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HB 1456: Hospitals and Tissue Banks - Autologous and Directed Blood Donations - Requirements
Position: UNFAVORABLE
February 28, 2025
House Health and Government Operations Committee

Chair Peña-Melnyk, Vice Chair Cullison and members of the committee, thank you for the opportunity to provide testimony in respectful opposition to House Bill 1456. My name is Meghan Delaney, DO, MPH, and I am the Chief of Pathology & Laboratory Medicine and the Director of Transfusion Medicine at Children's National Hospital. I also serve as the President of the Association for the Advancement of Blood & Biotherapies (AABB). Children's National has been serving the nation's children since 1870. Nearly 60% of our patients are residents of Maryland, and we maintain a network of community-based pediatric practices, surgery centers and regional outpatient centers in Maryland.

I am not in support of the Autologous and Directed Blood Donations Requirements bill that is before the Committee. I am a board-certified pathologist with additional board certification in Blood Banking and Transfusion Medicine. My practice of medicine is focused on the care of patients who need blood transfusion and donors who provide the blood. I have published over 120 peer reviewed manuscripts in the field, I speak nationally and internationally on transfusion safety, and I have conducted multiple research projects in the field of blood transfusion.

Those in support of HB 1456 may think that autologous or directed blood donations are safer than a blood transfusion received from the community volunteer donor blood supply. I am testifying today to describe why this is not the case and why the bill is not necessary. HB 1456 will risk our state's blood supply for patients who need blood transfusion by putting onerous unnecessary regulations over our blood donation services, which is a community resource for all patients.

The blood supply in the United States is exceptionally safe. There are a multitude of safeguards in place to ensure the highest level of safety. First, blood donors in the United States are donated by volunteers. The foundation of the nation's blood supply is volunteer community blood donation; more than 10.7M red blood cells are transfused annually in the United States.

These generous individuals are motivated to donate blood to help others and receive nothing in return. This altruistic relationship selects donors with low risks for infectious diseases. The next level of safety is that every person presenting to donate blood is evaluated with an extensive donor screening questionnaire to determine if a person is healthy enough to be a blood donor. This process weeds out people who engage in activities that may put them at risk for blood born infections, such as certain types of drug use, having multiple sex partners, etc. Only donors that pass all the screening questions and physical exam are allowed to donate blood. After each unit is collected, it is held in quarantine while it is tested for viruses and bacteria that are known to be transmitted by blood transfusion. If any of the tests are positive, the unit is not used, it is discarded, and the donor is informed and counseled to see a physician for treatment. These units never reach the blood supply. Only units that pass with no pathogens detected are released from quarantine and allowed to go to hospital blood banks to be used for patients.

Directed donations are not inherently safer. For example, the risk of transfusion-transmitted infections is higher in directed units when donors are personally selected by the patient than for units collected from volunteer blood donors who are under no pressure to donate. Also, blood transfusions from closely related family member donors can interfere with treatment, including patients' future transplant eligibility, and raise the risk of transfusion-associated graft versus host disease, which is associated with increased fatality risk. To mitigate the potential patient safety and health risks from directed donations that may not be medically necessary, patients' treating physicians often seek consultation with transfusion medicine physicians at hospitals and blood collectors to make these important medical treatment decisions.

Autologous donation is also not safer, as studies have shown that many autologous units collected before elective surgery are not needed and are discarded. Thus, the only effect they have is to make the patient anemic before a surgery procedure. Further, autologous donation procedures are more permissive from a regulatory standpoint, which leads to more donation reactions. Autologous donations also have a risk of being given to the wrong patient. Both directed and autologous blood donation requires separate procedures and increased administrative burden. Thus, using directed and autologous blood donation is not necessary and rarely medically indicated, as the volunteer community blood supply is collected, processed and tested under FDA regulations making it extremely safe and free from risk of disease transmission.

Currently, hospitals and blood collectors support medically indicated autologous and directed blood donations when they are truly needed. They have well-established processes to evaluate and qualify special transfusion needs for such requests, which generally include

consultation with patients' providers. Medically indicated autologous and directed blood donation account for about 0.1% of blood donations nationally.

In the United States, patients' blood needs, including those with complex blood type matching requirements, are routinely met through community volunteer blood donations and the work of highly skilled transfusion medicine professionals. Patients requiring specially selected units to meet their unique medical needs are transfused every day without special requests for directed donations.

HB 1456 is overly burdensome and has the potential to result in an increased number of medically unwarranted autologous and directed blood donations that require additional special handling outside the well-established processes that currently protect the safety and availability of blood for all patients. This may adversely affect patient care and will create new burdens for providers and blood collectors.

For these reasons, we respectfully request an **unfavorable report** on House Bill 1456. Thank you for the opportunity to submit testimony. I am happy to respond to any questions you may have.

For more information, please contact:
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