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Office of Health Plan Standards & Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210
Attn: GINA Comments

Re: RIN 1210-AB27

Dear Gentilepersons:

Medco Health Solutions, Inc., is a leader in managing prescription drug benefit programs that are designed to moderate cost and enhance the quality of pharmacy health care. Medco provides pharmacy benefit management for approximately 1 in 5 Americans, and operates one of the largest pharmacy practices in the United States through 9 mail-order pharmacies, 2 pharmacies that dispense diabetic supplies, 3 specialty distribution pharmacies and 87 specialty branch pharmacies. Medco employs more than 20,000 people nationwide, including 2,400 pharmacists and more than 500 nurses. We appreciate the opportunity to comment on issues raised by sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008 (GINA).

Medco is interested in pharmacogenomics because of the promise it holds for improving the safe and effective use of medications, and reducing the costs associated with adverse drug events and sub-optimal therapeutic outcomes. Genetic testing for drug use is not likely to lead to discrimination because a test is initiated only after the patient has been diagnosed with a disease or condition and is undergoing treatment. At Medco, we proceed only after we have the patient's approval. The test results are used by the treating physician to improve or target drug therapy.

Medco, in collaboration with the Mayo Clinic, is currently conducting a national study of pharmacogenomic testing for Warfarin. The study involves patients between the ages of 40 and 70 and their physicians in typical community practice settings rather than the controlled environment of an academic medical center. The study will provide insights into what pharmacogenomic testing does for Warfarin use by measuring hospitalization rates for thromboembolic or bleeding events, other elements of medical resource use such as doctor visits or number of INR tests, and time to achieve stable Warfarin dose. In response to the clinical

data published on Warfarin testing. FDA made changes in the Warfarin label in August 2007 reflecting that lower initial doses may be warranted for people with certain genetic variations.

Medco informed its client plan sponsors about the study and invited them to participate by providing access to the study to their plan members. The response was overwhelming: 28 plan sponsors agreed to participate and we are targeting additional clients to bring the pilot study to a close.

As a result of strong client interest in the Medco-Mayo Clinic study, Medco independently developed and launched two commercial programs, one involving Warfarin and the other, Tamoxifen. The genetic information obtained and used in these programs is not used to determine eligibility or premium rates. The individuals contacted are already covered by their group health plan and have been diagnosed with a condition requiring a drug where a genetic test can guide their physician on dosing or choice of drug therapy. The purpose for the genetic test is to better inform the physician and avoid adverse drug reactions or other adverse therapeutic outcomes. Participation by both patients and physicians is voluntary.

We have comments and suggestions on the items noted below from your Federal Register notice published on October 10:

B. Comments Regarding Regulatory Guidance

3. Under what circumstances do plans or issuers currently request or require an individual to take a genetic test?

Medco offers our plan sponsor clients the choice to participate in clinical programs where genetic testing is available and can be offered to those members whose drug therapy would be enhanced by the use of such tests. Eligible members have the option to participate in the program but are not required to do so. We believe that offering a member this option is not a prohibited "request" under GINA.

9. What terms or provisions would require additional clarification to facilitate compliance? What specific clarifications would be helpful?

The prohibition in GINA on group health plans and health insurance issuers from "requesting or requiring" an individual or family member of an individual to undergo a genetic test has raised concerns by plan sponsors about their ability to "offer" a genetic test relating to the use of certain prescription drugs covered by the plan. We recommend the "request or require" prohibition in GINA be clarified to ensure that "offering" a genetic test to a patient who is starting a particular drug therapy is allowed. These genetic tests are post-diagnostic tools designed to avoid adverse events (e.g., excessive bleeding) and determine whether a drug is effective for that patient. The tests are unrelated to any aspect of determining enrollment status or premium contributions, including the use of underwriting. Plan sponsors and issuers need the ability to communicate this information to members and beneficiaries in order to ensure their safety and the quality of their drug therapy.

It is clear from the House and Senate reports that payment of a plan benefit can be conditioned on the outcome of a genetic test. For example, the Senate Report on S. 358 includes a hypothetical situation in which a plan covers one colonoscopy every 10 years. However, for patients with a specific gene associated with an elevated risk of hereditary nonpolyposis colorectal cancer (HNPCC), the plan covers annual colonoscopies. Under the example, a patient seeking coverage for an annual colonoscopy is “required” to demonstrate that they had the genetic test and the results fell within the scope of conditions for coverage.

Although the Senate Report is clear that covered expenses may be conditioned on evidence of a genetic test, the “request or require” language of the statute creates confusion and could lead plan sponsors to avoid offering therapeutic genetic tests that are in the best interest of patients. This has caused some doubt as to the ability of a plan to incorporate genetic tests in its plan design. While the Senate Report fully supports a plan design that requires genetic testing as a condition of receiving a particular benefit under the plan (i.e., coverage of annual colonoscopies limited to patients with a specific gene), the statute has caused confusion among some plans.

Accordingly, we request that regulation relating to the Rule of Construction Regarding Payment be clarified to reflect congressional intent with respect to plan design, such as the examples from the Senate Report.

5. What types of research do plans or issuers currently conduct or support using genetic tests?

GINA includes a research exception, which allows group health plans or health insurance issuers to “request” a plan member or beneficiary to undergo a genetic test as long as five conditions are met. Genetic tests keyed to drug therapies are currently being developed. Prior to general availability of such tests, health plans and insurers may wish to avail themselves of the research exception to enable their members and beneficiaries to participate in clinical studies measuring the effectiveness of such tests in managing drug therapies.

Once the use of these tests become established as clinical best practices, plans and insurers should be encouraged to offer the tests to their members and beneficiaries as a covered benefit that enhances clinical effectiveness and quality of care.

The protections provided by GINA represent an important step in the future development and application of genomic information to clinical therapeutics. But, those protections should not have the unintended effect of stifling significant advances in prescription drug therapy that utilize genetic testing.

We appreciate the opportunity to comment on issues raised by GINA. Please contact us if we can provide additional information or assistance.

Sincerely,



Colleen M. McIntosh
Vice President and Assistant General Counsel