March 26, 2023

Robert M. Califf M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically via www.regulations.gov

Re: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products; Draft Guidance for Industry [Docket Number FDA-2015-D-1211]

Dear Dr. Califf:

Premier Inc. appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) in response to the draft guidance titled *Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products [Docket Number FDA-2015-D-1211].* The draft guidance describes how FDA intends to update eligibility requirements for blood donations to eliminate the time-based deferrals for men who have sex with men (MSM) and women who have sex with MSM. Instead, FDA recommends assessing donor eligibility using gender-inclusive, individual risk-based questions relevant to HIV risk.

Premier strongly supports the new draft recommendations as a positive step forward in ensuring blood supply safety and resiliency while addressing the inequities that exists for individuals who identify as LGBTQ+ and their eligibility to donate blood. Premier drew attention to the current discriminatory policy and has supported FDA's ongoing review of blood donation rules to expand eligibility criteria in a safe and equitable manner.

In our comments, Premier urges FDA to expeditiously finalize the draft guidance, minimize operational burden to implementing the new risk-based protocols and clarify that implementation of the guidance upon finalization is mandatory, not permissive.

I. Background on Premier Inc.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

Throughout the COVID-19 pandemic, Premier played a key role in developing and sharing conservation protocols with hospital leaders given the blood shortage crisis. By sharing best practices across the healthcare continuum, Premier was able to help mitigate supply disruptions and ensure continuity in patient care.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. Donor Educational Material and Donor History Questionnaire

The FDA notes that blood collection establishments must update their donor educational material, donor history questionnaire (DHQ), including full-length and abbreviated DHQs, and accompanying materials (e.g., flow charts) and processes to incorporate the recommendations provided in the draft guidance. Furthermore, educational material must be presented to donors in a manner they will understand, which may include oral, written or multimedia formats, and must instruct the donor not to donate when a risk factor for HIV infection is present.

To implement updates to educational materials and DHQs, FDA clarifies that licensed blood establishments that revise their own DHQs and accompanying materials must report the change to FDA in a Prior Approval Supplement (PAS) under 21 CFR 601.12(b). Alternatively, licensed blood establishments that implement a revised version of the DHQ and accompanying materials prepared by the AABB Donor History Task Force or the Plasma Proteins Therapeutic Association (PPTA) and found acceptable by FDA must report the changes to FDA in an annual report under 21 CFR 601.12(d), noting the date the process was implemented (21 CFR 601.12(a)(3)).

Under a PAS pursuant to 21 CFR 601.12(b), the applicant must obtain approval of the supplement from FDA prior to distribution of the product made using the change. Typically, a PAS supplement is reviewed by the FDA within 10 months of submission date if preapproval inspection is required and within 4 months of submission date if preapproval inspection is not required. Furthermore, per 21 CFR 601.12(b)(4), an applicant may ask FDA to expedite its review of a supplement for public health reasons.

Premier is concerned that the PAS approval timelines will hinder the ability of blood establishments to expeditiously implement the revised guidance if they are waiting upwards of 10 months to receive approval for changes to educational materials and DHQs. ***Given the importance of this revised guidance to the Administration's health equity goals and public health, Premier urges FDA to automatically expedite review of educational materials and DHQs pursuant to 21 CFR 601.12(b)(4) and ensure that review occurs within 60 days of the submission date.*** The submission and subsequent approval of a PAS should not serve as an operational barrier to implementing the new risk-based assessment for blood donors.

III. Scope of the Draft Guidance

As written, the draft guidance is *permissive* in allowing blood establishments to adopt a risk-based assessment for blood donors but falls short of *requiring* blood establishments to adopt a risk-based assessment. Premier is concerned that the permissive nature of the draft guidance can create further inequity and discriminatory practices throughout the nation as blood establishments will have an opportunity

to decide if they will or will not adopt a risk-based assessment for blood donors. ***Given that the FDA's draft guidance is rooted in science, and to avoid perpetuating further discriminatory practices and inequities, Premier urges the FDA to clarify that adoption of a risk-based assessment by blood establishments is mandatory and that all blood establishments must adopt a risk-based assessment approach within one year of finalization of the guidance.***

IV. Timeline for Final FDA Guidance

Critical to moving this new policy forward is the availability of final FDA guidance. Historically, FDA has been known to maintain guidance documents in draft format for extended periods of time. Absent final guidance, stakeholders are often hesitant to implement revised protocols for fear that final guidance may be counter to the principles outlined in the draft guidance resulting in non-compliance or the need to undo and redo processes. In addition, stakeholders are often concerned about litigious risk in implementing the principles outlined in draft guidance. Therefore, ***Premier urges the FDA to expeditiously issue final guidance no later than 90 days after the close of the comment period.***

V. Conclusion

In closing, Premier looks forward to continuing to work with the FDA to finalize this guidance and assist in our common goal of creating a more accessible and equitable healthcare system. If you have any questions regarding our comments or need more information, please feel free to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.