

PAHPA RFI JOINT BLOOD INDUSTRY DRAFT RESPONSES

*As the bipartisan leaders in the House of Representatives for PAHPA's reauthorization, we seek information from stakeholders in the public and private sectors on **how best to reauthorize and revise the following programs and initiatives contained in the past iterations of PAHPA** (listed in order of PL116-22). **Responses are due March 13, 2023.***

*In case you didn't click through to the google form – here are the detailed areas of feedback they are seeking request on: **Suggestions on how to reauthorize and revise existing PAHPA programs: Please provide suggestions for the programs listed below. If you do not have a suggestion for a specific program, please leave the form blank.***

1. National Health Security Strategy (NHSS)

1. The Association for the Advancement of Blood & Biotherapies (AABB), America's Blood Centers (ABC) and American Red Cross (ARC) encourage Congress to specify that the National Health Security Strategy consider strategies to ensure the safety and resilience of the blood supply. During disasters and emergencies, it is the blood on the shelf that saves lives. Thus, Congress should ensure that the National Health Security Strategy provides resources and support for: (1) a regular blood donor population to ensure the continuous availability of a stable blood supply, (2) ensuring the diversity of the blood donor population, (3) a sufficient laboratory workforce, which is needed to collect, process, distribute and transfuse blood, and (3) integration of considerations of the blood supply and the related supply chain into preparedness and response policies and practices. There are significant challenges with each of these priority areas that should be considered as part of the National Health Security Strategy.

2. Public Health Emergency Preparedness (PHEP) cooperative-agreement program

1. The PHEP cooperative-agreement program should include considerations related to ensuring the safety and adequacy of the blood supply, such as including but not limited to supporting manufacturing capacity for blood and blood components, supply chain redundancy and resilience, and the development of a timely regulatory pathway that enables access to products and technologies that are not currently available but that could be sourced during emergencies.

3. Hospital Preparedness Program (HPP)

- As part of the Hospital Preparedness Program, AABB, ABC and ARC request that Congress provide the Department of Health and Human Services with the explicit authority to fund activities that support access to pre-hospital blood transfusions. Despite evidence indicating that providing pre-hospital blood transfusions to patients significantly improves patients' outcomes and long-term survival,^{1,2,3} access to this service is quite limited. Traumatic injury resulting from hemorrhage is a leading cause of preventable death in trauma care, and delays in

¹ Butler FK, Holcomb JB, Schreiber MA, et al. Fluid Resuscitation for Hemorrhagic Shock in Tactical Combat Casualty Care: TCCC Guidelines Change 14-01-2 June 2014. J Spec Oper Med. 2014 Fall;14(3):13-38.

² Sperry JL, Guyette FX, Brown JB, et al. Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock. N Engl J Med. 2018 Jul 26;379(4):315-326.

³ Shackelford SA, del Junco DJ, Powell-Dunford N, 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.

PAHPA RFI JOINT BLOOD INDUSTRY DRAFT RESPONSES

providing blood products increases the risk of mortality in patients with severe traumatic bleeding.⁴ Unfortunately, only 0.6% of prehospital patients in the United States who could benefit from blood products are currently transfused.⁵ The use of pre-hospital blood products is widespread within the Department of Defense trauma system and civilian pilot projects have shown that pre-hospital transfusion programs can be successfully implemented. Early civilian EMS pilot projects have demonstrated success deploying pre-hospital blood products in both traumatic and other causes of hemorrhagic shock.

4. Regional Health Care Emergency Preparedness and Response Systems (RHCEPRS) Program (A tiered system that builds upon and unifies existing assets within states and across regions to support a more coherent, comprehensive, and capable health care disaster response system able to respond to health security threats.)

Your answer

5. Military and Civilian Partnership for Trauma Readiness Grant Program (These grants ensure trauma care readiness by integrating military providers into civilian trauma centers.)

1. Your answer

6. Public Health Situational Awareness and Biosurveillance Network Programs

1. AABB, ABC and ARC encourage Congress to explicitly recognize and dedicate resources to support the screening, testing and surveillance activities conducted by blood collection establishments, which possesses unique, well-established expertise that is critical to the nation's public health infrastructure. Blood collection establishments effectively recruited over 13 million healthy individuals who presented to donate in 2019,⁶ and test blood donations for a variety of infectious disease pathogens, such as human immunodeficiency virus (HIV), hepatitis B and C, West Nile virus, Babesia and Chagas disease among others.⁷ Many blood collectors implemented biosurveillance for COVID-19, which enabled the government to understand the percentage of people in the United States who had antibodies against SARS-CoV-2 and to track how that percentage changed over time.⁸ Similarly, the blood community was instrumental in surveillance related to Zika Virus, even though many significant activities were unfunded. These screening, testing and surveillance efforts are a critical part of the public health infrastructure, can benefit donors, patients, local communities, and the nation, and often support other non-health care sectors.

⁴ Holcomb JB, Tilley BC, Baraniuk S, et al. Transfusion of Plasma, Platelets, and Red Blood Cells in a 1:1:1 vs a 1:1:2 Ratio and Mortality in Patients With Severe Trauma: The PROPPR Randomized Clinical Trial. *JAMA*. 2015;313(5):471–482.

⁵ Hashmi ZG, Chehab M, Nathens AB, et al. Whole truths but half the blood: Addressing the gap between the evidence and practice of pre-hospital and in-hospital blood product use for trauma resuscitation. *Transfusion*, Accepted, 2021.

⁶ Mowla, SJ, Sapiano, MRP, Jones, JM, Berger, JJ, Basavaraju, SV. Supplemental findings of the 2019 National Blood Collection and Utilization Survey. *Transfusion*. 2021; 61: S11– S35. <https://doi.org/10.1111/trf.16606>.

⁷ Centers for Disease Control and Prevention, Blood Safety Basics, *available at* <https://www.cdc.gov/bloodsafety/basics.html> (last visited October 13, 2022).

⁸ Jones JM, Stone M, Sulaeman H, et al. Estimated US Infection- and Vaccine-Induced SARS-CoV-2 Seroprevalence Based on Blood Donations, July 2020-May 2021. *JAMA*. 2021;326(14):1400–1409. doi:10.1001/jama.2021.15161

PAHPA RFI JOINT BLOOD INDUSTRY DRAFT RESPONSES

7. Public Health Emergency Fund (PHEF)

8. Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VRP)

Your answer

9. National Disaster Medical System (NDMS) *(At a state's request, NDMS provides personnel, equipment, supplies, and a system of partner hospitals work together with state and local personnel to provide care when Americans need it most.)*

10. Medical Reserve Corps (MRC)

Your answer

11. Assistant Secretary for Preparedness and Response (ASPR)

1. AABB, ABC and ARC encourage Congress to ensure that ASPR considers the availability of a safe, adequate blood supply as an essential part of its programs, policies, and procedures. As a vital part of the U.S. health care system, the blood community must be considered as an integral part of emergency preparedness; the essential role of blood collectors must be considered right from the start by federal, state, and local officials during disasters, including public health emergencies.
2. Congress should require ASPR to work with federal, state, and local agencies to ensure the continuity of blood collection establishments' operations during disasters and public health emergencies by: (1) updating policies to prioritize blood collectors' access to PPE, blood bags, saline, reagents, vaccines and other critical supplies; (2) ensuring that blood collectors have priority access to transportation so that blood continues to be available to patients during an emergency; and (3) providing expedited customs clearance for critical items, equipment and supplies needed to maintain a safe and adequate blood supply.

12. Children's Preparedness Unit

Your answer

13. National Advisory Committee (NAC) on Children and Disasters

Your answer

14. National Advisory Committee (NAC) on Seniors and Disasters

Your answer

15. National Advisory Committee (NAC) on Individuals with Disabilities and Disasters

Your answer

16. Public Health Emergency Medical Countermeasures Enterprises (PHEMCE) *(Contributes to the nation's preparedness for chemical, biological, radiological, and nuclear threats, as well as emerging infectious disease threats. It does so by enhancing timely availability and equitable use of effective*

PAHPA RFI JOINT BLOOD INDUSTRY DRAFT RESPONSES

medical countermeasures (e.g., vaccines, treatments, devices, personal protective equipment) to protect Americans from those threats.)

1. Congress should ensure the continuity of blood collection establishments' operations during disasters and public health emergencies by: (1) updating policies to prioritize blood collectors' access to PPE, blood bags, saline, reagents, vaccines and other critical supplies; (2) ensuring that blood collectors have priority access to transportation so that blood continues to be available to patients during an emergency; and (3) providing expedited customs clearance for critical items, equipment and supplies needed to maintain a safe and adequate blood supply.

17. Strategic National Stockpile (SNS)

1. Congress should continuously evaluate the policies regarding medical countermeasures (MCMs), the supply chain, and the SNS to determine how they can support the availability of the blood supply, and include all items, supplies and equipment required to collect, test, store, transport, and transfuse blood. One designated medical countermeasure (MCM) that receives little attention is the nation's blood supply. Blood products have short shelf-lives; platelets can be stored for less than a week from the date they are donated, red blood cells can be stored for up to six weeks and plasma can be frozen and stored up to one year. Due to the unique nature of blood, it is not included in the SNS. Rather, the nation relies on a completely volunteer donor pool of millions of Americans annually to maintain the stockpile of this precious national resource. However, during the past several years there have been shortages of critical supplies and equipment needed to support the blood supply. Congress should ensure that blood collection establishments are prioritized as a critical part of the healthcare system for the purposes of distributing items from the SNS. Additionally, Congress should ensure that all items, equipment and supplies required to maintain a safe and adequate blood supply are available at all times.
2. Congress should require HHS to convene stakeholders, including hospitals, blood collection establishments, manufacturers, and suppliers that are part of the nation's blood supply, to develop recommendations on how to strengthen the resiliency of the blood supply chain.

18. Strategic Initiatives Program

Your answer

19. Federal Select Agent Program (FSAP)

Your answer

20. Medical Countermeasure Budget Plan

Your answer

21. Material Threat and Medical Countermeasure Determination

22. Biomedical Advanced Research and Development Authority (BARDA)

Your answer

PAHPA RFI JOINT BLOOD INDUSTRY DRAFT RESPONSES

23. BioShield Special Reserve Fund

Your answer

24. Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB)

Your answer

25. Medical Countermeasure Master Files

Your answer

26. Genomic Engineering Technologies

Your answer

27. Strengthening Mosquito Abatement for Safety and Health (SMASH) Program

Your answer

28. Epidemiology and Laboratory Capacity Grant Program

Your answer

29. Medical Countermeasure Innovation Partner (MCIP) Program

Your answer

30. Veterans Affairs Emergency Preparedness Readiness Grants for Medical Centers

Your answer

31. Strategy for Public Health Preparedness and Response to Address Cybersecurity Threats

32. Additional Policy Suggestions

If you have a policy suggestion that does not fit within one of the currently authorized programs or initiatives, please provide information about that request. If you are seeking statutory changes to a public health preparedness program that has been appropriated, but not authorized, please make that distinction.

1. We encourage Congress to establish a program within HRSA that is charged with addressing laboratory workforce challenges. Laboratory workforce shortages are pervasive and are impacting the availability of the blood supply. Examples of impacted positions include phlebotomists, medical laboratory technologists (also referred to as medical laboratory scientists), medical laboratory technicians, and supervisory staff roles in blood banking.
2. We encourage Congress to adopt and implement the recommendations that were included in the HHS Report to Congress: Adequacy of the National Blood Supply (2020),⁹ which include opportunities to improve the nation's blood safety and availability during public health

⁹ U.S. Department of Health and Human Services: Adequacy of the National Blood Supply: Report to Congress (2020), available at <https://www.hhs.gov/sites/default/files/hhs-adequacy-national-blood-supply-report-congress2020.pdf>.

PAHPA RFI JOINT BLOOD INDUSTRY DRAFT RESPONSES

emergencies. The recommendations in the [Report to Congress](#) are complimented by [recommendations](#) made at the September 25, 2020 meeting of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA).

3. Congress should continuously evaluate that the policies regarding medical countermeasures (MCMs), the supply chain, and the SNS to determine how they can support the availability of the blood supply, and include all items, supplies and equipment required to collect, test, store, transport, and transfuse blood. One designated medical countermeasure (MCM) that receives little attention is the nation's blood supply. Blood products have short shelf-lives; platelets can be stored for less than a week from the date they are donated, red blood cells can be stored for up to six weeks and plasma can be frozen and stored up to one year. Due to the unique nature of blood, it is not included in the SNS. Rather, the nation relies on a completely volunteer donor pool of millions of Americans annually to maintain the stockpile of this precious national resource. However, during the past several years there have been shortages of critical items, supplies and equipment needed to support the blood supply. Congress should ensure that blood collection establishments are prioritized as a critical part of the healthcare system for the purposes of distributing items from the SNS. Additionally, Congress should ensure that all items, equipment and supplies required to maintain a safe and adequate blood supply are available at all times.
4. Congress should require HHS to convene stakeholders, including hospitals, blood collection establishments, manufacturers, and suppliers that are part of the nation's blood supply, to develop recommendations on how to strengthen the resiliency of the blood supply chain.

33. If you view any of the current programs or initiatives as being duplicative to already existing efforts, or are proposing a program to replace currently existing efforts, please note that.

34. Top Three Priorities: Finally, please submit your top three priorities for the 2023 PAHPA reauthorization in order of preference. (Required)

1. Congress should ensure that ASPR considers the availability of a safe, adequate blood supply as an essential part of its programs, policies, and procedures. Additionally, Congress should require ASPR to work with federal, state, and local agencies to ensure the continuity of blood collection establishments' operations during disasters and public health emergencies by: (1) updating policies to prioritize blood collectors' access to PPE, blood bags, saline, reagents, vaccines and other critical supplies; (2) ensuring that blood collectors have priority access to transportation so that blood continues to be available to patients during an emergency; and (3) providing expedited customs clearance for critical items, equipment and supplies needed to maintain a safe and adequate blood supply.
2. Congress to explicitly recognize and dedicate resources to support the screening, testing and surveillance activities conducted by blood collection establishments, which possesses unique, well-established expertise that is critical to the nation's public health infrastructure.
3. Congress should require HHS to convene stakeholders, including hospitals, blood collection establishments, manufacturers, and suppliers that are part of the nation's blood supply, to develop recommendations on how to strengthen the resiliency of the blood supply chain.