

May 30, 2008

Reference No: SASC08049

VIA HAND DELIVERY

The Honorable Patty Berg
Chair, Assembly Budget Sub-Committee #1
State Capitol, Room 4146
Sacramento, CA 95814

RE: Proposed Budget Trailer Bill Language

Dear Assembly member Berg:

Plasma Protein Therapeutics Association (PPTA) is very concerned regarding proposed trailer bill language (“the trailer language”) which would authorize the Department of Health Care Services (DHCS) to enter into exclusive and nonexclusive contracts with providers of blood factor products, as well as provide authority to DHCS to develop a potentially restricted formulary should DHCS fail to collect additional rebates from manufacturers of blood clotting factors that participate in the California Children’s Services Program, the Genetically Handicapped Person’s Program (GHPP), and Medi-Cal. PPTA strongly urges that state-run health care programs not enter into single source provider arrangements. Moreover, PPTA strongly believes that both of these measures, if adopted, would severely impact open access to the life-saving plasma protein therapies that patients need to lead healthy and productive lives.

California has traditionally been a leader in ensuring that persons with bleeding disorders have open access to the full range of life-saving plasma protein therapies and their recombinant analogs. We applaud California’s leadership in this area and respectfully urge you to reconsider the above proposals.

We believe that the trailer language could threaten open access to life-saving treatments for individuals with bleeding disorders, such as hemophilia. Hemophilia is a genetic, chronic disease which, if left untreated, can result in permanent joint damage and crippling arthritis. Treatment options for hemophilia have progressed significantly over the past couple of decades. Specifically, with the production of highly purified blood clotting factors, people with hemophilia and other bleeding disorders have the opportunity to lead healthy lives.

Supplemental Rebates

On the question of negotiated supplemental rebates in the GHPP program, PPTA opposes that approach. Despite the fact that California is in a budget crisis, PPTA believes that imposing such rebates in government programs can adversely affect

access to patient care. Specifically, supplemental rebates may lead to an inability to access care from certain providers as well as difficulty accessing certain therapies.

Although federal Medicaid statutes allow California to exclude a product from coverage where it can show the product “does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other products in the formulary, under the trailer language, the sole criterion for formulary coverage is cost. Accordingly, this approach may violate the applicable Medicaid statute. It also runs counter to the central message of the National Hemophilia Foundation’s Medical and Scientific Advisory Council’s (MASAC) Recommendation #159 that states, ...“clotting factor therapies are neither pharmacologically nor therapeutically equivalent” and that limitations on use of products for purposes of cost containment are not supported by present clinical practice.

Furthermore, any potential prior authorization provision must satisfy federal Medicaid requirements that protect patient access to needed medications during the prior authorization process. It is well established that access to the full array of therapies from qualified treaters is conclusively linked to achieving the highest quality patient care. See *generally*, Baker, et al, “**A Model for a Regional System of Care to Promote the Health and Well-Being of People with Rare Chronic Genetic Disorders**”, **AMERICAN JOURNAL OF PUBLIC HEALTH**, November 2005, Vol. 95, No. 11, 1910-16.

Sole Source Arrangements

Blood clotting factors are high impact and high value therapies. In order for a person with a bleeding disorder to maintain a quality, active life; access to treatment is essential. Blood clotting factors are not a “one-size-fits-all” therapy. Blood clotting factors are biologics and throughout a person’s life their body may change and therefore respond differently to one brand or another. It is for this reason that PPTA objects to the trailer language which would allow the State to enter “into exclusive and nonexclusive contracts on a bid or negotiated basis...” PPTA is concerned that these types of arrangements could represent an approach that ultimately intends to avoid covering certain manufacturer products and therefore violate California’s obligation to cover the products of manufacturers who participate in the Medicaid Rebate program. Please be reminded that according to the Hemophilia Council of California, similar language was rejected by the State Legislature several years ago because it was acknowledged that sole source arrangements limit choice of providers of clotting factor to patients in California.

California should reconsider the approach of looking at exclusive provider type arrangements. Each of the reasons set forth below is aimed at protecting access for patients.

- 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 further arrangements 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 various considerations.

While federal law requires that all FDA approved drugs are available, and technically all therapies may be available, the provider may choose to “steer” a patient toward certain lower cost therapies. In addition, when a physician does not write a “branded” prescription (as is often the case), the provider may dispense the lowest cost therapy at their discretion without regard for what might be 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. Specifically, no two brands of clotting factor are pharmaceutically or therapeutically equivalent. Each branded therapy has been approved by the FDA for distinct clinical indications. There are no generic substitutes. Different therapies are appropriate only for specific populations, and may require unique dosages and regimen depending upon patient characteristics.
- 3) **Single source provider contracts may require that many patients switch providers** – Some Medi-Cal 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 Medi-Cal 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) **Hemophilia Treatment Centers should be a provider for Medi-Cal patients, but not the sole provider** – All manufacturers, distributors, and providers of plasma protein therapies should be permitted to provide therapies to Medi-Cal beneficiaries. Individuals with life-threatening conditions should not have their choice of provider limited simply because they are participants in the Medi-Cal program.

Background

PPTA is the primary advocate for the world’s leading producers of plasma protein therapies and their recombinant analogs (“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 emphysema and substantially limits life expectancy. PPTA member companies provide more than 80% of the plasma protein therapies used in the United States today. PPTA member companies include: Baxter BioScience, Biotest, CSL Behring, Grifols, Octapharma, and Talecris Biotherapeutics.

PPTA appreciates the opportunity to provide comments on the trailer language. We would like to reiterate that although California is faced with a budget crisis; putting a fragile patient population at risk of not receiving necessary access to lifesaving therapies is not an appropriate solution. Should you have any questions or if you require additional information, please do not hesitate to contact me.

Sincerely,



Ryan M. Faden, J.D., M.P.H.
Assistant Director, State Affairs