

2022 ABC ADVOCACY AGENDA

America's Blood Centers (ABC) urges the Administration, Congress, and industry stakeholders to promote the value of blood to patients, communities, and the healthcare system through the following actions:

- **Streamline product licensure to allow blood centers to meet unprecedented challenges in blood availability.**
Currently, blood centers wait as long as a year for blood components collected by automation to be fully licensed by the FDA.
WITH MORE DONATION SITES OPENING AROUND THE COUNTRY TO MEET THE INCREASED NEED FOR BLOOD DONATIONS, THIS BURDENSOME ADMINISTRATIVE PROCESS MUST BE MODERNIZED TO ENSURE THE AVAILABILITY OF BLOOD COMPONENTS TO PATIENTS.
- **Expand the pool of eligible blood donors and available blood by finalizing temporary changes to donor eligibility criteria and administrative regulations.** In 2020, FDA shortened the deferral period for certain individuals, including men who have sex with men (MSM), for the duration of the declared COVID-19 public health emergency. FDA also relaxed administrative regulations that limited the availability of blood components. The changes were based upon extensive safety data and allowed for the re-entry of thousands of previously deferred blood donors.
FDA MUST ACT TO ENSURE THESE CHANGES ARE MADE PERMANENT BEYOND THE PUBLIC HEALTH EMERGENCY.
- **Ensure blood centers are part of pandemic response and future disaster preparedness.** The blood supply is a vital component of the healthcare system. During COVID-19, blood centers have struggled to receive prioritization for critical supplies and infrastructure, as well as receive support for workforce challenges, stressing the already strained blood supply.
BLOOD CENTERS MUST BE EXPLICITLY RECOGNIZED IN LEGISLATION TO ADDRESS ISSUES IN THE HEALTHCARE WORKFORCE, TO REMEDY CURRENT AND FUTURE SUPPLY CHAIN ISSUES RELATING TO THE PANDEMIC, AND AS A UNIQUE CONSIDERATION FOR ANY PANDEMIC OR DISASTER PREPAREDNESS PLANS.

Promoting the value of blood to patients, communities, and the healthcare system.



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Streamline product licensure to allow blood centers to adapt to changing donor needs.

The pandemic has dramatically impacted the way blood is collected. As schools and workplaces moved virtual or limited who is allowed on site, blood drive cancellations threatened the stability of the blood supply. To meet the needs of donors, blood centers are now opening new locations to adapt to these enduring changes but face up to a one year wait while FDA reviews blood product licensure submissions. Until the new facility receives FDA approval, blood products manufactured (utilizing the same procedures already approved at other facilities operated by the same blood center) cannot be shipped across state lines, even though all products are already acceptable for distribution in the state of manufacture. To ensure a safe and available blood supply, **blood centers need to quickly be able to fully utilize these new locations.**

Make permanent donor eligibility criteria changes made early in the pandemic.

The FDA's actions have allowed for the re-entry of thousands of individuals to the donor pool who were previously deferred by shortened deferral periods for individuals at higher risk of HIV, including men who have sex with men (MSM), and individuals receiving recent blood transfusions, accidental blood exposures, tattoos, and piercings. Other changes eliminate the need to discard donations for errors that do not influence safety, purity, and potency. FDA relied upon robust safety data to justify the changes. **It is critical these changes are made permanent within 60 days of the end of the public health emergency** to avoid any lapse which again defer donors willing and safely able to provide much needed blood.

Ensure blood centers are part of pandemic response and future disaster preparedness.

In 2019, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act marked the first time-ever that the sweeping preparedness and response legislation specifically recognized the role of blood centers. This bill required the inclusion of blood centers as stakeholders that the U.S. Department of Health and Human Services Assistant Secretary for Preparedness and Response (ASPR) must consult in disaster planning. While this is an important step, more is required to ensure blood center operations can continue during any disaster and after a prolonged disaster such as the COVID-19 pandemic. Blood centers are not immune to the same stressors that are placed on hospitals and healthcare providers, including supply chain and workforce challenges, yet blood centers are often not considered as part of the healthcare system. Blood centers require many of the same healthcare workers such as phlebotomists, lab techs, nurses, and doctors, and utilize many of the same supplies for their laboratories. **Any programs addressing workforce and supply chain issues must specifically extend to blood centers.**

In addition to the above priorities, ABC supports the following policy positions and urges the Administration, Congress and industry stakeholders to promote the value of blood components to patients, communities, and the healthcare system through the following:

Support a robust donor base by prioritizing blood donation as a national imperative

- Establish targeted federal initiatives to support increased diversity in the donor base such as funding for increased molecular red blood cell typing for frequently transfused patients such as those with Sickle Cell Disease or Thalassemia.
- Establish funding for research on the predictive social and psychological factors in blood donor motivation in order to attract and retain donors and ensure long-term stability of the nation's blood supply.

Commit federal resources in support of the vital role of blood in the healthcare system

- Explore federal funding mechanisms to facilitate implementation of safety and technology measures when mandated by FDA, such as the recent platelet bacterial detection guidance, or when market incentives otherwise do not exist.
- Increase federal resources for data gathering on the collection and utilization of blood components as needed to support evidence-based decision making in federal regulatory policy.
- Expand availability of blood components to patients at the end of life by modifying hospice reimbursement rates to reflect the added cost of providing blood components.
- Support the establishment of a new reimbursement methodology for the transfusion of pre-hospital blood products. Pre-hospital blood use is supported by clinical research but current reimbursement does not adequately cover the cost.

Reduce unnecessary and burdensome regulation to support innovation and blood product availability

- Apply evidence-based decision making to FDA testing requirements to ensure testing burdens are justified by commensurate increases in safety, eliminating current FDA testing requirements without appropriate safety justifications (e.g. HBsAg).
- Advocate for FDA approval of extended shelf life for cold stored platelets to expand platelet supply availability for rural areas and in trauma with massive bleeding.
- Revisit FDA policy on the acceptance of international data for use in the approval of new products or technologies, and different policies and procedures.
- Encourage FDA to establish donor policies which promote inclusivity with research-based donor-screening alternatives based on individual behavior, not sexual or gender identity, to provide equivalent or superior transfusion safety.
- Lower the U.S. Platelet Content Requirement (PCR), the minimum number of platelets per unit, to expand platelet supply availability and in line with international standards.
- Implement a rational, flexible approach to the regulation of plasma products, advocating FDA licensure of recovered plasma to give blood centers the ability to convert plasma from transfusable to further manufacture for more effective blood inventory management.