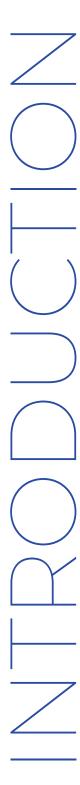


## ADVOCACY AGENDA

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





Every two seconds, someone in America requires a blood transfusion, and each day, over 42,000 units of red blood cells, platelets, and plasma used by patients.

These transfusions are essential in treating acute care needs such as trauma, as well as in disease management for patients facing cancer treatment, cardiovascular and orthopedic surgeries, and organ and bone marrow transplants.

America's Blood Centers and our members are committed to addressing the challenges facing community blood centers that ensure a safe and available blood supply is always available to meet patient needs.

Stay up to date on ABC's advocacy work online at AmericasBlood.org/Advocacy

#### **OUR PRIORITIES**

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:

Ensure patient access to blood by streamlining product licensure.

To meet evolving trends in where and when individuals prefer to donate blood, blood centers are now opening new locations that provide convenient opportunities to donate.

However, blood centers may face over a year's delay before they can open these locations due to regulatory wait times. Until the new facility receives final 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. These delays threaten patient access to life-saving blood for both routine and emergency care.

To ensure a safe and available blood supply, FDA product licensure should be streamlined to ensure blood centers are quickly able to fully utilize these new locations.

# Increase the number of blood donors nationwide through funding of local awareness programs.

Only 3% of Americans donate blood each year. Recent FDA changes in donor deferral criteria have expanded the pool of eligible individuals, but funding is needed to ensure awareness of these changes.

Recent changes include an end to the indefinite deferral for geographic exposure to bovine spongiform encephalopathy and a move to a universal individual behavior assessment for all donors. These changes will allow more gay and bisexual men to donate blood as well as many current and former members of the military and their families.

Congress should support local blood center efforts to recruit potential donors, including those that have previously been ineligible to donate due to these government policies, to ensure a robust blood supply.

## Ensure blood transfusions are available to patients when and where they need blood.

Blood centers throughout the U.S. work to ensure that blood is available to patients when they need it most.

Unfortunately, due to some payment policies, blood transfusions are not equally available to all patients, including those in the Medicare Hospice program, those receiving treatment in an outpatient clinic, or those suffering from trauma and receiving blood through emergency management services.

Studies show extensive benefits to patients and the healthcare system they rely on when they have access to blood transfusions and are assured care when and where it's needed.

Congress should ensure Medicare payment policies allow patient access to blood transfusions when and where the patients needs.

### **POLICY PRIORITIES**

In addition to the above priorities, ABC supports the following policy priorities:

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 including those with Sickle Cell Disease or Thalassemia.
- Establish funding for research on the predictive social and psychological factors in blood donor motivation 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 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.
- Advocate for funding and programs that increase the surge capacity of the nation's blood supply.

# 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).
- Revisit FDA policy on the acceptance of international data for use in the approval of new products or technologies, and different policies and procedures.
- Lower the U.S. Platelet Content Requirement (PCR), the minimum number of platelets per unit, to expand platelet supply availability and align 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 without requiring expiration for more effective blood inventory management.



For a complete list of ABC member centers across the United States and to access a member map, <u>click here.</u>

### HOW IT WAS DEVELOPED

Our Advocacy Agenda was built through our Value Framework, which consists of five core pillars that emphasize the contribution ABC member blood centers bring to their local communities and the nation's healthcare system.

Value 2  ABC members promote the altruistic gift of blood from millions of individuals nationwide, maintaining a critical donor base and educating current and future generations on the need for blood  ABC members re-invest in the health of their local communities through such things as cellular therapy services, transfusion medicine expertise, disease management programs, and research  Value 4  ABC members partner with federal, state, and local agencies to confront public health threats and promote medical and scientific innovation  ABC members provide competition in the market, ensuring value while controlling overall healthcare market expenditures for blood components	Value 1	ABC member blood centers ensure a safe and adequate blood supply, saving and improving the lives of millions of Americans each year
Value 2  millions of individuals nationwide, maintaining a critical donor base and educating current and future generations on the need for blood  ABC members re-invest in the health of their local communities through such things as cellular therapy services, transfusion medicine expertise, disease management programs, and research  ABC members partner with federal, state, and local agencies to confront public health threats and promote medical and scientific innovation  ABC members provide competition in the market, ensuring value while controlling overall healthcare		
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Value 5 ensuring value while controlling overall healthcare	Value 4	agencies to confront public health threats and promote
Value 5 ensuring value while controlling overall healthcare		
	Value 5	ensuring value while controlling overall healthcare

ABC's vision is a thriving blood center community ensuring safe and available blood for every patient in need. Our mission is to amplify and advance the contributions of community blood centers to individuals, communities, and the healthcare system. We accomplish our mission through advocacy, awareness, and collaboration.



Founded in 1962, America's Blood Centers (ABC) is
North America's largest alliance of communitybased, independent blood programs. One million
people walk through the doors of community blood
centers every month.

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