August 16, 2010

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: OCIIO – 9991 – IFC: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan

Dear Secretary Sebelius:

National Patient Advocate Foundation (NPAF) would like to thank you for the opportunity to submit comments on the Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act.

NPAF is a non-profit organization dedicated to improving access to healthcare services through both federal and state policy reform. Our mission is to be the voice for millions of patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained services from Patient Advocate Foundation (PAF), which provides professional case management assistance to patients. In 2009, PAF resolved 55,384 patient cases and received four million additional inquiries from patients nationally from all 50 states.

**Changes to a Prescription Drug Formulary**

NPAF would like to comment on the magnitude of changes to a prescription drug formulary that should result in a plan losing its grandfathered status. In 2009, almost 21 percent of privately insured patients contacting PAF reported pharmaceutical access/co-payment issues as their primary healthcare access issue. Over the years, PAF professional case managers have documented changes to drug formularies that result in significantly reduced prescription drug benefits and/or higher out-of-pocket spending on behalf of the patient. NPAF recommends that an insurance plan lose its grandfathered status if a patient’s out-of-pocket spending for any pharmaceutical agent increases by a cost sharing amount in excess of medical inflation.

A growing number of health plans are establishing specialty tiers for prescription drugs that treat diseases such as HIV/AIDS, cancer, and multiple sclerosis. Under the standard copayment structure, a patient may pay $55 for a $3,000 multiple sclerosis drug but is charged 25 – 33 percent in coinsurance under a specialty tier. Health plans should be limited in
their ability to create additional specialty tiers and/or their ability to move additional drugs to specialty tiers if they wish to maintain grandfathered status. In addition, health plans often use utilization management tools, such as step-therapies, prior-authorization etc., to limit patient access to newer, more expensive pharmaceutical agents. NPAF recommends that the imposition of additional utilization management tools result in a loss of grandfathered status.

NPAF recognizes the interim final rule provides that plans shall cease to be grandfathered if the plan imposes an overall annual limit on the dollar value of benefits that was not in place prior to March 23, 2010. However, NPAF recommends that a plan lose grandfathered status if they impose an annual limit on the dollar value of prescription drug benefits which was not in place prior to March 23, 2010. For plans with annual limits prior to March 23, 2010, NPAF recommends those plans shall lose grandfathered status if they decrease the dollar value of the annual limit.

Elimination of Benefits
NPAF recommends that guidance should clarify that access to treatments (drugs, biologics, surgeries, etc) for illnesses including cancer should include access to off-label uses consistent with the standards in the Medicare and Medicaid programs that ensure such off-label uses are evidence-based.

Changes to Provider Network
NPAF recommends additional guidance in order to clarify that grandfathered plans must maintain a robust network of providers as required in PPACA for plans operating in the exchanges. Reducing the network of providers generally or limiting access to certain specialists should be prohibited in order for a plan to maintain grandfathered status. An appropriate balance among providers must be guaranteed by the grandfathered plan.

Coverage of Routine Patient Care Costs in Clinical Trials
PPACA requires health plans to cover the routine patient care costs for those enrolled in cancer clinical trials beginning in 2014. NPAF urges the following actions so that the clinical trials provision is a meaningful protection for all cancer patients in advance of 2014:

- Guidance to grandfathered plans that the option to receive care in a cancer clinical trial, identified by the patient and care team as an appropriate treatment choice, is a necessary element of cancer care and may not be eliminated as a benefit if the plan has included such coverage in the past.
- Encouragement to those plans that have not provided clinical trials coverage to do so voluntarily. Some plans have agreed to such a coverage policy, which they see as advancing the state of knowledge about cancer care and therefore useful not just to those enrolled in trials but to all cancer patients. Others should be encouraged to follow that example.
- Comparison tools, on www.healthcare.gov and in other educational materials, which permit consumers to assess plans for their coverage of clinical trials.

Consumer Education Regarding Grandfathered Plans
NPAF supports the disclosure requirement for grandfathered plans that is part of the interim final regulations and encourages that grandfathered plans be required to list and describe the various consumer protections that do not apply to the plan because it is grandfathered. This disclosure requirement is especially important to patients with a private, grandfathered individual health insurance policy which is allowed under the rule to impose preexisting condition exclusions or other discrimination based on health status. Finally, NPAF recommends that a plan lose its grandfathered status is they fail to notify an enrollee they are approaching a benefit maximum.
We thank you for the opportunity to comment from the patient’s perspective on the rules relating to the status of grandfathered plans. We would be pleased to respond to any questions about our recommendations that may arise during the implementation of the PPACA.

Respectfully submitted,

Nancy Davenport-Ennis
President and Chief Executive Officer