



January 26 2012

Mr. Steve Larsen
Deputy Administrator and Director
Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
Re: "Essential Health Benefits Bulletin"

Submitted electronically to EssentialHealthBenefits@cms.hhs.gov

Dear Mr. Larsen:

The American Plasma Users Coalition (A-PLUS) and the National Organization of Rare Disorders (NORD) write to comment on the Essential Health Benefits Bulletin published on December 16, 2011. We are very concerned that the deference to state choices and insurer flexibility will reduce access to life-saving therapies and leave patients with rare and chronic diseases exposed to acute access and cost concerns.

A-PLUS is a coalition of national patient advocacy organizations created to address the unique needs of over 170,000 patients with rare diseases that use life-saving plasma protein therapies. The coalition represents disorders including Alpha-1 Antitrypsin Deficiency (Alpha-1), Guillain-Barré syndrome (GBS) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Hemophilia, Primary Immunodeficiency Diseases (PID) and Immune Thrombocytopenia (ITP). With continued access to needed treatments and therapies, as well as specialized medical professionals, our patients lead productive lives.

NORD represents the estimated 30 million men, women and children in the United States affected by one of the 7,000 known rare diseases, including Lou Gehrig's disease, Sickle Cell Anemia, Tay Sachs, to name a few.

With regard to state discretion to choose the benchmark plan, we are concerned that the Bulletin allows States to adopt the least generous and thus most problematic plans for patients with rare and chronic diseases. Since most health insurance plans have been created to protect acute episodic care, patients with rare and chronic diseases do not fit that model and are often required to "jump major obstacles" in order to be treated. Obstacles to care can be dangerous to patients with rare and chronic diseases and can lead to additional health care costs to treat resulting complications in the future. The lack of federally mandated benefits leaves individuals with chronic diseases with a precarious patchwork of care.

In particular, we are worried that allowing states and insurers so much flexibility will result in patients who will not have access to the treatments and the health care providers they need to lead healthy lives. For example:

- Given the rare nature of these conditions, it can be extremely challenging to receive appropriate care without seeing a specialist. In addition, treatment options may not exactly correlate with a specific EHB category. Benchmark plans offered by health insurance companies to cover EHBs may not create plan options that provide the comprehensive specialty care that is needed. How will HHS ensure that all patients can receive the care they need?
- Benchmark plans may have restrictive formularies or create specialty tiers to cover the expensive, life-saving treatments our patients need. Shifting a treatment to a tiered pharmacy benefit that relies on co-insurance – a percentage of the cost of treatment (10%, 20%, 30%)



versus a co-payment- a flat fee or dollar amount (\$10, \$20, \$30) jeopardizes the health of our patients who rely on these therapies. The treatments our patients need typically cost thousands of dollars per month. It is important to note that these products have no generic option. Under the rubric laid out by the Bulletin, how will HHS ensure that patients have access to the therapies and medications necessary to keep them healthy?

- It is not clear how claims denials can be appealed. HHS should require that the Benchmark plan have a transparent process to appeal claims denials. That process should provide assurance that the insurer must first confer with the patient's physician to discuss a possible denial and the grounds for rendering such a decision. If the insurer executes a denial, it should occur in a timely manner and must be in writing with a full and clearly understood reason for the denial. For the rare disease patient population, it may be necessary to put into place an external appeals process. (Perhaps this appeals process could be handled by the Secretary's office as a liaison to the governing body of each state's exchange.)
- A-PLUS recommends that there be a significant expansion of the medical necessity process anticipating that individuals with rare and chronic conditions may be denied access to care and will need a clear course to appeal and file grievances.
- Finally, the Bulletin is silent on many other important issues, such as whether plans will provide patients the full range of medically necessary treatment at all appropriate sites of care, and protections for continuity of care. This is of particular interest to our constituency, as many that we represent require daily, weekly or monthly infusion therapy.

We are very anxious that the states will concentrate on a benefits package focusing on relatively normal everyday health conditions and not give attention to patients with rare and chronic diseases that require long term or even lifetime treatment. Under the current health care system, patients with rare and chronic diseases are the proverbial "square pegs" being forced into "round holes". A-PLUS members and NORD expect the essential benefits package to provide a simple and expeditious pathway for patients with rare and chronic diseases to receive medical care for as long as it is needed, with the best treatment modality in the site of care most appropriate.

For further information, please contact Larry La Motte at llamotte@primaryimmune.org or 443-632-2552 or IDF, 40 West Chesapeake Avenue, Suite 308, Towson, Maryland 21204.

Thank you for your attention to this matter.

Alpha-1 Association
Alpha-1 Foundation
GBS/CIDP Foundation International
Committee of Ten Thousand
Hemophilia Federation of America
Immune Deficiency Foundation
Jeffrey Modell Foundation
National Hemophilia Foundation
Platelet Disorder Support Association
Patient Services Incorporated
And
National Organization of Rare Disorders