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March 1, 2013

Reference No. SPAC 13005

VIA EMAIL and U.S. Mail

**Sheri Dolan, BS Pharm.**

Bureau of Pharmacy Services  
Department of Healthcare and Family Services  
607 East Adams Street, 4th Floor  
Springfield, IL. 62701

RE: Illinois Medicaid's Actions May Negatively Impact Patients

Dear Ms. Dolan:

We are writing to you on behalf of the State Patient Access Coalition (SPAC). We are concerned that actions related to Medicaid pharmacy reimbursement for blood clotting factor will cause access issues for Illinois Medicaid recipients with bleeding disorders. Of concern are the two recent reimbursement reductions for clotting factor, the reduction of the dispensing fee, and the lag in payments that require specialty pharmacies to wait more than 200 days for payment for blood clotting factor. We request an opportunity to discuss a repeal of the rate reductions until a further review of the impact on patient access has been completed.

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 inform policy-makers about the unique process to manufacture and dispense this vital therapy. SPAC works to ensure that once educated, policy-makers will make sound decisions on policies that affect the purchase, dispensing and administration of blood clotting factor therapies.

- ◆ Accredo Health Group
- ◆ Baxter Healthcare Corp.
- ◆ Bayer Healthcare
- ◆ Biogen Idec
- ◆ BioRx
- ◆ CSL Behring
- ◆ CVS Caremark
- ◆ Express Scripts
- ◆ Grifols USA
- ◆ Kedrion Biopharma
- ◆ National Cornerstone Healthcare Services
- ◆ Novo Nordisk
- ◆ Plasma Protein Therapeutics Association
- ◆ Walgreens



One of the events that led to the creation of the SPAC was the release of the American Medicaid Pharmacy Administrators Association's white paper recommending average acquisition cost (AAC) as the new benchmark for Medicaid pharmacy reimbursement. SPAC members were concerned that if states implemented an AAC without addressing the dispensing fee for specialty pharmaceuticals, then there could be serious patient access issues. It appears that Illinois Medicaid is implementing an AAC while actually reducing the dispensing fee.

Illinois Medicaid has essentially implemented an AAC with the state maximum allowable cost (SMAC) reimbursement for blood clotting factor. Illinois Medicaid has changed the SMAC twice in the last six-months (10/18/12 and 1/1/13). Prior to the SMAC reductions, Illinois Medicaid implemented an emergency rule that reduced the dispensing fee from \$3.40 to \$2.40. This has created a situation where Illinois is the only state we know of reducing their ingredient cost while reducing their dispensing fee.

We understand the state's need to manage their resources when it comes to purchasing health care services through your state Medicaid program, but we are concerned that the new reimbursement rates do not take into account the extraordinary activities that are required of specialty pharmacies in dispensing blood clotting factor. They include:

- Increased education by pharmacist regarding mixing, storage and proper use to prevent waste and unnecessary costs
- Monitoring of bleeds and usage of product to avoid stockpiling
- Emergency delivery and 24 hour on call support by nurses, pharmacists, and support staff trained in bleeding disorders (which can avoid costly ER visits and hospitalizations.)
- Case management services to evaluate and promote adherence to variable and at times complex dosing guidelines as well as to facilitate patient access to care for co-morbidity or complications.
- Monitoring and reporting adverse drug reactions
- Specialized distribution channels and delivery requirements, including emergency delivery and temperature controlled shipments with proof of delivery
- Notification of product recalls and withdrawals
- Inventory management of products with variable assays to minimize waste and cost of excess product usage (assay management)
- Warehouse storage and facility costs for stocking product
- Medically necessary nursing services, including the administration of clotting factor therapies
- Medically necessary ancillary supplies, including IV start kits, dressings, needles,



pumps, tubing, and waste disposal services

As is outlined above, dispensing blood clotting factor requires enhanced services and activities that vary greatly from those performed by a typical retail pharmacy. In most cases, these services are unique even in comparison to other products sold by a specialty pharmacy. We also believe they meet the definition of dispensing fee in section 42 C.F.R. 447.502, and should be considered when determining if the dispensing fee is reasonable as required by 42 C.F.R. 447.512.

In addition to the SMAC reductions and the dispensing fee reduction, some of our members have been told that there is a policy in place to pay claims 51-weeks after they have been submitted. This appears to be true given some of our members have unpaid claims for blood clotting factor that was provided more than 10 months ago. The cost of blood clotting factor for a single patient averages \$100,000 a year. Section 1902(a)(30)(A) of the Social Security Act requires state Medicaid agencies to “assure that payments are consistent with efficiency, economy, and quality of care.” A policy that requires specialty pharmacies to wait up to a year for payments of these amounts is not efficient, economical nor the kind of policy that will assure quality of care.

It is well documented that blood clotting factor therapies provide an increased quality of life for patients with bleeding disorders and result in long-term savings for patients, providers and payers. Reimbursement proposals that hinder patient access may lead to delays in obtaining proper medical care, resulting in increased hospitalizations, joint damage necessitating surgical intervention, and long term debilitation.

We believe the new reimbursement rates may result in patients having difficulty finding qualified specialty pharmacies to service their unique needs. Because of our concerns we would ask that you repeal the rate reduction until the proper review has been completed to ensure patients have reasonable access to their blood clotting factor.

We thank you for your consideration of our concerns about Medicaid recipients’ access to their medically appropriate blood clotting factor. I am happy to answer any questions or comments you may have on the matter. I may be reached at 443-433-0900 or [bspeir@pptaglobal.org](mailto:bspeir@pptaglobal.org). We would like an opportunity to meet with you about our concerns.

Thank You,

A handwritten signature in black ink that reads "Bill Speir".

Bill Speir



cc: Ms. Lisa Arndt, Chief  
Bureau of Pharmacy Services  
Department of Healthcare and Family Services  
607 East Adams Street, 4th Floor  
Springfield, IL. 62701

Mr. Bob Robinson, Executive Director  
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Ms. Cindy Mann  
Deputy Administrator and Director  
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