Plasma Protein Therapeutics Association

April 12, 2022

VIA EMAIL
Mary T. Bassett, MD, MPH
Commissioner
Office of the Commissioner
New York State Department of Health
Riverview Center
150 Broadway, Suite 355
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Commissioner Bassett:

The Plasma Protein Therapeutics Association (PPTA) is writing to request that you please consider expeditiously granting a reasonable and necessary regulatory reform for the Source Plasma sector pertaining to two of New York's clinical laboratory regulations. If possible, we ask that you please consider granting this relief via an emergency rulemaking similar to the one that was initiated by the Council on Human Blood and Transfusion Services (COHBATS) for the Source Plasma sector on September 4, 2020. These farsighted changes were codified with the express intent of harmonizing New York's requirements with national standards and importantly, these new regulations incorporated by reference federal requirements. Further, these federal requirements were expressly adopted to replace existing New York State requirements. Additionally, the Source Plasma legislation that was signed into law by Governor Hochul in December 2021 and February 2022 also affirmatively aligned New York's requirements with federal standards. We respectfully ask that you also take this very approach – with regards to the role of clinical laboratory supervisor and supporting lab testing personnel – in the very limited context of Source Plasma testing facilities.

PPTA represents the private sector manufacturers of plasma protein therapies, and the operators of Source Plasma[1] donation centers. The first step in our members' manufacturing process is made when plasma donors visit plasma donation centers to donate Source Plasma. The donated plasma is used to create plasma protein therapies which treat a number of rare, chronic conditions including primary immunodeficiency diseases, chronic inflammatory demyelinating polyneuropathy; hereditary angioedema; and bleeding disorders, such as hemophilia.

Federal law[2] requires our members to test each donation for evidence of HIV, HBV, and HCV. They also collect a sample every four months to test for syphilis and to determine the immunoglobulin composition.[3] These tests are not performed at the donation center. The samples are sent to other laboratories to perform these non-diagnostic donor screening tests.

Recently, New York has taken steps to harmonize state law with federal law regarding Source Plasma donation. Section 10 NYCRR 58-2.14 was changed by rulemaking process to harmonize

[1] 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.
[2] 21 CFR 610.40
[3] 21 CFR 640.65

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regulations with federal law. The Legislature went further and passed legislation to alter existing rules and regulations surrounding Source Plasma donation centers to meet FDA standards. The legislation removed Source Plasma donation centers from the CLEP program and the definition of a blood bank. The Source Plasma legislation was signed into law by Governor Hochul in December 2021 and February 2022. Our members have had discussions with your Department and have been told that the changes codified to date relate only to tests performed at the Source Plasma donation centers.

If this is true, then we have a problem with tests described above since they are not performed at the donation center, but they are part of the federal regulations governing Source Plasma donation. The samples are sent to labs that we are being told must have a lab supervisor with a licensed medical technologist with 6 years' experience (10 NYCRR § 58-1.4) and lab testing personnel must meet NYS qualifications for medical technologists OR work in entirely exempt laboratories (Public Health Law § 579; 10 NYCRR § 58-1.4).

Medical technologists are an increasingly rare commodity in today's job market. The number of educational programs offering medical technologist degrees and training is steadily diminishing nationwide. Qualified personnel are less inclined to constrain themselves to a testing laboratory and/or supervisory role, rather than more lucrative (or rewarding) opportunities in the broader health care ecosystem. Most states require neither a medical technologist nor a medical technician degree for the laboratory supervisor role (or laboratory testing personnel) that plays an integral role in supporting plasma donation centers.

This change in the healthcare landscape is reflected in the Executive Order Governor Hochul issued in September declaring a statewide emergency due to healthcare staffing shortages that expanded the scope of care for some professionals, enabling them to help New Yorkers in urgent need. Additionally, in her State of the State, it was announced that Governor Hochul will propose legislation to modernize clinical laboratory supervisory requirements.

PPTA respectfully requests that you issue a rule that will clarify that the labs used for donor screening tests need only meet federal standards which is consistent with the recently codified rulemaking and enacted legislation in New York. We ask that given the emergent need for Source Plasma donations,[4] that you consider using the emergency rule making process.

Clinical laboratory requirements have evolved out of the need to ensure diagnostic testing is performed in a way that assists in patient care. Our members do not perform tests for patient care. These are non-diagnostic tests that are performed for donor screening purposes. If a donor's sample tests positive for a communicable disease, the donor is deferred from further donation, and they are recommended to see a physician. If the donor goes to a physician's office, the physician will surely order a diagnostic test. Therefore, the exempting of our labs will not impact patient care for New Yorkers.

Please know that this narrowly tailored carveout – from the State's current requirements for a clinical laboratory supervisor (10 NYCRR § 58-1.4) and laboratory testing personnel (Public Health Law § 579; 10 NYCRR § 58-1.4) – that we are seeking is truly needed and if granted, this reform will enable the Source Plasma sector to grow substantially in New York. And, this growth is necessary so that the growing demand for life saving plasma derived therapies can be met. As you are probably well aware, the protracted COVID-19 pandemic has unfortunately had a very

[4] https://www.wsj.com/articles/block-on-blood-plasma-donors-from-mexico-threatens-supplies-11646830295

pronounced and adverse impact on plasma donation nationwide; however, New York is now in a meaningful position to do its part to mitigate this vexing problem by enabling the substantial growth of this vital sector statewide.

Please know that by seeking this further limited reform that we are not looking to diminish or weaken the Department's crucial regulatory oversight authority whatsoever or compromise quality or safety standards in any way. Across the industry, the sole focus of these testing laboratories is the non-diagnostic analysis of plasma samples and specimens collected at Source Plasma donation centers located across the nation.

Many patients who live in New York and are living with rare or ultrarare diseases currently benefit from the life sustaining plasma-derived therapies that are produced with plasma that has likely been donated elsewhere in the United States given the very limited number of Source Plasma donation centers currently situated in New York. Notably, the plasma used to make these vital therapies has been carefully inspected at industry testing laboratories which are subject to the oversight authority of New York State's Department of Health and other regulatory agencies such as the U.S. Food and Drug Administration (FDA), Centers for Medical and Medicaid Services (CMS), Clinical Laboratory Improvement Amendments (CLIA) and the European Medicines Agency (EMA).

In closing, please know how profoundly grateful PPTA is for all that the New York State Department of Health has done over the last few years to modernize the regulatory landscape governing the source plasma sector. I can be contacted at (443) 994-0900 or by email at bspeir@pptaglobal.org if you have any questions.

Sincerely,

Bill Speir
Senior Director, Lead for U.S. Regulatory Policy

cc:

Angela Profeta, Deputy Secretary for Health
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Michael Ryan, Associate Director of Regulatory Affairs