

March 17, 2020

The Honorable Seema Verma
Administrator Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW Washington, DC 20201

Dear Administrator Verma,

I am writing to ask for your consideration as the Centers for Medicare and Medicaid Services explores avenues to protect vulnerable patient populations during the COVID-19 pandemic. The Plasma Protein Therapeutics Association (PPTA) is the standard setting and global advocacy organization that represents plasma donation centers and manufacturers of plasma protein therapies. Our membership accounts for approximately 80 percent of plasma therapies in the United States. These therapies treat individuals with rare, chronic, and life-threatening conditions, such as immune deficiencies, certain neurological diseases, alpha-1 antitrypsin deficiency, and bleeding disorders.

Patients who rely on plasma protein therapies have expressed concern of exposure to coronavirus in the hospitals and physician offices where they must obtain and infuse their therapies. Due to their conditions, these patients often lack protective proteins found in healthy individuals, and therefore are uniquely at risk in settings where COVID-19 might be present. For example, patients who have impaired lung function because of the absence of the tissue-protective alpha-1 antitrypsin protein are more susceptible of contracting serious infections or complications if exposed to COVID-19 than the general population.

While hospitals and physician offices have historically been acceptable, although not ideal, care environments, they now represent a potential threat with lethal outcomes for these vulnerable individuals. Patient advocacy organizations have expressed concerns and requested special consideration¹ by CMS to be able to obtain and infuse their life-saving therapies at home, providing a safer environment at this time.

PPTA supports the request of the Alpha-1 Foundation and protections that allow home infusion of plasma protein therapies for patients being treated for other immune system deficiencies. We urge the agency to take measures that will allow for home infusion during these extraordinary COVID-19 pandemic circumstances, including but not limited to waivers as described in CMS news release dated March 13, 2020. PPTA is ready to help CMS in any way we can to ensure continued and safe access to life-saving plasma protein therapies used by vulnerable patient populations.

Sincerely,



Amy Efantis
President and CEO