Submitted Written Testimony for HB 1456 Hospitals and Tissue Banks – Autologous and Directed Blood Donations

Written Submission Opposition Testimony
Regarding HB 1456 Hospital and Tissue Banks and Directed Blood Donations - Requirements

New York Blood Center Enterprises (NYBCe)

Introduction

Founded in 1964, New York Blood Center Enterprises (NYBCe) has proudly provided over 60 years of lifesaving research, innovation, and impact. NYBCe is one of the largest nonprofit blood centers in the country, spanning 17+ states and serving 75 million people. NYBCe operates various entities, including Blood Bank of Delmarva, Community Blood Center of Kansas City, Connecticut Blood Center, Memorial Blood Centers, Nebraska Community Blood Bank, New Jersey Blood Services, New York Blood Center, and Rhode Island Blood Center. Together, these centers deliver over one million blood products annually to more than 400 U.S. hospitals.

Additionally, NYBCe provides cellular therapies, specialty pharmacy, and medical services to over 200 research, academic, and biopharmaceutical organizations. The Lindsley F. Kimball Research Institute, a division of NYBCe, is a recognized leader in hematology and transfusion medicine research, dedicated to the study, prevention, treatment, and cure of bloodborne diseases. NYBCe plays a critical role in supporting both local communities and advancing global public health.

Concerns Regarding Donor Safety

NYBCe respectfully submits its concerns regarding the bill's failure to address safety for donors and transfusion recipients participating in autologous and directed blood donation programs. It is imperative that all donors meet established safety and eligibility criteria to ensure that they are in appropriate health to donate without posing a risk to themselves.

Specifically, directed donors—those donating blood for the benefit of a designated individual—must meet all eligibility criteria set by the U.S. Food and Drug Administration (FDA). This ensures that the transfusion is both effective and safe for the patient receiving the donation. Should a donor fail to meet these standards, they cannot donate, regardless of patient preference. Directed donations, in particular, may introduce additional risks such as:

- **Failure to Meet Standard Donor Screening Criteria:** Directed donors must meet all the standard blood donor criteria, including infectious disease screening, iron levels, and overall health assessments. Without adherence to these criteria, there is potential risk to both the donor and the recipient.
- **Compatibility Challenges:** Directed donations are not always medically viable due to factors such as CMV (cytomegalovirus) status, HLA (human leukocyte antigen) antibodies, or blood type mismatches. These limitations could result in delays in necessary transfusions, thereby negatively impacting patient care.

Issues with Supply Chain and Hospital Coordination

The use of autologous and directed donations that are not medically indicated presents challenges related to the transportation and storage of blood. In particular, several questions arise:

- **Blood Supply Management:** The bill suggests that a donor may provide blood directly to the hospital, a practice that is not currently feasible. This raises significant concerns related to the proper handling, testing, and compliance with existing blood banking regulations.
- **Contractual Agreements:** The bill does not require hospitals to establish contracts with blood centers (as opposed to tissue banks) supplying the blood. Without such agreements, hospitals may face logistical and operational challenges, including difficulties in ensuring the availability of blood when needed.
- **Existing Hospital Blood Suppliers:** If a hospital already has a primary blood supplier, this bill could create operational confusion both for hospitals and blood centers, further complicating the existing systems in place.

Regulatory and Financial Considerations
The bill's provision allowing tissue banks to charge a "reasonable fee" for facilitating autologous and directed blood donations raises significant concerns related to financial regulation and patient accessibility:

- **Participation and Financial Burdens:** The bill lacks clarity about which tissue banks are required to participate in the program and whether blood centers are included. This ambiguity could create an uneven financial burden for specific providers, while allowing others to potentially opt out.

Potential for Unintended Consequences
While the bill's goal to increase awareness of blood donation is positive, there are unintended risks that could arise. For instance, patients may demand blood collection from individuals with specific characteristics (e.g., rare blood types or genetic traits), even when such demands are not operationally feasible or medically justified. This could further strain resources and cause unnecessary complications in blood donation practices.

Conclusion
In conclusion, while the intentions of the bill may aim to increase blood donation awareness, it presents significant regulatory, logistical, and financial challenges that could negatively impact donor and patient safety. Additionally, it threatens to disrupt established blood supply chains and create unnecessary burdens on blood centers, hospitals, and patients. For these reasons, I strongly urge that further clarifications, safeguards, and amendments be made before moving forward with this legislation. As currently written, I must oppose this bill.

Thank you for your time and consideration. I would be happy to provide further insights or answer any questions you may have.

Sincerely,

Andrea H. Cefarelli
Senior Vice President Corporate Communications and Public Affairs
New York Blood Center Enterprises
914-760-3173
acefarelli@nybc.org