



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding and clotting disorders



April 10, 2009

To Whom It May Concern:

RE: 340B Sole Source Proposal for the Provision of Hemophilia Products

The National Hemophilia Foundation (NHF) and the Bleeding Disorder Foundation of Washington (BDFW) are writing to express our **opposition to the budget proposal which would allow the Department of Social and Health Services (DSHS) to enter into a sole-source contract with a 340B provider for the provision of blood clotting factor therapies.** Sole source contracts with a 340B provider, or any other provider, have the potential to severely limit a patient's ability to access the full range of services and products, and thereby reduce their quality of care and ultimately their health.

While we understand the state's need to reduce expenditures, we do not believe a sole-source contract is the way to go when it comes to the provision of blood clotting therapies. **Hemophilia and other bleeding disorders are complex conditions, and patients have very diverse needs with regard to how their clotting factor is provided.** For example, some individuals, especially those with newly diagnosed infants or a patient recovering from surgery, may require home infusion and other services provided by nurses with training and experience in hemophilia. Patients may at times also need emergency delivery of factor on short notice, and these can include individuals who do not live near a hemophilia treatment center (HTC), which is the case for many patients living in Washington. At the same time, there may be other patients with simpler needs for whom the full range of services may not be necessary. Therefore, it is necessary that patients, including those on state run health care programs, have alternatives so that they can obtain the specific products and services they need to maintain optimal health, and avoid the potentially debilitating and costly complications that can result from less than optimal care.

We are also concerned that the proposal did not take into consideration the manner in which 340B programs are allowed to operate. 340B entities are only supposed to dispense drugs to their own patients. In fact, patients must confirm that the 340B program meets their individual needs by designating it as their chosen provider, or otherwise choose an alternate provider. This requirement is specified in the "freedom of choice" provision of the guidelines issued by the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) of the U. S. Department of Health and Human Services Administration (HHS). Moreover, this provision was designed to prevent the appearance of a conflict of interest on the part of the health care providers who also sell products, and to ensure that consumers can access the full range of medical services that are most appropriate to their individual needs. HTCs with 340B programs, in particular, are **required to document that choice of factor provider was properly explained to the patient** regardless of what choice the patient ultimately makes. Unfortunately, by using 340B pricing as the basis for provision of clotting factors for patients on Medicaid, the State will potentially be creating a virtual sole-source contract with one provider, since only a 340B program that is able to acquire clotting factor at a PHS 340B price is likely to be able to accept a 340B-based reimbursement. This will force patients to end longstanding relationships with medical staff at other facilities throughout the state that do not have 340B programs. The proposal also undermines the spirit if not also the letter of the 340B program guidelines. More importantly, by virtually eliminating all but one option, it may have the effect of removing the benefits and protections for the patients that the guideline is designed to preserve.

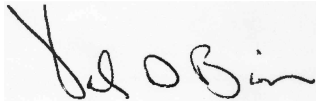
We strongly urge you and your colleagues to vote **"no"** on the sole source budget proposal for blood clotting products. As an alternate option, we recommend that DSHS work with the patient community and existing Medicaid providers to establish a better cost saving measure – one that will save the state money without limiting patient's access to much needed services.

The National Hemophilia Foundation (NHF) is the largest organization advocating for the needs of Americans affected by hemophilia and other bleeding disorders. The Bleeding Disorder Foundation of Washington (BDFW) is the state chapter of the NHF. BDFW works to improve the quality of life of Washingtonians affected by bleeding disorders and complications such as HIV/AIDS and Hepatitis.

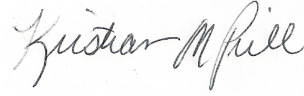
Thank you for allowing us to convey our concerns and for giving them your careful consideration. I am sure you and your colleagues in the Legislature are committed to ensuring the health and well-being of all Washingtonians, including individuals

with hemophilia and other bleeding disorders on Medicaid. Should you wish to discuss our comments further, please contact Ruthlyn Noel, NHF's Manager of Public Policy, at (212) 328-3730 or rnobel@hemophilia.org, or Tom McIntyre, BDFW, at (206) 935-3823 or tomctyre@peoplepc.com.

Sincerely,

A handwritten signature in black ink that reads "Val Bias". The signature is written in a cursive style with a large initial "V".

Val Bias
Chief Executive Officer
National Hemophilia Foundation

A handwritten signature in black ink that reads "Kristian Prill". The signature is written in a cursive style with a large initial "K".

Kristian Prill
President of the Board
Bleeding Disorder Foundation of Washington