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Jay Angoff, Director
Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
Attention: OCIIO-9992-IFC
P.O. Box 8016
Baltimore, Maryland 21244-1850

Sent by mail and electronic submission

RE: Comments to OCIIO-9992-IFC; Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

Dear Director Angoff;

We appreciate the opportunity to provide comments regarding the recently released interim final rule for group health plans and health insurance issuers relating to the "Coverage of Preventive Health Services" provision of Section 1001 of the Patient Protection and Affordable Care Act (PPACA). Thank you for your willingness to consider our views on this matter. In particular, we are seeking additional clarity from the Departments that these new mandates, which require that non-grandfathered plans cover preventive items and services without a patient cost-share, do not apply to certain drugs, over-the-counter (OTC) drugs or dietary supplements that may be discussed with or recommended by a provider during an office visit that ***is*** covered by the scope of this rule.

Medco looks forward to working with the Department, as well as with the Departments of Labor and Treasury, on implementing this new program and on helping to ensure the success of many other components of the recently enacted Health Care Reform law.

As the nation's leading pharmacy benefits management company, Medco provides clinically driven pharmacy services designed to improve the quality of care and lower total health care costs for private and public employers, health plans, labor unions, government agencies of all sizes, and for individuals served by Medicare Part D Prescription Drug Plans.

While we commend the Departments for their effort in drafting this interim final rule, we are seeking additional clarity around any impact this may have on pharmaceutical benefits of the type offered by our clients. In particular, the "Coverage of Preventive Health Services" provision of Section 1001 of PPACA (which amended Section 2713 of the Public Health Services Act) defines preventive items and services in part by reference to "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force." The law, and the interim final rule as well, go on to further outline three additional categories of preventive services which include immunizations and services and screenings specific to infants, children, adolescents and women.

Several of these items reference "counseling" specific to a particular preventive item, such as tobacco use and cessation products and/or the "use" of a drug that may be wholly or partially available over-the-counter without a prescription. The Task Force recommendations also include language calling for the use of folic acid supplements by all women planning or capable of pregnancy as well as language calling for the "use" of aspirin for certain at-risk men and women of specific age groups.

We believe it is important for the Departments to clarify that the Section 2713 mandates are intended for consultations and screenings, not for the products discussed or recommended by the provider.

There are a number of strong arguments to support this position. First, the scope of preventive items and services covered by this rule generally applies to tests, screenings, and counseling intended to detect and/or prevent a potential condition. Any subsequent treatment of an underlying condition would not generally be deemed to be a preventive item or service and therefore should not subject to the zero cost-share rule.

Second, the rule clarifies that with respect to a recommended preventive service that is provided during an office visit, the plan may not impose a cost-share in those instances where the recommended preventive service is not billed separately from an office visit and is the primary purpose of the office visit. On the other hand, the rule also establishes that the plan may impose a cost share if the preventive services are billed separately from the office visit, or if those services are not billed separately but are not the primary purpose of the office visit. In the case of prescription drugs generally, it is common that these items are not billed as part of the office visit but separately as part of the patient's prescription drug benefit. With regard to non-prescription OTC drugs or supplements specifically, even if an office visit resulted in a recommendation that a patient begin taking a particular OTC drug or supplement, it is unlikely that such a recommendation would meet the test of being the "primary purpose of the office visit."

Third, requiring that plans provide OTC products without a patient cost-share would invite numerous practical hurdles that could significantly complicate the implementation of this new program and drive up the cost of these benefits. For example, many of the recommendations are age and gender specific. Claims processing software would need to be

edited in order to confirm the patient meets coverage requirements and could result in the burdensome need for clarifying calls to physician offices.

In addition, if OTC purchases are to be adjudicated through the regular pharmacy claims process, this will likely add several fees that could significantly drive up the cost of an otherwise inexpensive transaction. For example, as a result of network contracts that are already in place between retail pharmacies and pharmacy benefit managers, covering OTCs through the pharmacy benefit would likely require that an additional "dispensing fee" be added to the cost of the product. Likewise, claims submissions also frequently include a claim submission fee and an administration fee. Together, these new costs would mean that adjudicating a claim for an OTC product would probably be more expensive than the actual cost of the drug itself.

In summary, because of the policy, practical and financial considerations outlined above, we believe it would helpful if the Departments provide specific guidance affirming the belief that the new mandates relating to the coverage of preventive items and services are intended for consultations and screenings, not for the products discussed or recommended by the provider.

Again, we appreciate your willingness to consider our comments on this matter and we look forward to working with the Department to promote the successful implementation of this new program.

Sincerely yours,

Colleen M. McIntosh
Vice President – Assistant General Counsel