

Colleen M. McIntosh
Vice President - Assistant General Counsel

Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, NJ 07417



tel 201-269-6017
fax 201-269-2880

colleen_mcintosh@medco.com

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Mr. Jay Angoff
Director,
Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
Attention: OCIIO-9986-NC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Sent by mail and electronic submission

RE: Comments to OCIIO-9986-NC; Request for Information Regarding Federal External Review Process

Dear Director Angoff;

We appreciate the opportunity to provide comments regarding the Department's recently released request for information ("RFI") regarding the Federal External Review Process to help inform the Department's development of any future Requests for Proposals in this area. Medco looks forward to working with the Department on implementing this new program and on helping to ensure the success of many other components of the recently enacted Health Care Reform law.

Medco Health Solutions is a leading health care company that is advancing the practice of pharmacy and serving the needs of approximately 65 million people. 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. About one third of the companies on the Fortune 500 list are Medco clients.

We would like to raise two concerns that we feel the Department ought to consider in order to avoid ambiguity or confusion that could otherwise complicate implementation of the Federal External Review Process.

Credentialing Standards for Legal Professionals:

Our first concern relates to Question 2 in the RFI which asks about the credentialing standards that IROs should require for medical and legal reviewers. We believe that there may be some uncertainty in the marketplace around the role that lawyers will play within an IRO. In fact, this belief comes directly from conversations Medco has had with organizations looking to participate in this space. Therefore, we believe that the Department could avoid ambiguity and confusion in the marketplace if it were to provide clear guidance on the role that lawyers should play within an IRO and the specific materials that they would be reviewing or the instances where they would be engaged.

Procedures and Resources for Appeals:

Our second concern relates to Question 12 in the RFI which asks about the differences in standard operating procedures and resources for appeals involving only medical necessity and those that involve both medical necessity and coverage questions. On this point, we believe the Department may be overlooking a third category of appeals which are those that involve *only* coverage questions. Many plans, particularly self-funded ERISA plans, offer pharmacy benefit packages where certain benefit determinations may be purely coverage in nature, meaning certain drugs may be excluded from the plan based solely on the plan's inability or unwillingness to fund the cost of these products. We believe this category is distinct from those that involve both medical necessity and coverage questions because in these instances it is common that drugs may not be covered regardless of medical necessity.

For example, a plan may decide to cover the drug Retin-A for acne but not for wrinkles. In this case, a Retin-A prescription may trigger a prior authorization. If the prescriber indicates that the script was for wrinkles, the claim would be denied -- because the drug is not covered for that indication.

Along with recognizing this category of purely coverage based appeals, we also think the Department should consider how IROs will approach these circumstances. For example, how will the IROs manage the vast number of unique plan designs that exist among ERISA plans. This will be important in order to avoid member confusion and prevent unnecessary and potentially costly appeals and possible judicial actions. The failure of IROs to follow each plan's unique design could result in confusion and considerable waste to the system.

Again, we appreciate your willingness to consider our comments on the above mentioned request for information and look forward to working with CMS to promote the successful implementation of these new programs in the future.

Very truly yours,



Colleen M. McIntosh
VP, Assistant General Counsel