

HEALTH LAW ALERT

October 7, 2009

OCR Proposes Privacy Rule Amendments on Genetic Information Would Require Revision of Most Insurers' Privacy Practices Notices

Today, the Department of Health and Human Services' Office for Civil Rights (OCR) published a proposal to amend the HIPAA Privacy Rule to implement provisions of the Genetic Information Nondiscrimination Act (GINA). The proposed amendments would prohibit health plans from using or disclosing "genetic information" for "underwriting purposes," in accordance with Title I of GINA. The proposal would require a health plan that uses other protected health information for underwriting purposes to explicitly state in its privacy practices notice that it does not use genetic information for underwriting.

The proposed amendments are published at 74 Federal Register 51698 (Oct. 7, 2009). Interested parties may submit comments on the proposed amendments by December 7, 2009. In addition to this proposal to amend the Privacy Rule, three federal agencies separately published interim final rules concerning GINA's provisions prohibiting insurance discrimination based on genetic information. [Click here](#) for a Health Law Alert on those interim final rules (look under "Health Law Alerts").

The Genetic Information Nondiscrimination Act

GINA requires the Department of Health and Human Services to revise the HIPAA Privacy Rule (45 C.F.R. Part 164, Subpart E) to prohibit certain health plans—health insurers, group health plans, and issuers of Medicare Supplement (Medigap) insurance—from using or disclosing genetic information for underwriting purposes.

Under the statute, genetic information is broadly defined to include information about "the manifestation of a disease or disorder in family members of [an] individual," in addition to information from genetic tests on the individual. Thus, information about the medical history of an individual's parents (or other family members) qualifies as "genetic information" subject to GINA. An individual's genetic information does not, however, include information about the individual's own manifestation of a disease or disorder. Accordingly, high blood pressure diagnosed in an individual's parent qualifies as genetic information about the individual, but high blood pressure diagnosed in the individual him/herself is *not* genetic information.

GINA also defines the term "underwriting purposes" broadly. The statute includes as "underwriting purposes" a health plan's (a) rules concerning eligibility for benefits and (b)

process of determining eligibility for benefits, as well as tasks traditionally considered underwriting, such as determining eligibility for coverage, premium amounts, and application of pre-existing condition exclusions. *See* Alert on interim final rules for more on “underwriting purposes.” ([Click here](#) to see Alert—look under “Health Law Alerts.”)

Proposed Changes to Privacy Rule

The OCR’s proposed amendments to the Privacy Rule add a provision that would explicitly prohibit any health plan from using or disclosing genetic information for underwriting purposes.¹ The prohibition would apply to uses and disclosures of “summary health information” related to employers obtaining premium bids and considering modifications, amendments, or termination of their group health plans. Even an individual’s signed authorization would not be sufficient to allow a health plan to use genetic information for underwriting.

In addition, the OCR would require health plans that use other protected health information for “underwriting purposes” to revise their privacy practices notices to explain that they do *not* use genetic information for such purposes. The OCR asserts that such a change is “material,” which (under the current Privacy Rule) would require health plans to send a revised notice to enrollees within sixty days. The OCR specifically requests comments on this consequence of their proposal, as it “recognizes that revising and redistributing a [privacy practices notice] may be costly for health plans.”

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¹ The OCR acknowledges that this prohibition would encompass health plans not included in its mandate from GINA, such as certain long-term care policies, limited scope dental and vision plans, and certain multiple employer health benefit plans. But the OCR asserts that HIPAA provides sufficient discretion in the agency’s authority to promulgate the Privacy Rule to allow the OCR to extend the prohibition on use and disclosure of genetic information for underwriting purposes to all health plans.