AMCP Academy of Managed Care Pharmacy®

Practice Advisory on the Impact of GINA to Managed Care Pharmacy

Significant advances in the field of genetics have resulted in the promise of new diagnostic tools, therapies, and avenues for research as well as the potential to identify future health risks of healthy individuals. The Genetic Information Nondiscrimination Act of 2008 (GINA) was enacted so that the public could take advantage of the availability of genetic services, including genetic testing, counseling, education, and research studies, in an environment where they are free from the fear of discrimination.

GINA provides protection against genetic discrimination from health insurance providers and employers. Since becoming law many questions have arisen about the implications of GINA on the practice of managed care pharmacy. The intent of this practice advisory is to provide a summary of GINA and review the impact the implementing regulations have on managed care pharmacy. This is not a comprehensive description of GINA requirements nor should the information presented here be construed as legal advice.

Background

GINA was signed into law on May 21, 2009 and is comprised of two parts. Title I prohibits genetic discrimination by group health plans and health insurers; and Title II prohibits genetic discrimination in employment. The Departments of Labor, Treasury, and Health and Human Services jointly published three interim final regulations under Title I of GINA on October 7, 2009.

GINA defines genetic information broadly and includes the following:[1]

- information about a genetic test of an individual or family member
- information about the request for or receipt of genetic services
- genetic information about a fetus carried by an individual or family member or an embryo legally held by an individual or family member using assisted reproductive technology
- family medical history
- genetic services including testing, counseling or education that are delivered through participation in clinical research

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[1] Department of Health and Human Services (HHS). "GINA" The Genetic Information Nondiscrimination Act of 2008: Information for Researchers and Health Care Professionals. April 6, 2009. http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf (accessed July 14, 2010)

GINA builds on existing protections within the Health Insurance Portability and Accountability Act (HIPAA) and prevents health plans from using genetic information to adjust group premiums or to use genetic information for underwriting purposes. In addition, health plans are generally prohibited from offering rewards in return for collection of genetic information. This includes family medication history that could be collected through the completion of a Health Risk Assessment (HRA).

With certain exceptions, GINA prohibits health plans from requesting or requiring that an individual or family member undergo a genetic test. This does not, however, prevent a health plan from offering a genetic testing benefit to their members.

GINA requires that employers maintain the confidentiality of genetic information in the same way that they protect other medical information. Employers may not discriminate against employees based on genetic information.

With the passage of health care reform legislation in 2010, the question of whether or not the Patient Protection and Affordable Care Act (PPACA) impacts GINA has been raised. Upon review it appears that the two laws are not contradictory, but complementary. While these two laws were introduced and enacted for different purposes – PPACA as comprehensive health care reform legislation and GINA as a civil rights statue – both share the goal of enhancing patient protections.[2]

Considerations for Managed Care Pharmacy

Coverage Authorization. While GINA states that health plans cannot request or require an individual to undergo a genetic test, there is an exception that allows a plan to require genetic information to determine coverage. The regulations state:

> *In some cases, the appropriateness of certain courses of treatment for a patient depends on the patient's genetic makeup. A plan or issuer is permitted to condition payment for an item or service based on medical appropriateness that depends on an individual's genetic makeup. Under these narrow circumstances, a plan or issuer may condition payment on the outcome of a genetic test, and may refuse payment for the item or service if the individual does not undergo the genetic test.*[3]

Therefore, a coverage authorization rule with criteria requiring genetic information for coverage determination is permitted under GINA. However, it is important to note that plans may only require the minimum amount of genetic information necessary to make a coverage decision.

HRA's, Wellness Programs, and Disease Management. Health Risk Assessments (HRA's) and wellness programs that request genetic information including family history and that provide an

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[2] Congressional Research Service, *The Genetic Information Nondiscrimination Act of 2008 and the Patient Protection and Affordable Care Act of 2010: Overview and Legal Analysis of Potential Interactions.* CRS Report to Congress. July 8, 2010.

[3] Department of Health and Human Services (HHS). Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans. http://edocket.access.gpo.gov/2009/pdf/E9-22504.pdf (accessed July 18, 2010).

individual any kind of reward or financial incentive are prohibited. However, a wellness program or HRA may collect genetic information through a *voluntary* program. It must be made entirely clear to the individual that the information is requested on a voluntary basis.

In addition, family medical information that has been obtained through an HRA may not be used to qualify an individual for participation in a disease management program. This restriction applies even if the HRA used to obtain the family history is not tied to a reward or incentive and is a voluntary program.[4]

Genetic Testing Benefit. GINA does not prohibit the coverage of genetic tests under a health plan's benefit. A health plan may communicate to members to inform them of the availability of a genetic testing benefit; however, special care must be taken to make sure that the communication is not misconstrued as a requirement that an individual must undergo genetic testing.

Research Studies. A health plan may request that an individual undergo a genetic test as part of a research study conducted by the health plan as long as certain requirements are met, however, the health plan may not require the individual to undergo the test. Genetic information gathered through a research study may not be used for underwriting purposes.

For more information, the Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans can be found at: http://edocket.access.gpo.gov/2009/pdf/E9-22504.pdf

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[4] New GINA Regulations Severely Hamper Heath Risk Assessments. Morgan Lewis Employee Benefits Flash. October 16, 2009. http://www.morganlewis.com/pubs/EB_GINARegulations_LF_16oct09.pdf (accessed July 14, 2010)