

**FOR IMMEDIATE RELEASE** Tuesday, July 15, 2025 Contact: Jeff Gohringer, (202) 654-2901

## <u>America's Blood Centers Applauds FDA's Proposed Change</u> <u>Eliminating Duplicative Hepatitis B Testing Requirement that Fails to</u> <u>Increase Safety</u>

Would reduce unnecessary regulatory burdens on blood centers while maintaining the highest standards of safety

**Washington, DC** – America's Blood Centers (ABC), the national organization of community-based, independent blood centers that supply 60 percent of the nation's blood supply, today applauds the Food and Drug Administration (FDA) for its <u>draft guidance proposing</u> the elimination of Hepatitis B Surface Antigen (HBsAg) testing for blood donations. This recommendation is based on scientific evidence indicating that the risk of Hepatitis B Virus (HBV) transmission is appropriately reduced by the other two tests currently required for HBV.

This proposed change aligns with ABC's long-standing advocacy efforts to reduce unnecessary regulatory burdens on blood centers while maintaining the highest standards of blood safety. The elimination of HBsAg testing could save blood centers an estimated \$15 to \$22.5 million annually, allowing for community blood centers to operate more efficiently while maintaining the safety and availability of the nation's blood supply.

"America's Blood Centers applauds the FDA for taking this evidence-based step towards streamlining blood donation testing requirements," said Kate Fry, CEO of America's Blood Centers. "We call upon FDA to continue to examine options to remove unnecessary, outdated, and burdensome requirements on blood centers, including other testing requirements that fail to increase the safety of the nation's blood supply."

ABC has long advocated for this change as part of its efforts to reduce unnecessary regulatory burdens. This priority is included as part of its <u>Advocacy Agenda</u> and has been shared regularly in its communications with federal agencies, including <u>a recent letter to Department of Health and Human Services</u> Secretary Robert F. Kennedy regarding de-regulation priorities.

Founded in 1962, America's Blood Centers (ABC) is the national organization bringing together communitybased, 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. For more information, visit <u>www.AmericasBlood.org</u>.