

December 21, 2007
Reference No.: SASC07078b

VIA FIRST CLASS MAIL

Mr. Albert Hawkins
Executive Commissioner
Texas Health and Human Services Commission
Brown-Heatly Building
4900 N. Lamar Blvd.
Austin, TX 78751-2316

Dear Mr. Hawkins:

The Plasma Protein Therapeutics Association (PPTA) would like to commend you on the bold initiative proposed in your health care reform concept paper. The idea of using special Medicaid payments to fund primary and preventative care is both innovative and visionary. The country will certainly closely watch the outcomes of this waiver project.

PPTA is the trade association and standard setting organization for the world's major producers of plasma derived and recombinant analog therapies (collectively, "plasma therapies"). These therapies are used by over 1,000,000 worldwide each year to treat a variety of diseases and serious medical conditions. PPTA members produce over 80 percent of the plasma therapies for the United States market and more than 60 percent worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, immune globulin intravenous used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitor (A1PI) used to treat people with alpha 1 antitrypsin deficiency, also known as genetic chronic obstructive pulmonary disease (COPD).

PPTA appreciates this opportunity to comment on the concept paper. Providing healthcare to the uninsured is a laudable goal and one that we support, but we are concerned with the potential impact of program changes on patients with rare, chronic diseases and disorders such as hemophilia and primary immune deficiency disorder. Any time an initiative as large as the one under consideration here is implemented there is concern about patients' continuity of care.

Patients who rely on plasma therapies to live are a unique group of individuals. They work closely with their doctors and their pharmaceutical provider to ensure they have the plasma therapy that is right for them. The concept paper is silent about the ability of patients to retain their current plasma therapies and outpatient prescription drugs and biologics generally, and providers when entering the program. PPTA would recommend allowing patients to continue using their current providers and therapies when they enter

the program. To do otherwise could result in severe negative impacts to a patient's health condition.

Plasma therapies are not interchangeable and each therapy has been approved by the federal Food and Drug Administration for specific clinical indications. These are branded therapies, with no generic substitutes. Different therapies may require different dosages and regimens, and may be appropriate only for specific populations. Further, the effectiveness of particular therapies may vary with different populations or with specific individuals.

PPTA is concerned about the potential impact of the cost-sharing requirements and the annual benefit limit on access to care and continuity of care. The concept paper states on page 17 that patients will be subject to cost-sharing requirements at rates comparable to commercial health benefit plans. These cost-sharing requirements are much greater than standard Medicaid cost-sharing. These additional out-of-pocket costs could result in cost sharing becoming a barrier to a patient's access to care. Further, the concept paper mentions on page 13 that enrollment will be revoked should an individual fail to pay necessary cost-sharing obligations and the individual will be subject to a six-month waiting period before participating in the program again. This penalty may result in patients choosing to forgo care when they need it but cannot pay the associated out-of-pocket costs rather than losing their insurance for six-months.

The annual benefit limit (concept paper Attachment D) may also have the unintended effect of patients limiting their utilization of otherwise medically necessary care to maintain coverage. The concept paper does not state what the limit will be, but individuals with rare, chronic disorders will need an annual limit that takes into account the high cost of their treatment.

If patients choose to limit their utilization because of the annual benefit limit or the cost-sharing requirements, the result could involve unnecessary pain and suffering. Consider a patient with hemophilia choosing to forgo appropriate usage of plasma therapies. The result may be painful and crippling injury to a patient's joints and organs. The treatment for the inevitable complications will result in trips to the emergency room and possible admission to the hospital.

PPTA is also concerned about the cost containment strategies that private insurers may implement when treating patients receiving coverage under the proposed program. The concept paper does not specifically mention if these private entities are limited to cost-sharing and annual limits. Often private insurers will implement prior authorization, preferred drug lists, single source contracts and life-time maximums to control growth in health care spending. These strategies may protect a corporate bottom line, but such strategies may also result in the denial of medically appropriate care.

PPTA believes appropriate care is dependent upon open access to quality care. To this end, we would like you to consider a system that guarantees patients access to their current providers as well as plasma therapies with a product-specific reimbursement methodology.

The Texas Bleeding Disorders Advisory Council was created during the last legislative session to advise on issues that affect the health and wellness of persons living with bleeding or clotting disorders. PPTA would suggest using this advisory body as a resource in guiding care management decisions with respect to the treatment of patients in the Medicaid waiver.

Once again let us commend you on this proposal that has enormous potential to provide health benefits to a population that desperately needs it. PPTA is willing to act as a resource for you as you develop the details of this dynamic plan. Should you have any questions, or if you require additional information, please do not hesitate to contact me at (443) 433-1110 or by email at bspeir@pptaglobal.org.

Sincerely,

Bill Speir
Manager of State Affairs

cc:

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