



April 17, 2020

Dr. Amy Acton
Director of Health
Ohio Department of Health
246 North High Street
Columbus, OH 43215

RE: Ensuring Plasma Donation Centers Remain Operational

Dear Dr. Acton,

The American Plasma Users Coalition (APLUS) would like to express concern for how the current COVID-19 crisis is currently impacting source plasma collection across the United States, and in Ohio. Source plasma and blood collection are vitally important, and we agree with the U.S. Department of Homeland Security Cybersecurity & Infrastructure Security Agency, which designated these activities as essential ones that must continue during the crisis.

Recognizing the unique challenges of managing the current crisis and operating plasma collection center, we support others' recommendations to temporarily suspend or amend the Ohio Revised Code Sec. 3725.05. Specifically, we support the suggestion by the Plasma Protein Therapeutics Association to suspend the above mentioned code to read:

“A licensed physician, a registered nurse, a medical technologist, a Licensed Practical Nurse, an Emergency Medical Technician, a Paramedic, or other healthcare professional approved by the Director of Health is in attendance at all times when a donor is undergoing plasmapheresis, and is responsible for supervising the procedure and the maintenance of sterile technique.”

Professionals with the occupations underlined above supervise plasma donation in others states as allowed by their state laws and federal law. The safety of the plasma donor is maintained in these states. Allowing these changes in Ohio during this time of crisis would relieve stress from the critical activities that provide essential therapies to individuals with rare, chronic conditions and allow registered nurses to be focus on work that is also essential but non interchangeable.

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 Ohio 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.

Thank you for your leadership in managing the current public health crisis. Please consider us a resource on this issue.

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