PLUS
AMERICAN PLASMA
USERS COALITION

December 21, 2012

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9980-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation (CMS-9980-P)

Dear Administrator Tavenner:

The American Plasma Users Coalition (A-PLUS) writes to comment on the proposed rule related to coverage of Essential Health Benefits. We appreciate the complexities and issues your department faces in implementing the Affordable Care Act (ACA). Yet, there still remain a number of serious concerns regarding how patients with rare diseases will be able to obtain medical care within the standards of care for their conditions.

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 (PIDD) and Immune Thrombocytopenia (ITP). With continued access to needed treatments and therapies, as well as specialized medical professionals, our patients lead productive lives.

Prescription Drug Coverage

Prescription Formularies

While we are pleased that the "one drug per class" minimum requirement has been changed to provide patients greater access to medications, we realize that even this more generous requirement will fail our patients with rare diseases who need blood plasma products. The proposed rule seems to focus on "quantity of drugs" rather than a specific drug's unique and therapeutic advantage. An unintended consequence could very well be an incentive to exclude effective treatments; thus violating other provisions of the ACA.

We urge you to require a robust formulary - especially for patients with lifelong rare diseases. Patients do not react to or tolerate all treatments, especially biologics such as blood plasma products, in the same manner. As just one example, the medical literature shows that forcing patients with primary immunodeficiency diseases to switch from one product to another is associated with an increased risk of mild to severe adverse reactions – including death. Patients need access to a full range of medicines. One size does not fit all!

Drugs Covered under the Medical Benefit

The proposed rule does not address drugs covered under the medical rather than pharmacy benefit, such as blood products. We respectfully request that the final rule be explicit about any minimum coverage requirements for drugs covered under the medical benefit. Also, the details on benchmark drugs CCIIO released coincident to the proposed rule does not include sufficient information on how these drugs are covered under benchmark plans today. There is information on whether classes of

medical provider-administered drugs are covered, but not how many products in the classes. Please release more information on how many drugs are covered under the medical benefit, as you have for the prescription drug formulary.

Access to Drugs Not on the Formulary

We appreciate that plans "must have procedures in place that allow an enrollee to request clinically appropriate drugs not covered by the health plan." However, there are insufficient details for what this process could entail. We appreciate HHS's desire to give states and issuers flexibility to comply with these new policies, but we respectfully request that HHS provide standards or guidelines for the appeals process so that there are not delays or disruptions that impact patient care.

Please also address whether a drug that a patient accesses that's not on the formulary counts as an EHB for purposes of the out-of-pocket maximum. Blood products of all types can be very expensive for patients, and it is critical that any spending on drugs, whether on or off the formulary, covered under the medical or pharmacy benefit, count towards an enrollee's out-of-pocket maximum.

Out-of-Network Cost-Sharing

Under your proposal, cost sharing requirements for services from a provider outside of a plan's network do not count towards the annual limitation on cost-sharing or and deductibles. Therefore, an enrollee could reach the annual limitation on cost-sharing, but still be required to pay cost-sharing if the enrollee must use an out-of-network specialist provider. The final rule must allow for access to specialty care without penalty.

A-PLUS is very concerned about the lack of protection against out-of-pocket costs for patients who receive out-of-network care. For our patients, access to specialty physicians and other clinicians is essential for their accurate diagnosis and effective treatment. Plan networks cannot include every specialist that a person with a rare condition might need nor are in-network specialists located in all geographic areas. Patients without such access are at grave risk of having their condition reach crisis stages, increasing human suffering and requiring more costly care, including avoidable hospitalization.

The inability to apply these out-of-pocket costs to annual spending limitations is especially problematic for patients like ours who must access highly-specialized care. This proposed rule would impede a patient's access to specialty care and treatment. As representatives of patient populations with complex and specialized health care needs, **A-PLUS urges you to re-consider this provision and protect all patients from exorbitant out-of-pocket expenses to access quality care.**

We thank you for the opportunity to comment on the proposed rule and look forward to the final rule ensuring the patient protections envisioned in the Affordable Care Act. If you have any questions or need further information, please contact Lawrence A. La Motte, Vice President, Public Policy at the Immune Deficiency Foundation llamotte@primaryimmune.org or 443-632-2552.

Alpha-1 Association
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