



PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

December 9, 2008

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: GINA Comments

To Whom It May Concern:

The Pharmaceutical Care Management Association (PCMA) is grateful for the opportunity to present comments regarding issues under sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008 (GINA), and respond to the specific questions posted in the Federal Register.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage, provided through Fortune 500 employers, health insurance plans, labor unions, government programs, and Medicare Part D.

Our specific concerns are as follows:

B. Comments Regarding Regulatory Guidance

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

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 prior to use of certain prescription drugs where such tests have become available.

As a November 2008 report issued by the Department of Health and Human Services acknowledges, the testing offers tremendous potential to improve patient safety:

"This effort recognizes how much more effective medical care could be, and how much more value we could achieve, if the drugs prescribed for us were the ones known to work for us, or for the subtype of disease being treated."ⁱ

We recommend the “request or require” prohibition in GINA be clarified to ensure that “offering” a genetic test to a patient prior to starting drug therapy is allowed. These genetic tests are diagnostic tools designed to avoid adverse events (e.g. excessive bleeding) and determine whether a drug is effective for that patient. They are unrelated to any aspect of determining enrollment status or premium contributions, including the use of underwriting. To deny plan sponsors or insurance issuers the ability to communicate this information to specific plan participants or beneficiaries would, in turn, deny those plan participants and beneficiaries access to a beneficial practice that could greatly enhance the safety and quality of their drug therapy.

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 participant or beneficiary to undergo a genetic test as long as five conditions are met. Genetic tests keyed to drug therapies are currently being developed. When such tests are available, health plans and insurers may wish to avail themselves of the research exception to enable their plan participants 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 participants and beneficiaries.

The protections provided by GINA represent an important step in the future development and application of genomic information to clinical therapeutics. However, these protections should not have the unintended affect of stifling significant advances in prescription drug therapy.

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

Sincerely,



Greg Johnson
Assistant Vice President
Federal and Regulatory Affairs

ⁱ “Personalized Health Care: Pioneers, Partnerships, and Progress”, U.S. Department of Health and Human Services, November 2008.