the conflicts in Iraq and Afghanistan, use of this traditional protocol was difficult due to the austere combat environment and limited availability of blood components, which often necessitated the use of fresh whole blood (FWB) in traumatic resuscitation.⁷⁷⁰ Data collected related to these conflicts demonstrated improvements in survival rate and reductions in transfusion requirements for military casualties in hemorrhagic shock who received FWB versus those receiving traditional blood component transfusion, and spurred research and interest in the use of WBT in civilian trauma.⁷⁷¹ Additional data demonstrating an improvement in 24-hour and

⁷⁶⁶ Levy MJ, Garfinkel EM, May ER, et al. Implementation of a prehospital whole blood program: Lessons learned. *J Am Coll Emerg Physicians Open*. 2024;5: Apr; 5(2): e13142. <https://doi.org/10.1002/emp2.13142>. Krohmer J, Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

⁷⁶⁷ Ibid.

⁷⁶⁸ Ibid.

⁷⁶⁹ Young PP, Cotton BA, Goodnough LT. Massive Transfusion Protocols for Patients with Substantial Hemorrhage. *Transfusion Medicine Reviews*. 2011, Vol 25(4). 293-303. Washington State Department of Health Office of Community Health Systems Emergency Medical Services and Trauma Section. Trauma Clinical Guideline: Massive Transfusion for Trauma.

⁷⁷⁰ Nessen SC, Eastridge BJ, Cronk D, et al. Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. *Transfusion*. 2013;53: 107S-13S.

⁷⁷¹ Spinella PC, Perkins GJ, Grathwohl KW, Beekley AC, Holcomb J. Warm Fresh Whole Blood is Independently Associated with Improved Survival for Patients with Combat-Related Traumatic Injuries. *J Trauma*. 2009 April; 66(4 Suppl): S69-S76. [doi:10.1097/TA.0b013e31819d85fb](https://doi.org/10.1097/TA.0b013e31819d85fb). Nessen SC, Eastridge BJ, Cronk D, et al. Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. *Transfusion*. 2013;53: 107S-13S. Gurney J, Staudt A, Cap A, Shackelford A, et al. Improved Survival in Critically Injured Combat Casualties Treated with Fresh Whole Blood by Forward Surgical Teams in Afghanistan. *Transfusion*. 2020;60: S180-S188.

30-day survival rate among medically evacuated combat casualties in Afghanistan who received prehospital transfusion encouraged research and interest in these techniques for possible deployment by EMS services.⁷⁷²

In the treatment of civilian patients with hemorrhagic shock from trauma, studies have demonstrated that WBT provides a substantial survival benefit versus traditional component therapy,⁷⁷³ especially when provided early in the prehospital and hospital settings.⁷⁷⁴ One study found WBT increased the survival of such patients by as much 60 percent and reduced the need for additional blood products in the 24-hour period following the initial transfusion by 7 percent.⁷⁷⁵ Another study noted that there was a significant increase in the 24-hour and 30-day survival rate in patients suffering from severe hemorrhage requiring a large transfusion volume.⁷⁷⁶

Patients suffering from hemorrhagic shock require stabilization in the field and rapid transport to an acute care hospital to treat the source of hemorrhage.⁷⁷⁷ Individuals who are experiencing hemorrhagic shock primarily due to blood loss may require WBT as their only resuscitative treatment. Each unit of whole blood takes 5-8 minutes to transfuse.⁷⁷⁸ Depending

⁷⁷² Shackelford SA, del Junco DJ, Powell-Dunford N, Mazuchowski EL, et al. Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan with Acute and 30-Day Survival. *JAMA*. 2017; 318(16):1581-1591.

⁷⁷³ Hazelton JP, Ssentongo AE, Oh JS, et al. Use of Cold-Stored Whole Blood is Associated with Improved Mortality in Hemostatic Resuscitation of Major Bleeding. A Multicenter Study. 2022. *Annals of Surgery*. Vol 276(4). 579-88.

⁷⁷⁴ b. Torres CM, Kent A, Scantling D, et al. Association of Whole Blood With Survival Among Patients Presenting With Severe Hemorrhage in US and Canadian Adult Civilian Trauma Centers. *JAMA Surg*. 2023;158(5):532-540. doi: 10.1001/jamasurg.2022.6978.

Brill JB, Tang B, Hatton G, Mueck KM, et al. Impact of incorporating whole blood into hemorrhagic shock resuscitation: Analysis of 1,377 consecutive trauma patients receiving emergency-release uncrossmatched blood products. *J Am Coll Surg*. 2022;234(4):408-418.

Guyette FX, Sperry JL, Peitzman AB, et al. Prehospital blood product and crystalloid resuscitation in the severely injured patient: a secondary analysis of the prehospital air medical plasma trial. *Ann Surg*. 2021;273:358-364.

⁷⁷⁵ Ibid.

⁷⁷⁶ Ibid.

⁷⁷⁷ Centers for Disease Control and Prevention. Guidelines for field triage of injured patients. *MMWR*. 2009;58 (RR-1):1-34.

⁷⁷⁸ Vitberg D. Assistant Medical Director. District of Columbia Fire and EMS Department. Zoom meeting. February 20, 2024. Bank EA. Assistant Chief of EMS. Co-Chair of the South East Regional Advisory Council Trauma Committee. Phone conversation, May 10, 2024.

on the time needed to transport and clinical need, patients generally receive 1-2 units of WBT during ground transport.⁷⁷⁹

While there may be variance between jurisdictions, the protocols for many EMS systems currently providing WBT are designed for patients who require complex management at the advanced life support level, demonstrating suspicion of blood loss along with evidence of physiologic shock as indicated by parameters such as low blood pressure, an elevated pulse rate, or slow capillary refill.⁷⁸⁰ Other relevant factors may include an elevated lactate level, an End-tidal carbon dioxide (EtCO₂) waveform capnography reading < 25 as surrogate for elevated lactate, a shock index (heart rate/systolic blood pressure) >1, and, where appropriate and consistent with protocol, authorization by online or other medical authority.⁷⁸¹

We believe that many ground ambulance transports providing WBT already qualify for ALS2 payment, since patients requiring such transfusions are generally critically injured or ill and often suffering from cardio-respiratory failure and/or shock, and therefore are likely to receive one or more procedures currently listed as ALS procedures in the definition of ALS2, with endotracheal intubation, chest decompression, and/or placement of a central venous line or an intraosseous line the most probable to be seen in these circumstances. Patients requiring WBT are typically suffering from hemorrhagic shock, for which the usual course of treatment includes airway stabilization, control of the hemorrhagic source, and stabilization of blood pressure using crystalloid infusion and the provision of WBT or other blood product treatments when available, but not necessarily the administration of advanced cardiac life support medications.⁷⁸² Consequently, we do not believe it is likely that most patients who may require

⁷⁷⁹ Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

⁷⁸⁰ Mark H. Yazer, Philip C. Spinella, Eric A. Bank, Jeremy W. Cannon, Nancy M. Dunbar, John B. Holcomb, Bryon P. Jackson, Donald Jenkins, Michael Levy, Paul E. Pepe, Jason L. Sperry, James R. Stubbs & Christopher J. Winckler (2022) THOR-AABB Working Party Recommendations for a Prehospital Blood Product Transfusion Program, *Prehospital Emergency Care*, 26:6, 863-875.

Ibid., <https://miemss.org/home/Clinicians/Whole-Blood>.

⁷⁸¹ *Ibid.*

⁷⁸² Prehospital Hemorrhage Control and Treatment by Clinicians: A Joint Position Statement. *Ann Emerg Med*. 2023;82:e1-e8.

WBT would trigger the other pathway to qualify as ALS2, that is, the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate).

However, not all ground ambulance transports providing WBT may currently qualify for ALS2 payment. An ambulance transport would not qualify for ALS2 payment where a patient received only WBT during a ground ambulance transport, and not one or more other services that, either by themselves or in combination, presently qualify as ALS2. We believe WBT should independently qualify as an ALS2 procedure because the administration of WBT and handling of low titer O+ whole blood requires a complex level of care beyond ALS1 for which EMS providers and suppliers at the EMT-Intermediate or paramedic level require additional training. In addition, WBT requires specialized equipment such as a blood warmer and rapid infuser.⁷⁸³ While there is no established national training protocol, many systems follow the guidelines of the Association for the Advancement of Blood and Biotherapies (AABB), which require additional training that is 4 hours in length for paramedics and 6 hours in length for EMS supervisory staff.⁷⁸⁴ Medicare's requirements for ambulance staffing at § 410.41(b) include compliance with state and local laws; those laws would establish appropriate training requirements with respect to WBT administration.

Therefore, we believe it is appropriate to modify the definition of ALS2 to account for the instances where patients are administered WBT but do not otherwise qualify for ALS2 payment. Of note, we do not have the authority to provide an additional payment, such as an add-on payment for the administration of WBT under the AFS.

⁷⁸³ Pokorny DM, Braverman MA, Edmundson PM, et al. The use of prehospital blood products in the resuscitation of trauma patients; a review of prehospital transfusion practices and a description of our regional whole blood program in San Antonio, TX. ISBT science series, 2018-08, Vol, 14(3), p 332-42.

Floccare D. Air Medical Director, State of Maryland. E-mail communication. May 14, 2024

Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

⁷⁸⁴ Bank EA. Assistant Chief of EMS. Co-Chair of the South East Regional Advisory Council Trauma Committee. E-mail correspondence and phone conversation, May 10, 2024.

We proposed in the CY 2025 PFS proposed rule (89 FR 62002 through 62004) to modify the definition of ALS2 at § 414.605 by adding the administration of low titer O+ whole blood transfusion to the current list of seven ALS2 procedures as a new number 8. We would also reflect this change in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services. Under this proposal, a ground ambulance transport that provides WBT would itself constitute an ALS2-level transport.

We are aware that some established EMS systems may already provide WBT to treat patients in hemorrhagic shock, while other jurisdictions, particularly including those in rural areas, often will rely on alternative blood product treatments such as PRBCs and plasma. The availability of WBT in rural areas is a complex and multifactorial issue. Fluctuating stock of the “raw product” (blood donations) along with local healthcare demands for blood products (PRBCs, platelets, plasma, etc.) affect the availability of WBT. Other issues in rural areas include the logistical challenges and the costs involved in acquiring fresh units of WBT and returning any unused units to a supplier.⁷⁸⁵

The training, administration, and monitoring is the same for these alternative blood product treatments as it is for WBT. While we did not include alternative blood product treatments in our proposal, we solicited comment on whether we should add them to the list of ALS2 procedures. We invited comments on this proposal to add the administration of low titer O+ whole blood transfusion as an ALS2 procedure and on whether we should add alternative blood product treatments such as the administration of PRBCs or plasma.

We received public comments on our proposal and solicitation of comments. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that whole blood is not the current standard of care in

⁷⁸⁵ Apelseth TO, Strandenes G, Kristofferson K, Hagen KG. How do I implement a whole blood-based blood preparedness program in a small rural hospital? *Transfusion*. 2020. Vol 60(12) 2793-2800. Schaefer RM, Bank E, Krohmer JR., Haskell A, et al. Removing the Barriers to Prehospital Blood: A Roadmap to Success. *Journal of Trauma and Acute Care Surgery*. 2024. 97(2S): S138-S144. doi: 10.1097/TA.0000000000004378.

pre-hospital transfusions, is very expensive, and is more difficult to source than individual blood components.

Response: As previously discussed, many ground ambulance transports providing WBT already qualify for ALS2 payment. WBT is a therapy that is currently being used and is considered to be medically appropriate in certain circumstances by the medical community. Our proposal aimed to ensure that payments for ground ambulance transports better reflect the complexity of the services provided. We are aware that WBT can be difficult to source, and access can be based on factors such as: donor availability, local manufacturing capabilities, demand and usage. We are also aware that geographic locale may be a factor as well.

Comment: Some commenters supported our proposal to add low titer O+ whole blood transfusion to the list of ALS2 procedures. Some commenters stated that the administration of low titer O-whole blood transfusion should also be added to the list of ALS2 procedures.

Response: We appreciate the commenters' support for our proposal and for bringing our attention that the administration of O- whole blood transfusions, like the administration of O+ whole blood transfusions, should independently qualify as an ALS2 procedure. Low-titer O- blood has the same hemostatic composition and resuscitative benefits as low titer O+ blood but can only be obtained from 3 percent of blood donations because of the rarity of this blood type. Because of its rarity, hospitals and blood banks tend to hold this product in reserve for use in certain patient populations (pediatric, women of childbearing age, sickle cell patients) or clinical conditions such as obstetric hemorrhage.⁷⁸⁶

For that reason—its rarity and general unavailability to ground ambulance providers and suppliers—we had refrained from adding low titer O-whole blood transfusion to our original proposal. After further discussion with EMS officials, we were made aware that some agencies may occasionally receive and use a unit of low titer O-whole blood as part of their transfusion

⁷⁸⁶ Transfusion. 2021 Jun;61(6):1966-1971. doi: 10.1111/trf.16380. Epub 2021 Mar 29. PMID: 33780020; PMCID: PMC8251973.

program. Transfusion of low titer O- whole blood requires the same handling and level of training as low titer O+ whole blood. We are therefore adding low titer O-whole blood transfusion to the list of ALS2 procedures at § 414.605.

Comment: Several commenters provided feedback on whether we should add alternative blood product treatments in addition to low titer O+ WBT to the list of ALS2 procedures.

Several commenters stated that, given the complexity involved in administering alternative blood products and their expense, the administration of all FDA-approved blood and blood components products (whole blood, plasma, PRBCs, platelets, and clotting fractions such as cryoprecipitate) should be included in the list of ALS2 procedures.

A commenter stated that HHS' 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+ and O- whole blood transfusion, component blood therapy transfusion, and fluid resuscitation. The commenter stated that 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.

In addition to the ongoing studies and systematic review, the commenter stated that 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. The commenter stated that 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.

Response: We appreciate the commenter bringing to our attention the ongoing studies and systematic reviews. CMS looks forward to the results of the study, but we note that current research, guidelines, and EMS protocols indicate that the administration of these services is sufficiently complex that, upon our review, they each should independently qualify as an ALS2 procedure. Many ground ambulance transports already provide blood and blood product transfusions. Based on our review and feedback received from interested parties, we are not aware of any evidence indicating issues with safety or efficacy that may lead CMS to consider not paying for these services furnished as part of a ground ambulance transport.

Upon further review and feedback from interested parties, we have determined that all prehospital blood transfusions (PHBTs), which refer to the administration of low titer O+ and O- WBT, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma, should independently qualify as an ALS2 procedure; the administration of low titer O+ whole blood transfusion should not be the only PHBT that independently qualifies as an ALS2 procedure, as we had proposed in the CY 2025 PFS proposed rule (89 FR 62004). The administration, handling, training, specialized equipment, and medical criteria of low titer O- whole blood, PRBCs, and plasma are the same as previously described with respect to low titer O+ whole blood; they require a complex level of care beyond ALS1 for which EMS providers and suppliers at the EMT-Intermediate or paramedic level require additional training.

Use of PHBT is currently considered to be the best practice recommendation by the Trauma, Hemostasis and Oxygenation Research Network and the American Association of Blood Banks Working Party.⁷⁸⁷ An early study found that using PRBCs during transport improved the prehospital mortality rate for patients in hemorrhagic shock.⁷⁸⁸ A recent study of penetrating injuries in an urban setting found an in-hospital mortality benefit of 22 percent if a

⁷⁸⁷ Weykamp MB, Stern KE Brakenridge SC, Robinson BRH, et al. Pre-Hospital Crystalloid Resuscitation: Practice Variation & Associations with Clinical Outcomes. *Shock*. 2023. January; 59(1): 28-33.

Ibid.

⁷⁸⁸ Rehn M, Weaver A, Brohl K, Eshelb S. Effect of Prehospital Red Blood Cell Transfusion on Mortality and Time of Death in Civilian Trauma Patients. *Shock*. 2019; Vol. 51, No. 3: 284-288.

PHBT was performed within 15 minutes of the initial patient-EMS encounter.⁷⁸⁹ The study also found that the mortality rate increased by 11% for every minute a blood transfusion was delayed after that initial 15 minute period.⁷⁹⁰ Another recent study in which the use of two units of PRBCs were central to its initial resuscitation of massively hemorrhaging patients found that this PHBT reduced both prehospital and overall mortality.⁷⁹¹

The American College of Surgeons Committee on Trauma, the American College of Emergency Physicians, the National Association of EMS Physicians and the U.S. Military's Tactical Combat Casualty Care (TCCC) guidelines recommend WBT as the first line of resuscitative therapy for trauma patients in hemorrhagic shock, followed by PRBCs, and plasma in lieu of crystalloids. To clarify our earlier TCCC statement, traditional resuscitation protocols for massive hemorrhage from trauma and other medical conditions such as gastrointestinal bleeding consisted of crystalloids alone in the field and followed in the hospital with blood component transfusions, which consists of a balanced portion of PRBCs, platelets and fresh frozen plasma. Studies cited previously and noted below have demonstrated a mortality benefit in the use of these products for patients in hemorrhagic over traditional crystalloid therapy especially when provided earlier in the resuscitative process. One early study evaluated patients receiving four different prehospital resuscitation methods: crystalloid only; PRBCs; plasma; and PRBCs and plasma.⁷⁹² Data showed that any blood product resuscitation was associated with a lower mortality than crystalloid alone. PRBCs and plasma have similar reductions in mortality; however, PRBCs and plasma had a much greater reduction in mortality than either PRBCs or plasma alone. When used alone, crystalloid fluids in this study demonstrated the greatest

⁷⁸⁹Duchesne J, McLafferty BJ, Broome JM, Caputao S, et al. Every minute matters: Improving outcomes for penetrating trauma through prehospital advanced resuscitative care. *J Trauma Acute Care Surg.* 2024 May 1 doi: 10.1097/TA.0000000000004363. Online ahead of print.

⁷⁹⁰ Ibid.

⁷⁹¹ Ritondale J, Piehl M, Caputo S, Broome J, et al. Impact of Prehospital Airway-Breathing-Circulation Resuscitation Sequence on Patients with Severe Hemorrhage. *J Am Coll Surg.* 2024, Vol. 238(4). 367-72

⁷⁹² Guyette FX, Sperry JL, Peitzman AB, Billiar TR, et al. Prehospital Blood Product and Crystalloid Resuscitation in the Severely Injured Patient. A Secondary Analysis of the Prehospital Air Medical Plasma Trial. *Ann Surg.* 2021;273:358-364.

mortality.⁷⁹³

Other blood products such as platelets and cryoprecipitate are used as part of the resuscitative process after the patient arrives in the hospital. At this time there is little data of their use in the field by EMS providers for patients in hemorrhagic shock. Furthermore, at this time, the use of these products in the field is limited by factors such as their expiration dates and storage requirements. Platelets have a 5 day expiration date and require continuous agitation while in storage at room temperature. Cryoprecipitate requires storage at negative 18 degrees Celsius and thawing before delivery.

Comment: Several commenters stated that the WBT proposal will not have any positive effect on actual reimbursement of the cost associated with keeping and administering blood products because patients sick enough for blood administration already meet the ALS2 criteria. Several commenters stated that the current rate for ALS2 is far too low to accommodate the cost of providing pre-hospital blood transfusions. One commenter stated that they do not support including whole blood or blood products within the AFS unless there are appropriate increases in payment.

Some of these commenters recommended that CMS create a new level of service, ALS3. One commenter recommended a new ALS3 level for critical care that would include, but would not be limited to, the following procedures: blood transfusions, ventilator administration, rapid sequence intubation, chest tube placement, surgical airway placement, heparinization of patients suffering from an acute myocardial infarction, and placement of umbilical vein catheters in newborns. Other commenters suggested a new level of service for prehospital blood programs.

Several commenters recommended additional funding to fully support adding the administration of low titer O+ WBT as an ALS2 procedure. One commenter recommended a CMMI payment and service delivery model that would incorporate pre-hospital blood transfusions into EMS, where the model should include a pre-hospital blood product add-on

⁷⁹³ Ibid.

payment that incorporates the costs associated with procuring, storing, and administering blood transfusions. The commenter offered that model activities may include, but should not be 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.

Response: We noted in the CY 2025 PFS proposed rule (89 FR 62004) that we do not have the authority to provide an additional payment, such as an add-on payment for the administration of WBT under the AFS. We may consider the other commenter suggestions for future rulemaking.

Comment: One commenter was concerned about budget neutrality with this proposal, expressing concern that it ought not potentially reduce reimbursement for other appropriate ambulance services.

Response: AFS payment for the other levels of ground ambulance services will not be reduced by virtue of the policies we finalize here.

Comment: Several commenters recommended that payment for WBT and alternative blood product treatments should also be included in air ambulance transport payment.

Response: We appreciate the commenters' input, but comments relating to air ambulance transport are out of scope for this rule.

Comment: One commenter requested clarification that the administration of WBT also meets the requirements for specialty care transport (SCT) if all other requirements are met. The commenter noted that the phrase "critically injured or ill" appears in the definition of SCT and in the rationale for including the administration of low titer O+ WBT as an ALS2 procedure.

Response: At § 414.605, SCT means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health

professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training. We define interfacility transport in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, Chapter 30.1.1, Definition of Ground Ambulance Services, as: for purposes of SCT payment, an interfacility transportation is one in which the origin and destination are one of the following: a hospital or skilled nursing facility that participates in the Medicare program or a hospital-based facility that meets Medicare's requirements for provider-based status.

An interfacility transport of a critically injured or ill beneficiary by a ground ambulance vehicle does not meet the definition of SCT if the only service provided to the patient during the transport is the administration of low titer O+ whole blood transfusion. The administration of low titer O+ whole blood transfusion requires an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. It does not require a level of service beyond the scope of the EMT-Paramedic, as required under § 414.605 although CMS notes that requirements may vary by state. We also note that it may be possible, during a transport that otherwise meets the definition of SCT, that the administration of low titer O+ whole blood transfusion may be provided as a medically necessary service, and that the service would therefore be payable as part of a SCT.

Comment: A commenter requested clarification as to whether the medical monitoring of WBT qualifies for ALS2 as it does for endotracheal intubation. The commenter stated that in certain situations, primarily interfacility transports, another healthcare provider may initiate WBT, which an ALS provider or supplier will monitor and maintain during transport. The commenter believes that the transport should qualify as an ALS2 based on the monitoring and maintenance of WBT.

Response: In the Medicare Benefit Policy Manual, Chapter 10, Section 30.1.1, under Application for ALS 2, we state: Endotracheal (ET) intubation (which includes intubating and/or monitoring/maintaining an ET tube inserted prior to transport) is a service that qualifies for the

ALS2 level of payment. Medical monitoring of WBT by an EMT-Intermediate or paramedic with additional training to administer WBT during a ground ambulance transport would qualify for ALS2 payment.

After consideration of public comments and upon further review, we are modifying our proposed policy to add the administration of low titer O+ whole blood to the list of procedures that independently qualify as an ALS2 procedure and finalizing a policy to change the definition of ALS2 at §414.605 by including all PHBTs in the list of procedures that independently qualify as an ALS2 procedure. Specifically, we are modifying the definition of ALS2 at §414.605 so that the list of ALS2 procedures now includes, as a new number 8, prehospital blood transfusion, which includes the administration of low titer O+ and O- whole blood; the administration of packed red blood cells; the administration of plasma; or the administration of a combination of packed red blood cells and plasma.

hepatitis B vaccines paid under Medicare Part B. For these reasons, we do not anticipate that expanding the definition of intermediate risk for hepatitis B vaccine will result in a significant financial impact to the Medicare Program. We did not receive any public comments on our impact analysis.

17. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

As outlined in section III.N of this final rule, we are finalizing our proposal to modify the definition of ALS2 at § 414.605 by adding the administration of low titer O+ whole blood transfusion. In addition, we are also modifying the definition of ALS2 at § 414.605 by adding the administration of low titer O- whole blood transfusion therapy, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma, collectively termed prehospital blood transfusion (PHBT) as a new number 8.

We would also reflect this change in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services. Under this proposal, a ground ambulance transport that provides one of the PHBT will itself constitute an ALS2-level transport.

We believe that many ground ambulance transports providing PHBT already qualify for ALS2 payment, given that patients requiring such transfusions are generally critically injured or ill and often suffering from cardio-respiratory failure and/or shock and are therefore likely to receive one or more procedures currently listed as ALS procedures in the definition of ALS2, such as endotracheal intubation, central venous line, chest decompression, and placement of an intraosseous line. For impact analysis, for ground ambulance transports that provide PHBT only and currently do not qualify for ALS2 payment, we assume that these transports are reported as ALS1 (advanced life support, level 1) emergencies.

In order to help identify the number of ground ambulance transports that could potentially be affected by this proposal, we analyzed inpatient hospital claims related to multiple-trauma that started with an ALS1 emergency ambulance transport and also included a blood

transfusion done in the hospital. The inpatient admissions were identified by DRG code “813” and diagnosis code of “24,” the ambulance transport is identified by HCPCS “A0427,” and the blood transfusion administered to these patients in the hospital setting is identified by the presence of covered charges, patient liability amounts, and replacement units for blood.

Since payments vary for urban, rural, and super-rural ground ambulance transports, we calculated the average Medicare payment amount for ALS2 (HCPCS A0433) and ALS1 (HCPCS A0427) over the last several years. The average payment differential over calendar years 2019 and 2023 is estimated to be roughly \$162 per transport. It is difficult to make an assumption for the number of transports that will be impacted by this proposal, but the potential number over the last several years, based on an analysis of actual experience, is very few. Even if all of these ALS1 emergency transports shifted to being ALS2 transports, which is very unlikely, the impact would be negligible.

We did not receive any public comment on our impact analysis and therefore, we are finalizing our proposal to modify the definition of ALS2 at § 414.605 by adding the administration of low titer O+ whole blood transfusion. In addition, we are also modifying the definition of ALS2 at § 414.605 by adding the administration of low titer O- whole blood transfusion therapy, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma, collectively termed prehospital blood transfusion (PHBT) as a new number 8.

18. Updates to the Quality Payment Program

In this section of this final rule, we estimated the overall and incremental impacts of the Quality Payment Program policies. We estimated participation, final scores, and payment adjustment for eligible clinicians participating through traditional MIPS, MVPs, and the Advanced APMs. We also presented the incremental impacts to the number of expected Qualified Participants (QPs) and associated APM Incentive Payments that result from our policies relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

29. In § 414.605 amend the definition of “Advanced life support, level 2 (ALS2)” by adding paragraph (8) to read as follows:

§ 414.605 Definitions.

* * * * *

Advanced life support, level 2 (ALS2) * * *

(8) Prehospital blood transfusion which includes:

(i) Administration of low titer O+ and O- whole blood (WBT);

(ii) Administration of packed red blood cells (PRBCs);

(iii) Administration of plasma; or

(iv) Administration of a combination of PRBCs and plasma.

* * * * *

30. Section 414.902 is amended by revising the definition “Refundable single-dose container or single-use package drug” to read as follows:

§ 414.902 Definitions.

* * * * *

Refundable single-dose container or single-use package drug means:

(1) A single source drug or biological or a biosimilar biological product for which payment is made under this part and that is —

(i) Furnished from a single-dose container or single-use package based on FDA-approved labeling or product information; or

(ii) Furnished from an ampule for which product labeling does not have discard statement or language indicating if the container is single-dose container, single-use package, multiple-dose container, or single-patient-use container; or

(iii) Furnished from a container with a total labeled volume of 2 mL or less for which product labeling does not have language indicating if the container is single-dose container, single-use package, multiple-dose container, or single-patient-use container.