



August 27, 2010

Jay Angoff, Director
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9994-IFC
P.O. Box 8016
Baltimore, MD 21244-1850

RE: Comments on Interim Final Rules for Group Health Plans and Health Insurance Coverage Regarding Preexisting Condition Exclusions, Lifetime and Annual Dollar Limits on Benefits, Rescissions, and Patient Protections.

Dear Director Angoff:

The National Organization for Rare Disorders (NORD), and the American Plasma Users Coalition (A-PLUS) are pleased to submit comments on the Interim Final Rules for Group Health Plans and Health Insurance Coverage Regarding Preexisting Condition Exclusions, Lifetime and Annual Dollar Limits on Benefits, Rescissions, and Patient Protections under the Patient Protection and Affordable Care Act (“Affordable Care Act”), which was published in the Federal Register (Vol. 75, No. 123) on June 28, 2010.

NORD was founded in 1983 to advocate for the enactment of the Orphan Drug Act, and remains the leading advocate for the 30 million patients with the estimated 7,000 known rare diseases. The A-PLUS is a coalition of national patient organizations created to address the unique needs of over 125, 000 patients with rare diseases that use life-saving plasma protein therapies.

We are pleased to offer our suggestions and comments on the following provisions in the rules:

1. Preexisting Condition Exclusions

NORD and A-PLUS strongly support the rules eliminating the ability of group health plans or group health insurance coverage to impose preexisting condition exclusions. As you are aware, the Affordable Care Act prohibits preexisting condition exclusions for new and grandfathered group plans beginning on or after January 1, 2014, but for enrollees under 19 years of age, this prohibition becomes effective for plan years beginning on or after September 23, 2010.

NORD and A-Plus strongly believe that affordable health insurance should be available to all regardless of health status and without any exclusions or waiting periods based on a preexisting condition. Gaps in health insurance coverage due to preexisting condition exclusions are particularly devastating for patients with rare disease, who often rely completely on treatments and therapies. We appreciate that the rules clarify that the definition of preexisting condition exclusions includes the limitation or exclusion of benefits, as well as a denial of coverage.

2. Lifetime and Annual Limits

NORD and A-PLUS strongly support the rules eliminating lifetime and annual limits on the dollar value of benefits. As you are aware, the Affordable Care Act prohibits lifetime limits, and generally annual limits, on the dollar value of health benefits from being imposed by group health plans, group health insurance coverage, and individual health insurance coverage on “essential health benefits.” Lifetime limits are prohibited for all plans – both new and grandfathered – for plan years on or after September 23, 2010. Annual limits are prohibited for new plans and grandfathered group plans beginning on or after January 1, 2014. Prior to 2014, new and grandfathered group plans may impose “restricted annual limits.”

An individual can easily reach the limit in the case of a rare disease, catastrophic medical condition, or a chronic disease. People who have spending that exceed health plan limits have to find other ways to pay for medical costs, which involves a combination of paying more out-of-pocket, finding new public or private insurance sources – often through Medicaid – and curtailing medical care.

Essential Health Benefits

Under the interim final rules, for plan and policy years beginning before the Department issues regulations defining “essential health benefits,” health plans and issuers may use “good faith efforts” to comply with a “reasonable interpretation” of the term “essential health benefits.” The rules also state that health plans and issuers must apply their definition of “essential health benefits” uniformly.

NORD and A-PLUS urge the Departments to issue regulations defining “essential health benefits” as soon as possible. Without clear guidance from the Departments, plans may be able to widely vary their definition of “essential health benefits”, potentially limiting critical benefits for patients with rare diseases, chronic conditions and catastrophic illnesses. The lack of consistent, understandable definitions and messages across ALL plans will create confusion and uncertainty.

Restricted Annual Limits

NORD and A-PLUS strongly support the “restricted annual limits” set forth in the rules, but remain concerned about patients who will exceed their annual limits in the first year. Under the interim final rules, annual limits on the dollar value of “essential health benefits” may not be less than \$750,000 for plan or policy years beginning on or after

September 23, 2010 but before September 23, 2011; \$1.25 million for plan or policy years beginning on or after September 23, 2011 but before September 23, 2012; and \$2 million for plan or policy years beginning on or after September 23, 2012 but before January 1, 2014.

We appreciate the Departments' efforts to mitigate the potential for premium increases while ensuring access to critical benefits. While we support the Departments' three-year phased approach for restricted annual limits, we remain concerned that many patients who require expensive treatments and therapies will exceed the \$750,000 annual limit in the first year. Unlike people with common diseases who have many treatment options to choose from, people with rare and catastrophic diseases often rely on therapies that are more expensive than commonly-used drugs. Using the blood-clotting disorder hemophilia as an example, the average cost of treatment with anti-hemophilia clotting factor concentrates cost between \$100,000 and \$150,000. This does not take into account treatment for co-morbidities as well as any immune tolerance therapy for the development of an inhibitor which can drive treatment costs to more than \$1 million annually. We hope to work with you during the three-year phase out of annual limits to ensure that all rare and catastrophic disease patients have access to their life-saving therapies.

3. Rescissions

NORD and A-PLUS also strongly support the interim final rules regarding rescissions. Under the Affordable Care Act, health plans and issuers are prohibited from rescinding coverage except in the case of fraud or an intentional misrepresentation of a material fact. We appreciate this new Federal standard that is more protective of individuals by requiring that any misrepresentation be made knowingly, or intentionally. We also support the advance notice requirement, which requires health plans and issuers to provide prior notice for rescissions.

Thank you for the opportunity to submit comments. We look forward to working with you on the implementation of the Affordable Care Act, and ensuring that patients with rare disorders have access to quality, affordable health care.

For additional information, please contact Diane Edquist Dorman, NORD Vice President for Public Policy (ddorman@rarediseases.org) or Kisa Carter, HFA Public Policy Director (k.carter@hemophiliafed.org).

Sincerely,
American Plasma Users Coalition¹
National Organization for Rare Disorders

¹ American Plasma Users Coalition (A-PLUS) membership includes: Alpha-1 Association, Alpha-1 Foundation, Committee of Ten Thousand, GBS/CIDP Foundation International, Hemophilia Federation of America, Immune Deficiency Foundation, Jeffrey Modell Foundation, National Hemophilia Foundation, Patient Services Incorporated, Platelet Disorder Support Association