

April 7, 2020

VIA EMAIL

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

RE: ORC §3725.05 Requirements

Dear Director Acton:

The Plasma Protein Therapeutics Association (PPTA) is concerned about the current COVID-19 crisis (crisis) and its impact on plasma donations in the entire United States including Ohio. The current crisis is disproportionately impacting the health care workforce at a time when they are most needed. Therefore, we are requesting that Ohio Department of Health temporarily suspend or amend Ohio Revised Code Sec. 3725.05 (D) for the duration of Executive Order 2020-01D declaring a State of Emergency in the state of Ohio.

PPTA is the standards-setting and global advocacy organization that represents the private sector manufacturers of plasma-derived and recombinant analog therapies, collectively known as plasma protein therapies, and the collectors of Source Plasma<sup>1</sup> used for manufacturing of plasma protein therapies. PPTA members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies. Our membership accounts for approximately 80 percent of plasma protein therapies in the United States.

Plasma protein therapies are primarily used in the treatment of genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. These therapies include blood clotting factors for individuals with bleeding disorders, immunoglobulins (Ig) to treat a complex of diseases in persons with antibody deficiencies and severe autoimmune disorders, and albumin, which is used to treat individuals with severe liver diseases and, in emergency-room settings, shock, trauma, burns, and other conditions.

The plasma donations in Ohio are the first step in the manufacturing of plasma protein therapies. Our members operate 41 plasma donation centers in the state. The operations of these centers are identified as Essential Businesses and Operations under the Stay At Home Order dated March 22, 2020.

Ohio Revised Code Sec. 3725.05 (D) requires that a "licensed physician, a registered nurse, or a medical technologist approved by the Director of Health is in attendance at all times when a donor

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<sup>1</sup> 21 CFR 640.60 defines Source plasma as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use.

is undergoing plasmapheresis, and is responsible for supervising the procedure and the maintenance of sterile technique.” The current crisis is causing a strain on workers of all kinds, but especially on licensed health care workers. As our members prepare for the staffing shortages that will result from the crisis, flexibility in staffing would limit disruption on plasma donations in the state.

Therefore, we are requesting that you use your authority to allow other licensed healthcare professional to supervise plasmapheresis at our plasma donation centers. We would suggest that you temporarily suspend ORC §3725.05 (D) or temporarily amend the section 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<sup>2</sup>. The safety of the plasma donor maintained in these states. Allowing these changes in Ohio during this time of crisis would assist our members’ performance of their critical activities that provide essential therapies to individuals with rare, chronic conditions.

We are grateful for your consideration of our request. We are available to assist in this matter in way possible. If you have any question or comments, please contact me at 443-433-1110 or [bspeir@pptaglobal.org](mailto:bspeir@pptaglobal.org).

Sincerely,



Bill Speir  
Senior Director, Advocacy and Regulatory Policy

cc: Mr. Russ Kennedy  
Deputy Director/Director of External Affairs  
Ohio Department of Health

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<sup>2</sup> 21 CFR 630.5