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January 24, 2002

Jo Anne B. Barnhart
Commissioner
Social Security Administration
P.O. Box 17703
Baltimore, MD 21235-7703

Re: RIN 0960-AD67

Dear Commissioner Barnhart:

The **Hemophilia Association of the Capital Area (HACA)** is a not-for-profit organization established in 1964 that seeks to improve the quality of life for persons with bleeding disorders and their families within the Washington, D.C. region. HACA appreciates this opportunity to comment on the SSA's proposed "Revised Medical Criteria for Evaluating Hematological Disorders and Malignant Neoplastic Diseases", published at 66 Fed. Reg. 59305 (Nov. 27, 2001).

HACA wholeheartedly supports the views expressed by the National Hemophilia Foundation (NHF) in its comment letter to you of January 12, 2002.¹ HACA also strongly agrees with the comments submitted by Gentiva Health Services' A.C.C.E.S.S. Program on January 22, 2002.² HACA, like these other commenters, is concerned that SSA's proposed revisions embody some important misconceptions about hemophilia and von Willebrand disease (vWD). We believe that, if the proposed revisions are adopted, SSA's listings will exclude large numbers of people with bleeding disorders who are in fact disabled within the meaning of Titles II and XVI of the Social Security Act.

SSA's Proposed 7.00E, in conjunction with 7.03B, would require that an individual with hemophilia have at least three bleeding episodes within a 12 month period in order to fall within the disability listings. Section 7.00E would specify that there must be at least one month between each of the bleeding episodes, "to ensure that we are evaluating separate episodes".

Based on the experience of our members, HACA believes that these proposed requirements reflect an incomplete understanding of hemophilia. Bleeding episodes can be very frequent in a person with severe hemophilia; it may in fact be rare for such an individual ever to have a one-month respite between bleeding episodes.³ For this reason, HACA joins A.C.C.E.S.S. in urging SSA (at a minimum) to clarify that any interval required under proposed 7.00E pertains only to

bleeding episodes **involving a single site.**' But it is **also important** to recognize, as NHF points out, **that it** may be less **disabling for an individual to** experience **three** separate **bleeding** episodes **over** the course of a year **than a protracted or** recurrent bleed involving one area **of** the body.'

Proposed 7.00G(3) sets out criteria for documenting and evaluating bleeding **disorders in** connection with disability determinations. **HACA** supports **NHF's** comments with respect to these provisions.

Proposed 7.03B would include (in **SSA's listings** of disabling **bleeding** disorders) "hemophilia with **spontaneous** bleeding **despite prophylactic factor replacement**". **SSA's** description of this proposed revision states that

current treatment for **most individuals** with hemophilia includes **the use** of prophylactic factor replacement. Consistent **with this** treatment, we **propose to replace** the requirement for transfusions with a criterion indicating that the bleeding occurs despite prophylactic factor replacement.

This **suggests** that a person cannot **fall** within the **SSA listing** for **hemophilia unless** that person undergoes prophylactic factor replacement **and still** experiences the requisite number of **bleeding** episodes.

HACA notes **that** prophylaxis **is not** a universal treatment. Prophylaxis regimens (which in any event vary **widely from** patient to patient)" are not medically indicated **for all** hemophilia patients. Moreover, prophylactic factor replacement **is an** extraordinarily expensive therapy⁷ and, **as a result, it is unavailable** to **individuals** without generous **insurance** coverage. It **also** appears that, **to** the extent Medicaid benefits hinge **on a** determination **of disability under** the **SSA** listing, **an** uninsured, low-income individual could **wind up in a** classic "Catch-22": without **Medicaid he** could not afford prophylaxis, but without prophylaxis **he** could not **be** considered disabled under the listings and, in consequence, could be deemed ineligible for **Medicaid**. In addition, **an** ongoing severe world-wide shortage **of** clotting factor has prevented some individuals from beginning or continuing prophylactic factor replacement therapy.⁸

HACA agrees with **A.C.C.E.S.** that

[r]ather **than tying** the evaluation **of** hemophilia claims to a particular treatment [**which is** not in **any** event universally available], the better choice would be to **simply evaluate** them in terms **of** the frequency **and** severity **of** the bleeding episodes despite compliance with prescribed therapy, whatever **that** therapy **may** be.⁹

For these **reasons**, prophylactic factor replacement should not **be** considered a prerequisite to a finding **of** disability under **the listings**.

Proposed 7.03C would include **vWD** as a listed bleeding disorder, but only if an individual experiences 'spontaneous bleeding **requiring hospitalization (for 24 hours or more), occurring** at least **3** times in a consecutive 12-month period". **HACA** strongly **opposes** the hospitalization

requirement **under this section. HACA concurs with NHF that**

[t]he standard of care **for individuals with vWD, as with hemophilia, does not require** routine hospitalization. Furthermore, the **SSA recommendation goes** against shifts in our health *care* delivery **system away from** in-patient care to treatment in **an outpatient facility or at home."**

HACA recommends that the listing for vWD, like the listing for hemophilia, should instead evaluate **the severity of bleeding episodes that** occur despite **compliance with** prescribed therapy.

Proposed 107 sets forth the criteria used in determining whether children affected by bleeding disorders are eligible **for disability** benefits. **In** most respects, **proposed 107 tracks the proposed provisions for adults. HACA** therefore reiterates, with respect **to this** section, **the concerns stated above. HACA also joins NHF in objecting** to the criteria **set forth** in proposed 107.03(c) **for evaluating the level of joint deformity required in** children with bleeding disorders. As NHF describes in detail, it **is** inappropriate **to specify a level of joint deformity** for these children by **reference to the listing for juvenile rheumatoid arthritis, a wholly distinct disorder.**

Thank you for considering these comments. We hope they **will** be **useful as SSA** moves **forward to revise its listing for bleeding disorders.**

Sincerely,



**Susan Yamamoto,
President**

Endnotes

1. Letter from Mark W. Skinner, President, NHF, to Jo Anne B. Barnhart, Commissioner, Social Security Administration (Jan. 12, 2002) ("NHF letter").
2. Letter from Kim Bernstein, Director, A.C.C.E.S.S. Program, regarding proposed changes to listings for bleeding disorders (Jan. 22, 2002).
3. See, e.g., "Basic Hemophilia Statistics" provided by Hemophilia Health Services, Inc., at www.accedohealth.net (patients with severe hemophilia have estimated average of 52 bleeding episodes per year).
4. See A.C.C.E.S.S. letter at 2.
5. See NHF letter at 2. In fact, it can be just this kind of chronic bleeding that leads to degenerative joint disease in people with hemophilia. See J. Gill, J. Thometz, et al., "Musculoskeletal Problems in Hemophilia," in *Hemophilia in the Child and Adult* (3rd ed. 1989) at 28.
6. See A.C.C.E.S.S. letter at 1. Because the proposed listing does not define the term "prophylaxis," HACA shares this commenter's concern that disparate interpretations and outcomes are likely.
7. Prophylactic factor replacement therapy for a child with Factor VIII deficiency ("hemophilia A") can cost over \$100,000 per year. Because an individual's factor requirements are proportional to his body weight, the costs of prophylaxis only rise as children grow to adulthood. These costs clearly exceed almost anyone's ability to bear, without insurance; the costs of prophylaxis can also quickly exceed the lifetime caps on various insurance policies. See R.L. Bohn, J. Avorn, et al., "Prophylactic Use of Factor VIII: an Economic Evaluation," 79 *Thrombosis Haemostasis* 932 (1998).
8. See V. Furmans, "Bayer Vows to Fix Problems causing Shortage of Hemophilia Treatment," *Wall Street Journal* (Dec. 21, 2001).
9. A.C.C.E.S.S. letter at 2.
10. NHF letter at 4; similarly, see A.C.C.E.S.S. letter at 2.