



April 17, 2020

The Honorable Evan Low
Chair of the Committee on Business and Professions
Legislative Office Building, Room 379
Sacramento, CA 95814

RE: APLUS Comment Letter in Support AB 2199

Dear Assembly Member Low,

The American Plasma Users Coalition (APLUS) would like to share with you its support for Assembly Bill 2199 (Nazarian). This bill will remove the sunset and the pilot verification provisions from Section 1246.7 of the California Business and Professions Code.

APLUS is a coalition of national patient organizations created to address the unique needs of patients with rare diseases who use life-saving plasma protein therapies. The organizations representing these patients share a common desire to ensure that the patient voice is heard when relevant public policies, regulations, directives, guidelines, and recommendations affecting access to safe and effective therapy and treatment are considered. Together, our coalition represents more than 125,000 Americans living with chronic disorders dependent upon plasma protein therapies for their daily living. Safety is of utmost concern to APLUS: we believe that plasma collection regulations should always prioritize the safety of the donor and the safety of the eventual plasma user.

Plasma collected at donation centers in California and across the United States is used in a complex manufacturing process to produce life-saving plasma-derived medicines. It takes many donations to manufacture the plasma protein therapies that are used to treat an individual with a rare, chronic condition that requires plasma protein replacement. It is estimated that it takes 130 donations to produce enough immunoglobulin to treat an adult with primary immune deficiency for a year. For someone with alpha-one antitrypsin deficiency or hemophilia, the estimated number of donations needed for one year of therapy exceeds 900. For this reason, it is essential that policies and regulations promote efficient plasma donation policies.

It is our understanding that AB 2199 will ensure that licensed professionals are utilized to the highest level of their job skills resulting in more efficient source plasma donor screening. It will free up specialized staff to perform other essential functions in these source plasma donation centers, such as conducting new donor physical examinations. This is critical because the growing clinical need for plasma medicines means we need more source plasma donations.

California currently has 26 source plasma donation centers. This is likely a result of regulations that are not conducive to source plasma donation. For comparison, there are more than 100 source plasma donation centers in Texas, more than 60 in Florida, and more than 40 in Ohio. Passage of AB 2199 will make permanent laws that harmonize California's laws with those in



the rest of the country. The result of passing AB 2199 would likely be more source plasma collection centers in California that allow for more efficient collection of plasma without compromising safety for the plasma donor or the eventual plasma user.

Thank you for your leadership in changing policies in California and please consider the community a resource in this regard.

Signed,

APLUS Members

GBS|CIDP Foundation International

Immune Deficiency Foundation

Patient Services, Inc.

US Hereditary Angioedema Association

Hemophilia Federation of America

Coalition for Hemophilia B

National Hemophilia Foundation