



America's Blood Centers®  
It's About *Life*.

# Advocacy Agenda

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

2025

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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.

## 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:

## Cut red tape to support the safety and availability of the blood supply.

As blood centers work to adapt to the needs of blood donors and the patients they serve, government regulations impose unnecessary and burdensome barriers to a safe and available blood supply. One glaring example of this is the outdated regulations that currently govern the ability to collect apheresis blood products at a new donation site.

Blood centers rely on blood collected at more than 800 donation sites across the country. Each time a new donation site is opened, a blood center must go through an extensive licensure process to add the new site to their existing Blood License Application (BLA). This process can take more than a year, despite the blood center using the same Standard Operating Procedures (SOPs), devices, and staff as their primary licensed facility. With new locations opening every month across the country, this unnecessarily delays the availability of blood to patients when and where it is needed and largely duplicates review FDA has already undertaken.

**America's Blood Centers urges the FDA to update the licensure process to allow blood centers to quickly and safely meet the changing demands for blood components for patients.**

## Exempt lab developed tests (LDTs) utilized by blood centers from reforms to diagnostics regulation.

In May 2024, the Food and Drug Administration (FDA) issued a final rule that made in vitro diagnostic products (IVDs) subject to additional regulatory burden, including some tests utilized by blood center laboratories.

LDT procedures in blood centers are usually performed in urgent, life-saving situations and are always performed for patients being treated in a healthcare setting. These tests are already highly regulated, with blood centers having significant safeguards in place when developing and utilizing LDTs. Blood center laboratories ensure the quality and validity of tests through the existing regulatory framework and safeguards, including (1) federal, state, or local licensure of the facility; (2) Clinical Laboratory Improvement Amendments (CLIA) certification; (3) compliance with extensive FDA regulatory requirements; (4) state requirements; and (5) accreditation.

**Given the oversight and inspection already in place for blood centers, adding an additional layer of regulation is unnecessary and has the potential to impact patient care.**

## Improve patient access to blood transfusions on ambulances.

Extensive evidence shows the benefits of receiving blood transfusions as soon as possible after a traumatic injury. However, most patients do not receive their first transfusion until they arrive at a hospital, regardless of the amount of time required for transportation. Blood transfusions are not equally available to all patients because payment policies and scope of practice laws mean not all ambulances can carry lifesaving blood. Medicare, TRICARE, Medicaid and most private insurance does not cover the cost of providing blood on an ambulance. As a result, the only ambulances that can provide this lifesaving treatment are those that receive grant funding, are supported by local taxes, or that can absorb the costs.

**Payment policy for federal insurance programs must be updated to provide sufficient reimbursement to allow for broader adoption of prehospital blood transfusions.**

## Strengthening the cyber resilience of the blood community.

Blood centers play a vital role in our healthcare system, ensuring the availability of a safe and sufficient blood supply for patients in need. However, blood centers are increasingly becoming targets of sophisticated cyberattacks, threatening critical operations relied upon by patients. Recent incidents have highlighted the devastating impact of such attacks, including disruptions to blood collection and distribution, potential breaches of confidential data, and significant financial losses. The consequences of a successful cyberattack on a single blood center can have ripple effects on the blood supply nationwide as other blood providers assist in ensuing patient needs are met.

**To address this urgent issue, blood centers need increased support and resources to update their current information technology infrastructures and strengthen their ability to prevent potential attacks.**

**Learn  
More**

*Stay up to date on ABC's advocacy work online at [AmericasBlood.org/Advocacy](http://AmericasBlood.org/Advocacy)*

# 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.
- Expand the pool of blood donors and available blood by funding local awareness efforts to recruit new and previously deferred donors, especially those made eligible by recent FDA eligibility changes.
- Expanding the availability of blood transfusions by ensuring sufficient reimbursement within the Medicare hospice program to ensure all patients can benefit from the end-of-life care provided through hospice while maintaining the quality of life provided by blood transfusions.
- Provide Medicare reimbursement for blood transfusions in outpatient clinics to allow patients to receive care in their preferred settings.

**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.
- Support robust funding for research supporting a safe and available blood supply and the patients benefitting from blood components and transfusion medicine.
- Advocate for funding and programs that increase the surge capacity of the nation's blood supply including pre-determined/approved regulatory flexibility, funding for increased local awareness, national target for days on hand, funding for critical infrastructure, and a mechanism to understand both blood center and hospital inventory levels.

## 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 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 transfusible to further manufacture without requiring expiration for more effective blood inventory management.
- Allow blood to be held for up to 24 hours prior to processing into components in line with current evidence and international standards.
- Reduce the deferral period for those incarcerated for more than 72 hours to three months, in line with other deferrals for similar risk of contracting diseases that are transfusion transmitted.

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**Learn More**

*For a complete list of ABC member centers across the United States and to access a member map, [click here](#).*

# OUR VALUE FRAMEWORK

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 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

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

Value 3

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

Value 5

ABC members provide competition in the market, ensuring value while controlling overall healthcare market expenditures for blood components

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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.



## America's Blood Centers® It's About *Life.*

Founded in 1962, America's Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers across North America. These organizations operate in more than 1,100 communities and provide close to 60 percent of the U.S. and a quarter of the Canadian blood supply. ABC member organizations serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities. All ABC U.S. members are 501(c)(3) organizations licensed and regulated by the U.S. Food and Drug Administration or Health Canada.

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