



BENEFIT NEWS BRIEFS

Proposed Regulations Under GINA Will Impact Health Plan's Privacy Notices

The Department of Health and Human Services (HHS) recently issued proposed regulations modifying certain provisions of the *HIPAA Privacy Rule*. The proposed changes intend to implement section 105 of Title I of the *Genetic Information Nondiscrimination Act of 2008 (GINA)* regarding the privacy and confidentiality of genetic information, as well as to make certain other changes to the *HIPAA Privacy Rule*. The *Proposed Rule*, as published in the *Federal Register* is available by "[clicking here](#)" or at <http://edocket.access.gpo.gov/2009/pdf/E9-22492.pdf>. A specially prepared version of the published *Proposed Rule* is available by "[clicking here](#)."

See [Research Memo 2008-26](#) for more background on *GINA*. A helpful EBSA *Fact Sheet* on the protections of *GINA* is available by "[clicking here](#)" or at: <http://www.dol.gov/ebsa/newsroom/fsGINA.html>

Impact to Current HIPAA Privacy Rule

The *Preamble* contains a nice discussion of the *HIPAA Privacy Rule* and *GINA* before discussing the proposed changes created under *GINA*. The following highlights are drawn from the *Preamble*, which notes the new privacy protections for "genetic information" under *GINA*. In particular, *GINA* amends the *HIPAA Privacy Rule* to address the application of genetic information and requires HHS to revise the *Privacy Rule* to clarify that genetic information is health information and to prohibit group health plans, health insurance issuers (including HMOs) and issuers of Medicare supplemental policies from using or disclosing genetic information for underwriting purposes.

In response to *GINA*, HHS proposed to modify the *HIPAA Privacy Rule* to:

- (1) explicitly provide that genetic information is health information for purposes of the *Privacy Rule*;
- (2) prohibit health plans from using or disclosing protected health information that is genetic information for underwriting purposes;

- (3) revise the provisions relating to the *Notice of Privacy Practices (Privacy Notice)* for health plans that perform underwriting;
- (4) make a number of conforming modifications to definitions and other provisions of the *Rule*; and
- (5) make technical corrections to update the definition of "health plan."

HHS stated it believes that individuals have a right to be specifically informed of the fact that health plans that intend to use or disclose their *Protected Health Information (PHI)* for underwriting nonetheless may not use or disclose their genetic information for such purposes. Therefore, HHS proposes to require health plans that use or disclose *PHI* for underwriting to include a statement in their *Privacy Notice* making clear that they are prohibited from using or disclosing *PHI* that is genetic information about an individual for such purposes.

HHS believes that without such a specific statement, individuals would not be aware of this restriction and the general statements regarding permitted uses and disclosures for treatment, payment, and health care operations in the *Privacy Notice* of a health plan that performs underwriting would not be accurate (i.e., the *Privacy Notice* would state that the health plan may use or disclose *PHI* for purposes of payment and health care operations, which would not be true with respect to genetic information when the use or disclosure is for underwriting purposes).

How Will The Proposed Changes Affect a Plan's Privacy Notice

According to HHS, the proposed prohibition on the use of genetic information and the proposed requirement to explicitly include a statement regarding the prohibition would represent a **material change** to the *Privacy Notices of health plans that perform underwriting*, and the *Privacy Rule* requires that plans provide notice to individuals covered by the plan within 60 days of any *material revision* to the *Privacy Notice*. Thus, the result could require health plans to modify their *Privacy Notices* and incur the cost of informing people about a change that is probably of no real interest anyone. If the notice reading-rate of a plan's *Privacy Notice* is similar to the reading rate for the myriads of other helpful notices we receive, then the extra cost seems especially for nought.

Request for Comments

However, in a show of good sense, HHS recognizes that revising and redistributing a *Privacy Notice* may be costly for health plans that perform underwriting and therefore is **requesting comments** on ways to inform individuals of this change to privacy practices without unduly burdening health plans, **particularly given there may be other material changes to the Privacy Notice due to the modifications to the Privacy Rule** required by the provisions of the *Health Information Technology for Economic and Clinical Health (HITECH) Act*, enacted as part of the *American Recovery and Reinvestment Act of 2009*.

In particular, the *Preamble* notes HHS is considering a number of options in this area:

- (1) Replace the 60-day requirement with a requirement for health plans to revise their Privacy Notice and redistribute them (or at least notify members of the material change to the Privacy Notice and how to obtain the revised Privacy Notice) in their next annual mailing to members after a material revision to the Privacy Notice, such as at the beginning of the plan year or during the open enrollment period;
- (2) provide a specified delay or extension of the 60-day timeframe for health plans that perform underwriting to implement and inform individuals of the underwriting prohibition;
- (3) retain the provision generally to require health plans to provide notice within 60 days of a material revision but provide that the Secretary will waive the 60-day timeframe in cases where the timing or substance of modifications to the Privacy Rule call for such a waiver; or
- (4) make no change and thus, require that health plans that perform underwriting provide notice to individuals within 60 days of the material change to the Privacy Notice that would be required by this proposed rule.

HHS requests comment on these options, as well as any other recommendations for informing individuals in a timely manner of this proposed change or other material changes to the *Privacy Notice*. Information on making comments is available at the beginning of the *Preamble*.

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