



August 6, 2010

Jay Angoff, Director  
Office of Consumer Information and Insurance Oversight  
Department of Health and Human Services  
Attention: OCIIO-9991-IFC  
P.O. Box 8016  
Baltimore, MD 21244-1850

**RE: Comments on Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as Grandfathered Health Plan under the Patient Protection and Affordable Care Act**

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 Relating to Status as Grandfathered Health Plan under the Patient Protection and Affordable Care Act ("Affordable Care Act"), which was published in the Federal Register (Vol. 75, No. 116) on June 17, 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 appreciate the efforts of the Office of Consumer Information and Insurance Oversight (OCIIO) to provide guidance on the definition and limits of a grandfathered health plan. As you are aware, the Affordable Care Act provides that certain group health plans and health insurance coverage existing as of March 23, 2010 (the date of enactment) are only subject to certain insurance reform provisions. We are very pleased that the Affordable Care Act applies the insurance reform provisions related to lifetime and annual limits, preexisting condition exclusion, and rescissions to grandfathered health plans.

NORD and A-PLUS support the conditions set forth in the interim final rule that limit a health insurance plan's ability to maintain grandfather status. We support the rights of patients to maintain their existing coverage. However, health insurers should not be

permitted to abuse the exemption for grandfathered health plans to avoid critical insurance reforms. We believe the interim final rules strikes a proper balance between preserving the ability to maintain existing coverage with the goals of expanding access to and improving the quality of health coverage.

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

## **1. Annual Limits**

The interim final rules set restrictions on the imposition of new or modified annual limits by a plan, or group or individual health insurance coverage. NORD and A-PLUS strongly support these restrictions which limit the ability of plans and coverage to impose or modify annual limits based on whether they imposed annual limits and/or lifetime limits prior to the enactment of the Affordable Care Act.

As you are aware, lifetime limits are eliminated for plans years beginning on or after September 23, 2010, while annual limits are not eliminated until January 1, 2014. Due to the delay in the elimination of annual limits, we are concerned that insurers will impose or decrease such limits to compensate for the elimination of lifetime limits. The restrictions set forth in the rules are an important step in prohibiting this practice.

## **2. Disclosure of Grandfather Status**

Under the interim final rules, a plan or health insurance coverage must include a statement in any plan materials provided to a participant or beneficiary describing benefits that the plan or coverage believes it is a grandfathered plan. The model language provided in the rules does not require plans to list and describe each consumer protection that: (i) does not apply because of the grandfather exemption, or (ii) does apply regardless of the grandfather exemption.

NORD and A-PLUS strongly believe that plans and health insurance coverage should list and describe each consumer protection affected by its grandfather status. The majority of Americans are unaware of all the consumer protections in the Affordable Care Act. According to a Kaiser Family Foundation *Health Tracking Poll* (conducted April 9-14, 2010), 55 percent of Americans feel “confused” about health reform, and 56 percent say they don’t yet have enough information to understand how health reform will affect them personally<sup>1</sup>. Given the critical importance of consumer protections, particularly for patients with rare disorders, plans should be required to list and describe all the applicable and non-applicable consumer protections in their statements.

NORD and A-PLUS suggest that the model language list all consumer protections that either apply or do not apply to grandfathered plans. For example, in addition to noting that the Employee Benefits Security Administration (EBSA) website has a table summarizing

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<sup>1</sup> See <http://www.kff.org/kaiserpolls/8067.cfm>.

which protections do and do not apply to grandfathered health plans, we recommend including the EBSA table or the table drafted by the National Association of Insurance Commissioners (NAIC) (see attached) in the model language.

### **3. Prescription Drug Formulary**

In addition to the changes identified in the rules which would cause a plan or health insurance coverage to no longer be considered a grandfathered health plan, we support the loss of grandfather status if a plan sponsor or issuer should make changes to the prescription drug formulary.

Patients with rare diseases who rely on orphan drugs and/or biologics are sometimes temporarily or permanently denied access to orphan drugs and/or biologics because plans tend to exclude them from drug formularies due to low demand and/or high cost. Orphan drugs and/or biologics that treat patients with rare diseases often represent the first or only effective treatment for an individual with a rare disease.

Changes, such as removal of an orphan drug and/or biologic, from a plan's prescription drug formulary can have a drastic impact on rare disease patients who rely on life-saving medications. These changes constitute the type of substantial change to overall benefit design that should cause a plan or coverage to lose its grandfathered status.

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](mailto:ddorman@rarediseases.org)) or Kisa Carter, HFA Public Policy Director ([k.carter@hemophiliafed.org](mailto:k.carter@hemophiliafed.org)).

Sincerely,

American Plasma Users Coalition<sup>2</sup>  
National Organization for Rare Disorders

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<sup>2</sup> 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