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November 25, 2012

VIA EMAIL AND U.S. MAIL

Mr. Michael Watson
Director of Medical Assistance
State of North Carolina, Department of Health and Human Services
1985 Umstead Drive, 2501 Mail Service Center
Raleigh, NC 27699-2501

RE: Proposed Policy 9B, Hemophilia Specialty Pharmacy Program

Dear Director Watson:

The State Patient Access Coalition (SPAC) appreciates this opportunity to comment on the North Carolina Division of Medical Assistance's Hemophilia Specialty Pharmacy Program draft policy (hereinafter "draft policy"). SPAC represents the world's leading manufacturers and the nation's leading distributors of blood clotting factor. Blood clotting factors are lifesaving therapies for individuals with bleeding disorders, such as hemophilia and von Willebrand Disease.

SPAC was created to address issues of patient access to blood clotting factor and to educate policy makers about the unique processes required to manufacture and dispense this vital therapy. SPAC advocates for sound policies related to the purchase, dispensing and administration of blood clotting factor therapies.

SPAC has reviewed the draft policy. We have a few concerns that we would like to address.

Least Costly Alternative

We are particularly concerned with the language in subsection 3.1(b). We believe it is contrary to quality patient care for individuals with hemophilia and would request its removal from the final policy. The section states, "Procedures, products, and services related to this policy are covered when they are medically necessary and ... (b) *the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide.*"

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|------------------------------|---------------|--------------------|----------------|---|
| ■ Accredo Health Group, Inc. | ■ Biogen Idec | ■ Curascript, Inc. | ■ Novo Nordisk | ■ Plasma Protein Therapeutics Association |
| ■ Baxter Healthcare Corp. | ■ CSL Behring | ■ CVS Caremark | ■ Pfizer | ■ Walgreens |
| ■ Bayer Healthcare | | ■ Grifols USA | | |



Step-Therapy

We are concerned that subsection 3.1(b) is step-therapy language. The language may be read to allow the state to require a patient to fail on a “*less costly treatment*” to prove there is “*no equally effective*” product. Our concern is that implementation of a restrictive formulary for blood factor therapies would be contrary to the well established medical principle that access to a full array of therapies 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. Blood factor therapies are high value, high impact therapies used to treat rare conditions among very fragile populations.

We have serious concerns where the sole criterion, or even a primary criterion, of appropriate blood factor therapy is cost, because these therapies are not interchangeable. Decision-making based on cost alone runs counter to the central message of the National Hemophilia Foundation’s Medical and Scientific Advisory Council’s (MASAC) Recommendation #159 that states, ... “[blood] 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. MASAC is a leading authority on care for individuals with hemophilia and other bleeding disorders.

Prior Authorization

North Carolina General Statutes § 108A-68.1. prohibits the implementation of a prior authorization review for blood clotting factor. The review process in subsection 3.1.(b) that considers whether, “*no equally effective and more conservative or less costly treatment is available statewide*” would probably require a prior authorization process. Therefore, we suggest that the language in subsection 3.1.(b) is contrary to North Carolina law.

Sole-Source Specialty Pharmacy

We are concerned that subsection 3.1(b) is sole-source specialty pharmacy language. This language may be read to allow the state to require a patient to receive services from a specialty pharmacy or 340b provider that may “*safely furnish*” product in a “*less costly*” manner. We are well aware of the continued financial difficulties facing North Carolina and other states across the county that are necessitating creative cost containment approaches to save on state budgeted health care costs. However, we respectfully do not believe that requiring individuals to obtain clotting factor therapies through a single provider is the best way to accomplish that goal. Unfortunately, this type of arrangement has the potential to restrict patients’ overall access to care which



could ultimately lead to higher health care costs rather than the savings the state may be contemplating in this proposal.

Recommendation

We share your goal of providing North Carolina residents access to high quality health care. For the reasons explained above, we believe the language in subsection 3.1(b) of the draft policy is contrary to that goal and also contrary to North Carolina law. We would recommend its removal from the final policy.

Reporting Requirements

There are numerous reporting requirements in the draft policy. It is our understanding that the reporting requirements will apply to all specialty pharmacy providers, including hemophilia treatment centers. If this is not the case, please let us know. We also recommend working with the specialty pharmacies to streamline the reporting requirements to minimize the administrative burden of the reports.

We appreciate your consideration of our concerns and would welcome the opportunity to discuss them with you further. Should you have any questions or require additional information please do not hesitate to contact me at: bspeir@pptaglobal.org or (443) 433-1110.

Best Regards,

A handwritten signature in black ink that reads "Bill Speir". The signature is written in a cursive, flowing style.

Bill Speir

cc: Ms. Lisa Weeks, PharmD, RPh
Chief, Pharmacy and Ancillary Services
NC Division of Medical Assistance