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August 16, 2010

Phyllis C. Borzi
Assistant Secretary of Labor
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

Attention: RIN 1210-AB42

Dear Ms. Borzi:

Express Scripts Inc. (ESI) appreciates 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," published in the Federal Register on June 17, 2010. Express Scripts is one of the largest pharmacy benefit management (PBM) companies in North America, providing PBM services to over 60 million patients. We serve thousands of client groups, including managed-care organizations, insurance carriers, third-party administrators, employers and union-sponsored benefit plans. Express Scripts is headquartered in St. Louis, Missouri.

Express Scripts is supportive of the purpose of the Grandfathered Health Plan IFR: allowing plan sponsors to make certain changes to health coverage and still maintain their Grandfathered status. Allowing patients to maintain the coverage in existence on March 23, 2010, when the Affordable Care Act was enacted was an important goal of Congress.

The following are specific comments about the interim final rule which are concerning to us. We respectfully request that the agency consider these comments as it finalizes this rule. Additionally, we are active members of the Pharmaceutical Care Management Association (PCMA) and incorporate their comments to the IFR by reference.

Section II: Section 1251 of PPACA, Preservation of Right to Maintain Existing Coverage

Maintenance of Grandfathered Status of Paragraph (g) of 45 CFR 147.140

Elimination of benefits (Paragraph (g)(1)(i)) -- The language of this section of the rule states that the elimination of benefits for "any necessary element" to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition, and would result in the loss of grandfathered status. ESI is concerned about how "any necessary element" might be applied to the coverage or formulary status of a particular medication. We are also concerned about who will determine what is "necessary" and whether that determination will be based on medical authority or evidence.

As you know, the specific drugs on a health plan formulary often change as new products come to market, older products lose their patents and become available as less costly generic versions, or products are removed from the market for safety or supply reasons. ESI believes grandfathered plans must be allowed to continue to make formulary changes that maintain a commensurate level of coverage without risking the loss of their grandfathered plan status. If grandfathered plans were not allowed the flexibility to modify their formularies, it would impede a plan sponsor's ability to negotiate with pharmaceutical manufacturers, leading to higher drug prices. Additionally, it would hamper a plan sponsor's ability to manage the formulary to encourage generics when a branded drug loses its patent or to make appropriate adjustments to the formulary when supply issues arise.

ESI recommends *that the Departments clarify that grandfathered plans retain the ability to make routine formulary changes consistent with those made prior to March 23, 2010, as long as a commensurate level of coverage is maintained. We also request that the Departments clarify that grandfathered plans may continue to encourage the use of generic drugs and utilize incentives to encourage clinically appropriate drug utilization. Finally, we recommend that the Departments further clarify the basis for determining what constitutes "any necessary element" to treat a condition so that it is based upon medical criteria and evidence.*

Increase in Fix-Amount Copayment (Paragraph (g)(1)(iv)) -- This requirement states that any increase in a fixed-amount copayment causes a plan to lose grandfathered status if the increase is greater than the maximum percentage increase of medical inflation plus 15 percentage points or five dollars increased by medical inflation. While this requirement may be appropriate with respect to the medical component of the health benefit, ESI believes that application of this requirement on a per prescription basis would be extremely restrictive given the tiers of coverage used by most plan sponsors. For example, a grandfathered plan should be allowed to move a branded pharmaceutical to a higher formulary tier once a generic version becomes available without losing grandfathered plan status. However, under the IFR, a move to a higher tier could subject the brand to a higher copayment, exceeding the cap imposed by the formula in the IFR.

Instead of the requirements proposed in the IFR, ESI believes this section of the rule should apply only to increases in the first and second tiers of a prescription drug benefit formulary. Copay increases to third or higher tiers of a prescription drug benefit for non-specialty drugs should be excluded from this cap on increases to fix-amount copayments. Most prescription drug benefit plans incentive plan members to use the most cost-effective drugs on the formulary, which are purposely placed on the first and second tiers. Alternatively, ESI recommends that an actuarially equivalent standard be utilized to allow plans to adjust their copayments with some

flexibility provided they are actuarially equivalent to the plan benefits that were in existence on March 23, 2010.

Furthermore, ESI suggests that the Departments adopt prescription drug inflation rather than general medical inflation as the benchmark for allowable increases in drug benefit copayments. Data on prescription drug inflation is collected and published by the Bureau of Labor Statistics (BLS). ESI is concerned the CPI-U for medical care does not reflect the fact that prescription drug costs have increased at a much faster pace than the medical inflation rate. For example, the hypothetical CPI-U for medical care used in Example 3 of the IFR gives an inaccurate perception of acceptable changes. The CPI-U used in the example is 87 points higher than the current CPI-U for medical care and, because it is skewed so high, the example conveys an incorrect result. If actual 2009 data were used in the example, the result would be that the subject plan would cease to be grandfathered: exactly the opposite of what is depicted in the IFR. The parameters for permissible increases in copayments under the IFR formula are considerably tighter than what Example 3 would lead the reader to believe.

***ESI recommends** that the Departments apply any cap on increases to fixed-amount copayments be applied only to the first two tiers of a drug formulary. Alternatively, the Departments should allow an actuarially equivalent standard for prescription drug benefits. Furthermore, ESI recommends that the benchmark for allowable copayment changes be prescription drug inflation and not general medical care inflation.*

Request for Comments on Additions to the List of Changes that Result in Loss of Grandfathered Status

Changes in Plan Structure – ESI believes that changes in plan structure should not, in and of itself, be cause for a plan losing its grandfather status. For example, it is irrelevant to the plan members whether the plan sponsor moves from a fully-insured financing arrangement to a self-funded one. In fact, such a move is likely to be seamless to plan members. Rather, the test should be the scope of coverage, access to providers, employer contribution, and general level of subscriber cost-sharing, and not the structural elements of how those benefits are financed or delivered.

***ESI recommends** that the Departments not add changes in plan structure to the list of causes for loss of grandfathered status.*

Changes in Plan Provider Networks – ESI believes that plan sponsors must be able to make changes to their networks of participating providers in order to assure member access and maintain quality. As you may know, there are nearly 70,000 pharmacies in the United States. To maintain a static network of pharmacies would be simply infeasible. Throughout any given year, pharmacies go out of business, owners retire and/or sell their pharmacies, new pharmacies open, and providers are disbarred from participating due to fraud. Therefore, plan sponsors routinely make changes in their provider networks throughout the year. As long as members are assured reasonable access to pharmacies providers to receive their covered benefits, the Departments should allow grandfathered plans the discretion of managing their provider networks. For example, ESI currently holds the Department of Defense's TRICARE contract.

The DoD requires ESI to adhere to beneficiary access standards and to maintain a sufficient number of pharmacies within an adequate range – not maintain a static network.

***ESI recommends** that the Departments not add changes in a network plan's provider network to the list of changes that would cause a plan to lose its grandfathered status as all plan sponsors already maintain networks that address member access.*

Changes to a Prescription Drug Formulary – Prescription drug formularies are "living" arrangements that adapt to changes in available therapy and contemporary standards of medical practice. ESI believes that grandfathered plans should be able to make changes in their formularies that are consistent with best practices, enhance the quality of care, ensure safety, and improve the cost-effectiveness of the member's drug benefit. Locking grandfathered plans in the formularies they had in place on March 23, 2010, would discourage plans from providing access to new and innovative drugs, disadvantage plans in their negotiations with pharmaceutical manufacturers, and could result in unnecessarily increasing the cost of providing drug benefits. ESI believes that as long as formulary changes are subject to objective standards, such changes should not result in jeopardizing the grandfathered status of a plan sponsor. Such objective standards would include review and approval by an independent pharmacy and therapeutics (P&T) committee.

***ESI recommends** that the Departments not add changes to a prescription drug formulary to the list of changes that would result in the loss of grandfather status as long as formulary changes are made based on objective standards such as those made by independent P&T committees.*

In closing, we appreciate the Departments' consideration of our comments. Successful implementation of the Patient Protection and Affordable Care Act is of utmost importance to Express Scripts.

Sincerely,

Mary Rosado
Vice President, Federal Government Affairs