



January 26, 2011

Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Honorable Hilda L. Solis
Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Dear Secretary Sebelius and Secretary Solis:

The American Plasma Users Coalition (A-PLUS) is a coalition of national patient advocacy organizations created to address the unique needs of over 125,000 patients with rare diseases that use life-saving plasma protein therapies. The disorders that the coalition represents include Alpha-1, Antitrypsin Deficiency (Alpha-1), Guillain-Barré syndrome (GBS) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP); Hemophilia, Primary Immunodeficiency Diseases (PIDD) and Immune Thrombocytopenia (ITP). With continued access to needed treatments and therapies, as well as specialized medical professionals, our patients lead productive lives.

As you work to implement section 1302 of the Patient Protection and Affordable Care Act (PL 111-148) by defining “essential health benefits,” we wanted to express our concern with recent reports that the Department of Labor is not planning to write and conduct a survey specific to the reform law but instead pull data from its annual National Compensation Survey. While this survey provides some information to assist with defining “essential health benefits,” we remain concerned that the information provided within this survey will be too granular and not shed light on key issues of importance to individuals with rare diseases that use life-saving plasma protein therapies.

Specifically, we believe that the National Compensation Survey will not address key issues, such as whether current employer-based plans provide access to specialty physicians, have an appropriate transparent process to appeal claims denials, whether certain biologics are covered by a formulary (including whether the plan has “specialty tier” medications), and whether certain biologics are considered to be a pharmacy benefit or medical treatment. Therefore, we urge you to seek alternative methods by which to gain a better understanding of these key issues and how they would relate to individuals with chronic rare diseases.

While the A-PLUS Coalition is aware of specific issues related to coverage of these particular components (as outlined below), we still believe that if the Department of Health and Human Services and the Department of Labor were to examine these issues carefully, most if not all of these advocated coverage requirements would be part of a typical employer plan. And, as such, should be covered as an essential health benefit. However, if neither Department directly addresses some of these key issues, then patients will likely suffer as health plans opt to use various methods by which to control costs and not provide this essential coverage.

Specialty physicians. A-PLUS recommends that the definition of medical necessity also include access to specialty care physicians and treatment regimens determined by physicians. Our patient communities require services and care from members of the medical profession who have specialized knowledge of the diagnosis, treatment and management of their respective disorder. The A-PLUS Coalition recommends that any definition of medical necessity be expansive enough to

understand that patients respond differently to treatment and the need to access multiple treatments is imperative. A-PLUS recommends that the patient-physician relationship determine what is necessary for medical treatment plans to determine insurance coverage.

Process to appeal claims denials. The essential benefits package should always include a transparent process to appeal claims denials, as defined below. That process should provide assurance that the insurer has an obligation to 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.

Denial notices must also comply with the following:

- Any notice of an adverse benefit determination must include information sufficient to identify the claim involved, including the date of service, health care provider, claim amount (if applicable), diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning.
- The notice of adverse benefit determination not only must include the reason for the adverse determination, but must include the denial code and its corresponding meaning, as well as a description of the plan's standard, if any, used in denying the claim. The notice of denial on a final appeal must include a discussion of the decision.
- The denial must be made in a timely manner within 60 days of date of medical service.
- The plan must provide a description of available internal appeals and external review processes, including information on how to initiate an appeal.
- The plan must provide information on how to contact any applicable consumer assistance established under the Public Service Health Act to assist individuals with the claims process.

Under no circumstances should such an appeal process be used to diminish coverage by the essential benefits package. The essential benefits package should make it clear that the current practice by some insurance companies of "Coverage by Appeal" will no longer be tolerated.

Formulary coverage. Insurers may also have very limited formularies, forcing patients with chronic conditions to make a difficult decision between obtaining the more optimal treatment (and paying for it out of pocket) or switching to a suboptimal therapy or prescription regimen, which is covered by the limited formulary. While requiring patients to consider generic alternatives is appropriate in many cases, forcing patients to forego optimal treatment options for chronic rare conditions is a very short-sighted approach to patient care management and can ultimately result in avoidable disease exacerbations that require expensive hospitalizations.

Shifting medical benefits to pharmacy benefits, Some insurers have opted to move immunoglobulin and clotting factor from a medical benefit to a Specialty Tier IV pharmacy benefit in order to shift more costs to patients. Whereas patients usually share in costs by paying co-payments under their medical benefit, patients whose benefits have been shifted to Tier IV pharmacy benefits usually pay on a co-insurance basis (rather than a co-payment basis) a percentage of the cost of the treatment—which can sometimes mean 20 to 35% of the cost of a treatment.

Generally, in response to such high copayments, individuals with primary immunodeficiency diseases go without or stretch their treatment to the point of ineffectiveness. If chemotherapy was



treated as a pharmacy benefit rather than a medical treatment, it is probable that most people with cancer could not afford to receive treatment and thus would die. The same is true for patients whose use of plasma based biologics is their medical treatment. Life threatening sickness is the prospect should such patients not be able to afford the treatment that leads to health and not further sickness.

As highlighted in a recent article in the Annals of Internal Medicine, the widespread shifting of costs to patients affects the ability of patients to obtain key prescriptions. The authors of the article reported medication abandonment increased with the more money required of patients. When patients do not utilize prescriptions, they may jeopardize their health. With our patients, it is a guarantee that their health and life will be jeopardized. In addition, their medical records may be inaccurate because the information in those records will lead providers to believe that medicines are not working, when in fact they were never taken.

Especially for the chronic rare disease community, limitations on patient costs are needed on the various methodologies (deductibles, co-pays and co-insurance) are needed to assure that patients with chronic rare diseases are able to receive their life-saving treatments for the rest of their lives.

The fear in the chronic rare disease community is that an essential benefits package will concentrate on a benefits package focusing on relatively normal everyday health conditions and not paying enough attention to patients with chronic rare diseases that require long term or even lifetime treatment. Under the current health care system, patients with chronic rare diseases are the proverbial “square pegs” being forced into “round holes”. We A-PLUS members expect that the essential benefits package will provide a simple and expeditious pathway for patients with chronic rare 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 Incorporate