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Will the Mega Rule Have a Mega Impact on Long-Term Care Insurers' Use of Genetic Information?

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On Jan. 25, the Department of Health and Human Services (HHS) published its long-awaited "Mega Rule," which interprets, clarifies and, in some instances, extends the provisions of both the Health Insurance Portability and Accountability Act (HIPAA) and the Genetic Information Nondiscrimination Act of 2008 (GINA). In the lead-up to the publication of the Mega Rule, there was much speculation over how HHS would protect genetic information and, in particular, whether the provisions of GINA prohibiting the use of genetic information in underwriting certain types of insurance would be extended to all HIPAA-covered entities—including issuers of long-term care insurance.

Due in large part to successful lobbying efforts and persuasive public comments submitted to HHS on behalf of the long-term care industry, the final Mega Rule exempted long-term care insurers from the blanket ban on the use of genetic information in underwriting that many in the industry expected. The Mega Rule did, however, extend this ban to every HIPAA-covered entity other than long-term care insurers. HHS appeared particularly persuaded by the argument that prohibiting the use of genetic information in long-term care underwriting would result in large-scale rate increase requests and/or threaten the viability of long-term care insurance generally.

If long-term care insurers are inclined to breathe a sigh of relief and continue business as usual, however, a close reading of the Mega Rule should disabuse them of that notion. While the present changes are less drastic than they might have been, HHS unequivocally conveyed its position that individuals have the utmost privacy interest in their genetic information. This is significant because it may be a harbinger of HHS' inclination to extend the underwriting prohibition to long-term care insurers in the future. Further, HHS reiterated that genetic information was protected health information and is covered by HIPAA's privacy rule. The Mega Rule did not stop there, however. It extended the HIPAA privacy rule beyond just HIPAA-covered entities to all business associates who receive protected health information from HIPAA-covered entities—including long-term care insurers. The practical effect of this is to extend the enforcement of HIPAA downstream from covered entities to those business associates, increasing the federal privacy protection afforded to protected health information. Perhaps most importantly, the Mega Rule made clear that HHS will revisit the question of whether the blanket ban on the use of genetic information should be extended to long-term care underwriting. The net effect of the Mega Rule on long-term care underwriting therefore remains to be seen.

FEDERAL REGULATION OF THE USE OF GENETIC INFORMATION: GINA AND THE MEGA RULE

GINA was signed into law by President George W. Bush on May 21, 2008. With the passage of GINA, the collection, use and disclosure of genetic information was regulated at the federal level for the first time. Generally speaking, in the insurance

context, GINA prohibits discrimination based on an individual's genetic information with respect to health insurance coverage. Additionally, GINA extends HIPAA's "privacy rule" to cover genetic information.[1] GINA specifically prohibits the following groups from using genetic information for underwriting purposes: (i) group health plans; (ii) health insurers issuing health insurance coverage; and (iii) issuers of Medicare supplemental policies.

In 2009, HHS released a proposed Mega Rule for public comment. In the proposed rule, HHS planned to extend the prohibition on using or disclosing genetic information for underwriting purposes beyond the present three affected groups to all health plans that are HIPAA-covered entities—including long-term care insurers. This led to significant push-back from the industry. The Society of Actuaries (SOA) and American Council of Life Insurers (ACLI) lobbied against a blanket ban on the use of genetic information in underwriting, concluding that such a ban could threaten the long-term viability of the private long-term care insurance market. These public comments and lobbying efforts proved effective.

The "final" Mega Rule was published on Jan. 25, 2013. It becomes effective on March 26, 2013. Covered entities and their business associates must comply with its requirements by Sept. 23, 2013. Notably, the Mega Rule prohibits the disclosure or use of "genetic information for underwriting purposes to all health plans that are covered entities under the HIPAA Privacy Rule, including those to which GINA does not expressly apply, *except with regard to issuers of long-term care policies"* (emphasis added). Even with the exemption for long-term care insurance, this was a significant extension of the prohibitions in GINA. Although there was public comment that HHS did not have the authority to extend the prohibitions, HHS disagreed. HHS concluded that there was no problem with HHS granting the same privacy protections outlined in GINA to those health plans that are not explicitly covered by GINA. HHS' conclusion could lead to an interesting legal debate about the extent of power vested in bureaucratic agencies. For the time being, however, HHS' guidance is the law of the land and all covered entities—except long-term care insurers—will be prohibited from using genetic information for underwriting purposes.

THE MEGA RULE'S IMPACT ON "BUSINESS ASSOCIATES"

Though it exempted long-term care insurers, HHS emphasized that "long-term care plans, while not subject to the underwriting prohibition [on genetic information], continue to be bound by the Privacy Rule, as are all other covered health plans, to protect genetic information from improper uses and disclosures, and to only use or disclose genetic information as required or expressly permitted by the Rule, or as otherwise authorized by the individual who is the subject of the genetic information." Because long-term care insurers continue to be bound by the privacy rule, there is a second aspect of the Mega Rule that will impact the long-term care industry immediately—the extension of the HIPAA privacy rule to business associates. The Mega Rule requires business associates of HIPAA-covered entities to safeguard individuals' protected health information (PHI)—including genetic information. Because business associates receive PHI from HIPAA-covered entities, this extension of the privacy rule will require long-term care carriers to review and likely revise their contracts with business associates to ensure that they require the business associates to safeguard the privacy of PHI in compliance with HIPAA's privacy rule.

DOES THE MEGA RULE OFFER A GLIMPSE OF THE FUTURE?

The Mega Rule does not appear to be the end of federal regulation of genetic information. Though HHS exempted long-term care plans from the blanket underwriting ban, the Mega Rule tracks HHS' observation that an individual has a strong privacy interest in his own genetic information. However, HHS could not, as of the Jan. 25, 2013 release of the Mega Rule, determine the "proper balance between the individual's privacy interests and the [long-term care] industry's concerns about the cost effects of excluding genetic information." For that significant reason, the fate of the industry vis-à-vis the use of genetic information in underwriting remains uncertain.

> In terms of the future of the use of genetic information, HHS stated:
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> [W]e are looking into ways to obtain further information on this issue, such as through a study by the National Association of Insurance Commissioners (NAIC) on the tension between the use of genetic information for underwriting and the associated privacy concerns in the context of their model long-term care rules. Based on the information the Department may obtain, the

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> Department will reassess how best to move forward in this area in the future."

This portends a future reevaluation of the exemption granted to long-term care insurers, which could result in a restructuring or elimination of their exemption.

The Mega Rule also failed to set a uniform, federal standard on how genetic information can be used in underwriting long-term care insurance. In addition to the limited federal regulations on the use of genetic information set by GINA and the Mega Rule, most states have enacted statutes that require compliance from all insurers. Many of these statutes qualify, restrict, ban or otherwise regulate the use of genetic information in underwriting. Although each state statute is different, the states that have enacted laws generally fall into one of three categories: (1) permissive use of genetic information is allowed; (2) use of genetic information is permitted but with restrictions; or (3) use of genetic information is prohibited. The result is a patchwork of regulations that range widely from complete prohibition to liberal use of genetic information. Long-term care insurers must therefore ensure that if they are using genetic information in underwriting, their guidelines are responsive to each state's regulations and their underwriters and producers, among others, are trained accordingly.

IMPORTANT CONSIDERATIONS IN THE WAKE OF THE MEGA RULE

So what does this mean for long-term care insurers moving forward? In the short term, insurers can continue to use genetic information as they have in the past, provided they pay close attention to individual state laws which govern the use of genetic information in underwriting. Beyond the underwriting component, however, long-term care insurers, as covered entities under HIPAA, must ensure that their business associates are affording PHI the privacy protections required by HIPAA.

The long-term takeaways are less clear. What would happen, for instance, if the prohibition on the use of genetic information in underwriting were extended to long-term care insurers in the future? HHS has made it abundantly clear that individuals have a strong privacy interest in their own genetic information. Moreover, HHS did not extend a permanent or unequivocal exemption to long-term care carriers—instead, HHS exempted long-term care carriers based on the current information available to HHS. Indeed, the Mega Rule contemplates a study by the NAIC to examine the effect of the underwriting prohibition on long-term care insurance. The current reprieve is hardly a long-term guarantee.

It also seems fair to speculate that prohibiting long-term care insurers from using genetic information altogether in underwriting could influence the need for rate increases due to anti-selection. Though far too early to draw fatalistic conclusions, it is not entirely out of the realm of possibility that an outright ban on the use of genetic information could discourage some wary insurers from remaining in the long-term care space. At a minimum, such a ban could complicate the underwriting and pricing processes.

Another interesting legal question is whether HHS actually has the authority to extend the underwriting prohibition to all HIPAA-covered entities. The original underwriting prohibition, found in GINA, applies strictly and specifically to group health plans, health insurance issuers and issuers of Medicare supplemental policies. Several commenters have suggested that HHS lacked the power to extend the underwriting prohibition beyond those three groups, as doing so would result in an executive-branch agency improperly abrogating powers reserved for the legislature. HHS dismissed these concerns on the grounds that GINA and HIPAA authorized HHS to devise the Mega Rule, and that nothing in the Mega Rule is contrary to the statutory text of GINA. Nevertheless, the extension of the Mega Rule certainly goes beyond the plain language of GINA, and one could foresee a legal challenge seeking to strike down portions of the Mega Rule. ■

ENDNOTES

[1] The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients' rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections. See The Privacy Rule, Department of Health and Human Services, available at http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html (last accessed Feb. 28, 2013).