

## Single Source Provider Contracts Restrict Consumer Choice and Compromise Patient Health

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### Summary

“Single source provider” contracts for the provision of life-saving plasma protein therapies to beneficiaries within state run health care programs, including those with entities participating in the federal 340B drug discount program, limit access to all providers<sup>1</sup> and have the potential for limitations on access to all therapies. Any restriction on access to providers or therapies compromises patient health, restricts consumer choice, and potentially violates federal law. A Medicaid recipient with a life-threatening chronic condition treated by plasma protein therapies, such as hemophilia and primary immune deficiencies, should not have access to the provider or life-saving therapy of their and their physician’s choice limited via a contract between the state and a single provider.

### About PPTA

The Plasma Protein Therapeutics Association (PPTA) is the primary advocate for the world’s leading producers of plasma protein therapies. Plasma protein therapies treat unique, life-threatening diseases and disorders. Life-saving therapies produced by PPTA members include blood clotting factor therapies for individuals with hemophilia and other bleeding disorders, immune globulin intravenous (IGIV) for the treatment of primary immune deficiencies and complex neurological disorders, and therapies for individuals who have Alpha-1 antitrypsin deficiency which typically manifests as adult onset Chronic Obstructive Pulmonary Disease (COPD) and substantially limits life expectancy.

### Background

In an attempt to control state Medicaid prescription drug expenditures, Arizona and Utah have entered into contracts with one organization (in each state) for the provision of blood clotting factor therapies (in these cases, the state contractor is a “covered entity” under the federal 340B drug discount program). In those states, Medicaid beneficiaries with hemophilia MUST obtain their life-saving blood clotting factor therapies only from the state contractor. In New York and Georgia one private organization in each state has become the *de facto* single source provider of blood clotting factor although they do

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<sup>1</sup> For purposes of this Issue Brief, the term provider refers to a full service home care provider, mail order pharmacy, 340B program, hospital pharmacy or other dispenser of plasma protein therapies.

not have a formal contract with the state Medicaid agency. In Louisiana, the Department of Health & Hospitals operates its own pharmacy that serves as the provider of factor to individuals in the Medicaid program. Other states (including Massachusetts, Minnesota and West Virginia) have also attempted, or are attempting, to implement similar single source provider programs, some with 340B “covered entities”, others with commercial providers.

Currently, beneficiaries in state-run health care programs in other states have the ability to obtain their plasma protein therapies from “any willing provider” that is a participating provider in the state’s Medicaid program.

### **Arguments Against Single Source Provider Contracts**

- 1) Limitations on choice of provider may lead to limitations on choice of therapy** – The provider that enters into a single source provider contract with the state must enter into a further contract of its own with the manufacturers, wholesalers, and distributors to purchase the needed therapies and medications. When this occurs, the provider may decide to provide beneficiaries with only certain therapies based upon cost considerations.

While federal law requires that all drugs are available, and technically all therapies may be available, the provider may “steer” a patient toward certain lower cost, or higher “spread” therapies. In addition, when a physician does not write a “branded” prescription (as is often the case), the provider may dispense the lowest cost or highest spread therapy at their discretion without regard for what is most appropriate for the patient.

- 2) Plasma protein therapies are not interchangeable** – Some providers may believe that all plasma protein therapies in a specific class are interchangeable, and that they can substitute one therapy for another without having any impact on the patient. However, they are not. No two brands of clotting factor, IVIG, or Alpha-1 proteinase inhibitor are pharmaceutically or therapeutically equivalent. Each branded therapy has been approved by the federal Food and Drug Administration (FDA) for distinct clinical indications. There are currently no generic substitutes. Different therapies are appropriate only for specific populations, and may require different dosages and regimens. The effectiveness of specific therapies may vary with different populations or with specific individuals.
- 3) Single source provider contracts will require that many patients switch providers** – Some Medicaid beneficiaries may have been utilizing the services of their current provider for many years. At birth, many families invite providers into their home to teach appropriate therapeutic preparation and infusion techniques. When a child is old enough, a home health care provider teaches the individual how to self-infuse. These personal relationships contribute greatly to the overall quality of care. Requiring that Medicaid beneficiaries utilize the services of a single provider that has a state contract can disrupt these relationships and negatively impact on the overall quality of care.

- 4) Not all providers offer the same level of service** - The life-long relationships that are built between a patient, his physician, his provider, and all others in the care system contribute significantly to the successful treatment of these life-threatening diseases.

The providers of plasma protein therapeutics do not offer just therapies. Instead, they provide a wide range of other services that significantly improve the quality of life for an individual with a life-threatening disorder. These additional services include home nursing services, 24-hour telephone access to disease management consultants and social services, waste pickup, medical jewelry, helmets and padding, advance notice of product withdrawals and recalls, camp sponsorships and social services.

Many of these services are provided to beneficiaries at no cost to the beneficiary or to the state Medicaid program. If only one provider were authorized to provide therapies to Medicaid beneficiaries, it is not likely that personal relationships would be at the center of their program. In addition, it is not likely that the single provider would make additional services available to participants in the program. In fact, it is likely that the selected vendor will choose to not make these additional services available.

- 5) 340B law requires the establishment of a physician-patient relationship** - Not all individuals with the conditions treated by plasma protein therapeutics are patients at the hemophilia treatment centers, hospitals, or community health centers that are “covered entities” under the 340B program. They may be seen by private hematologists, immunologists, and other specialists.

However, federal law requires that a person have a patient relationship with a “covered entity” in order for the entity to provide/sell them drugs obtained at a discount from manufacturers under the federal 340B program. If a state Medicaid program were to enter into a single source provider contract with a 340B “covered entity”, those patients that are not currently patients of the 340B entity will need to establish a physician-patient relationship with the entity in order to have access to the entity’s discount drugs.

- 6) 340B “Covered Entities” may be a provider for Medicaid patients, but not the sole provider** – All manufacturers, distributors, and providers of plasma protein therapies should be permitted to provide therapies to Medicaid beneficiaries. Individuals with life-threatening conditions should not have their choice of provider limited simply because they are participants in the Medicaid program.

## **Summary**

A Medicaid recipient should not have his or her choice of therapies or providers restricted simply because he or she is a Medicaid recipient, or simply because he or she suffers from a chronic illness. Decisions on which therapy a patient receives, and which provider they receive it from, should not be based solely on cost or budgetary considerations. These decisions should be made by the prescriber and should not violate the sanctity of the physician-patient relationship. An individual with hemophilia, primary immune deficiency disorder, or alpha-1 antitrypsin deficiency should have access to the full range of plasma derived and recombinant therapies from the provider of their and their physician's choice.

Individuals with the life-threatening conditions treated by plasma protein therapeutics need options in pharmacy and the delivery of home supportive services. Besides mail order pharmacies, and 340B prescription drug distribution programs patients need full service provider options as well. Having only one pharmacy option available is not acceptable. The type of home supportive services that a patient needs is a medical decision and is best made by the physician and patient, not a payer.

## **PPTA's Request**

PPTA urges that state-run health care programs not enter into single source provider arrangements for the provision of life-saving plasma protein therapies. This will ensure that individuals with life-threatening conditions continue to have access to the full range of life-saving plasma derived and recombinant analog therapies from the provider of their and their physician's choice.