United States Senate
WASHINGTON, DC 20510

January 18, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

We write concerning HHS' proposed rule (74 Fed. Reg. 51698) to implement section 105, Title I, of the Genetic Information Nondiscrimination Act of 2008 (GINA). For reasons discussed below, we believe that the proposed rule's prohibition on the use of genetic information by long-term care insurance carriers for underwriting purposes is overreaching.

Long-term care insurance carriers, and disability and life insurers, have traditionally used family histories and, more recently, genetic information, to underwrite applicants. As a corollary, individuals who wish to apply to purchase such policies provide voluntary, informed, written consent to releasing their protected health information to long-term care insurers, which then use it for underwriting purposes. The legislative history of GINA recognizes this in its discussion of long-term care insurance, which is among the "excepted benefits" under ERISA and the Public Health Service Act.

The Senate Health, Education, Labor and Pensions Committee Report (S. Rep. No. 110-48) published to accompany the markup of GINA (S. 358) states:

> "....[I]t has never been the intent of the bill to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services. "Excepted benefits," including benefits for long-term care, are not subject to the provisions of sections 101 or 102 which track the HIPAA framework that exempts "excepted benefits" from its substantive provisions. Accordingly, long-term care insurance is not subject to section 104 [the precursor to GINA section 105]."

Additionally, the Congressional Record of April 25, 2007, includes the following statement from Rep. Gene Green, a leading proponent of GINA, that "sponsors and supporters all agreed that this bill was never intended to regulate the long-term care insurance market." Rep. Green further urged Members of Congress to work toward

ensuring "that future legislation extends the patient protections inherent in this bill to consumers who want to plan for their future and purchase long-term care." (153 Congressional Record H4100 (daily ed. April 25, 2007).

However, the proposed rule issued by HHS, published on October 7, 2009, (74 Federal Register 51698) to amend the Health Insurance Portability and Accountability Act privacy rule would *remove* the ability of individuals to control the release of their protected health information through written informed consent for use in underwriting for long-term care insurance products. We urge the Department to re-examine and revise the proposed regulation to permit such written authorizations for underwriting purposes for these products. [i]

Subjecting private long-term care insurance carriers to GINA's prohibitions on the use and disclosure of genetic information at this juncture could jeopardize the viability of this still-evolving market. It would also undermine Congress' intent that long-term care insurance should play a helpful role in financing the nation's long-term care costs, and would ensure that those individuals who can afford and wish to purchase such policies can readily do so, if they provide written authorization before releasing their protected health information for purposes of underwriting.

In closing, we would note that Congress, State legislatures or the National Association of Insurance Commissioners may decide to examine whether underwriting practices in the long-term care insurance market need to be revisited at the point that advances in genetic testing technology allow illness and disability to be predicted years before a condition actually manifests. Until such time, the legislative history of GINA makes it clear that Congress did not intend to include long-term care insurance in GINA's prohibitions on use and disclosure of protected health information in the context of underwriting.

Sincerely,

Herb Kohl
U.S. Senator

Olympia Snowe
U.S. Senator

[i] In March 2010, the Patient Protection and Affordable Care Act (PL 111-148 and 111-152) was enacted, which includes a new publicly financed long-term care program known as the Community Living Assistance Services and Supports (CLASS) program. In contrast to GINA, this program expressly prohibits an individual's health and genetic information from being used for purposes of underwriting.

Congressional Research Service

MEMORANDUM November 22, 2010

To: Senate Special Committee on Aging
Attention: Anne Montgomery

From: Edward C. Liu, Legislative Attorney (7-9166)
Amanda Sarata, Specialist in Health Policy (7-7641)

Subject: **Analysis of HHS' Proposed Rule Implementing § 105 of the Genetic Information Nondiscrimination Act**

This memorandum is being furnished to you pursuant to your request for clarification of an October 7, 2009 HHS Proposed Rule (74 Fed. Reg. 51698) implementing § 105 of the Genetic Information Nondiscrimination Act (GINA, P.L. 110-233). Specifically, you asked for an analysis of: 1) the reach of the proposed rule with respect to long term care insurance carriers; 2) congressional intent to include long term care insurance carriers within the scope of GINA; and 3) secretarial authority with respect to including long term care insurance carriers by regulation.

We have provided the requested analysis below. The memo begins with an overview of the HIPAA Privacy Rule; GINA; and the reach of the proposed rule with respect to long term care insurance carriers specifically. It then provides an analysis of the relevant legal issues that are raised by the expanded scope of the proposed rule implementing § 105 of GINA and concludes with an analysis of potential policy issues relevant to such an expansion.

Since the subject of this memorandum is of general interest to Congress, excerpts may be provided to other congressional requesters, or may be used to generate a general distribution report to Congress. As always, in such situations, your confidentiality as a requester would be preserved. Please feel free to contact us with additional questions at the numbers listed above.

The HIPAA Privacy Rule

In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA)[1] to "improve portability and continuity of health insurance coverage in the group and individual markets."[2] HIPAA also

[1] P.L. 104-191, 110 Stat. 1936 (1996), codified in part at 42 U.S.C. §§ 1320d *et seq.*

[2] H.Rept. 104-496, at 1, 66-67, reprinted in 1996 U.S.C.C.A.N. 1865, 1865-66.

included administrative simplification provisions[3] requiring "the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information."[4] In order to protect the privacy of individuals' health information, § 264 of HIPAA directed the Secretary of Health and Human Services (HHS) to recommend, and ultimately promulgate regulations establishing, "standards with respect to the privacy of individually identifiable health information" that is transmitted in connection with the administrative simplification provisions mentioned earlier.[5] These regulations are known as the HIPAA Privacy Rule (Privacy Rule) and govern the use of protected health information (PHI) by health care providers who transmit financial and administrative transactions electronically, health plans, and health care clearinghouses (known collectively as covered entities).[6] Failure to comply with the Privacy Rule may subject a covered entity to civil or criminal penalties.[7]

The Genetic Information Nondiscrimination Act

On May 21, 2008, GINA was enacted to prohibit discrimination based on genetic information by health insurers and employers. Title I of GINA strengthens and clarifies existing HIPAA nondiscrimination and portability provisions through amendments to the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHSA), and the Internal Revenue Code (IRC), as well as to the Social Security Act (SSA). Broadly, GINA prohibits health insurers from engaging in three practices: (1) using genetic information about an individual to adjust a group plan's premiums, or, in the case of individual plans, to deny coverage, adjust premiums, or impose a preexisting condition exclusion; (2) requiring or requesting genetic testing; and (3) requesting, requiring, or purchasing genetic information for underwriting purposes.

Congress enacted GINA in part to prevent certain health plans and health insurers from using genetic information to underwrite individuals seeking health insurance. Toward this end, GINA directs the Secretary of Health and Human Services to revise the HIPAA Privacy Rule[8] to reflect that genetic information shall be treated as health information and the use or disclosure by a covered entity of protected health information (i.e., genetic information) for the purposes of underwriting shall not be a permitted use or disclosure. The Secretary, in consultation with the Secretaries of Labor and the Treasury, had 12 months after enactment to issue final regulations to carry out these revisions. Specifically, § 105 of GINA directs the Secretary of HHS to amend the Privacy Rule so that:

> the use or disclosure by a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a Medicare[sic] supplemental policy of protected health information that is genetic information about an individual for underwriting purposes under the group

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[3] 42 U.S.C. §§ 1320d—1320d-8.

[4] 110 Stat. 2021.

[5] P.L. 104-191, § 264(a), (c)(1).

[6] 45 C.F.R. parts 160 and 164.

[7] CRS Report RL33989, *Enforcement of the HIPAA Privacy and Security Rules*, by Gina Stevens.

[8] 45 C.F.R, Part 46.

> health plan, health insurance coverage, or Medicare[sic] supplemental policy shall not be a permitted use or disclosure.[9]

Under the existing Privacy Rule, a covered entity generally may not use or disclose an individual's PHI without the prior authorization of the individual, unless it is being used for treatment, payment, or health care operations.[10] Underwriting is also expressly included as a health care operation under the Privacy Rule. Therefore, a health plan's use of PHI, including genetic information, for underwriting purposes is not prohibited by the existing Privacy Rule.[11] As discussed below, this would be changed by the proposed rule.

In October of 2009, HHS issued a proposed rule to amend the Privacy Rule to implement § 105 of GINA.[12] Among other things, the proposed rule would provide that:

> Notwithstanding any other provision of this subpart [the HIPAA Privacy Rule], a health plan shall not use or disclose protected health information that is genetic information for underwriting purposes.[13]

Additionally, under the terms of the proposed rule, the use of an individual's genetic information for underwriting purposes is barred even if authorized by an individual.[14]

The scope of the proposed rule's prohibition on the use of genetic information for underwriting purposes appears to be broader than what is required under § 105 of GINA. The proposed rule would apply to all health plans, as that term is defined under the Privacy Rule, including an "issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy."[15] In contrast, § 105 of GINA only requires the prohibition to be extended to group health plans, health insurance issuers that issue health insurance coverage, and issuers of Medicare supplemental policies.[16]

Analysis

The differences between the scope of the proposed rule and § 105 of GINA raise legal and policy questions. First, does the Secretary of HHS have the discretion to prohibit long-term care insurers from using genetic information for underwriting purposes? Second, if the Secretary does have the discretion to do so, what policy considerations may be raised by such an expansion of the application of GINA?

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[9] P.L. 110-233, § 105(a) codified at 42 U.S.C. §1320d-9(a)(2).

[10] 45 C.F.R. § 164.502.

[11] It may be prohibited by other federal or state laws.

[12] 74 Fed. Reg. 51698 (Oct. 7, 2009).

[13] 74 Fed. Reg. 51709.

[14] 74 Fed. Reg. 51703, 51709.

[15] 45 C.F.R. § 160.103.

[16] 42 U.S.C. § 1320d-9(a)(2).

Legal Issues

Section 105 of GINA directs the Secretary of HHS to amend the Privacy Rule so that it is "consistent with" a prohibition on the use of genetic PHI for underwriting purposes by group health plans, health insurance issuers and Medicare supplemental plans.[17] However, it may be argued that § 105 does not give the Secretary the authority to extend the genetic underwriting prohibition to other classes of health plans.

GINA did not otherwise modify the Secretary's existing authority to promulgate regulations governing the privacy of individually identifiable health information held by covered entities under HIPAA. Therefore, HHS could argue that it is authorized under HIPAA to extend the genetic underwriting prohibition to all health plans. The 1996 legislative delegation to the Secretary under HIPAA itself provides little guidance regarding the substance of the regulations, other than requiring that they address "at least"[18] the following subjects:

> (1) The rights that an individual who is a subject of individually identifiable health information should have.
>
> (2) The procedures that should be established for the exercise of such rights.
>
> (3) The uses and disclosures of such information that should be authorized or required.[19]

Where Congress has explicitly delegated the authority to "elucidate a specific provision of [a] statute by regulation," courts traditionally provide executive agencies broad deference. Such regulations are given controlling weight unless they are "arbitrary, capricious, or manifestly contrary to the statute."[20]

Arbitrary or Capricious

The Supreme Court has held that an agency acts in an arbitrary or capricious manner where it "has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[21]

In its Federal Register notice accompanying the proposed rule, HHS noted that under the Privacy Rule:

> an individual's privacy interests and rights with respect to the use and disclosure of PHI are protected uniformly without regard to the type of health plan that holds the information. Thus, under the Privacy Rule, individuals can expect and benefit from privacy protections that do not diminish based on the type of health plan from which they obtain health coverage.[22]

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[17] 42 U.S.C. § 1320d-9(a)(2).

[18] P.L. 104-191, § 264(c)(1).

[19] P.L. 104-191, § 264(b).

[20] Chevron, Inc. v. Natural Resources Defense Council, 467 U.S. 837, 844 (1984).

[21] Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

[22] 74 Fed. Reg. 51700.

Therefore, it concluded that application of the genetic underwriting prohibition to all health plans was "in keeping with a uniform privacy construct."[23] HHS also considered the adverse impact that the proposed rule could have on health plans that were not subject to GINA, but noted that it did not "expect that all of the health plans subject to the Privacy Rule use or disclose PHI that is genetic information for underwriting today."[24]

It is not possible to fully apply the arbitrary and capricious standard described above in this case because HHS has not yet issued a final rule, and the administrative record is incomplete. However, applying the standard to the record thus far, it seems unlikely that a court would describe the agency's decision as arbitrary or capricious. In directing HHS to promulgate national standards, the uniform application of those standards was likely one of the factors Congress intended HHS to consider. HHS has also appeared to consider adverse impacts on the industry. It is possible that comments submitted in response to the proposed rule will raise evidence that the agency would need to respond to, but thus far it does not appear that the rationale offered by HHS would be regarded by a reviewing Court as so implausible as to be arbitrary or capricious.

Manifestly Contrary to the Statute

HIPAA provides few requirements regarding the Privacy Rule, so it would be difficult to say that the proposed rule is contrary to HIPAA. However, it might be argued that the proposed rule is contrary to § 105 of GINA because it expands the scope of health plans beyond what is required in that statute. In essence, this argument asserts that § 105 of GINA limited the broad discretion afforded to the HHS Secretary by HIPAA in the area of prohibitions on genetic underwriting.

In some respects, this assertion is true. If the Secretary had issued a proposed rule that limited the genetic underwriting prohibition to fewer health plans than § 105 required, this would not appear to be consistent with GINA because compliance with the proposed rule would not guarantee compliance with the requirements of § 105. In this case, the broad authority under HIPAA would have been in direct conflict with GINA, and GINA would likely have prevailed as the more recent and more specific enactment.

However, this does not necessarily mean that using the broad authority under HIPAA to provide more expansive protections against genetic underwriting is similarly in conflict with the requirements in § 105 of GINA. Arguably, § 105 merely establishes a minimum level of protection below which the Privacy Rule may not fall. Therefore, if finalized, the proposed rule would not be manifestly contrary to § 105 because compliance with the broader protections in the proposed rule would still logically guarantee compliance with § 105 of GINA.

Policy Issues

This section discusses two policy issues around the broad application of GINA § 105 to all plan types encompassed under the HIPAA Privacy Rule definition, including long term care insurers. First, it appears from the legislative history that it was not the intent of Congress to apply the prohibitions in GINA to long term care insurers. Second, the application of § 105 of GINA to all plan types encompassed under

[23] *Id.*
[24] *Id.*

the Privacy Rule would create inconsistencies internally within the statute in terms of the prohibitions on the use, disclosure, and collection of genetic information.

Legislative History

It is arguable that Congressional intent was to exclude long term care insurance from the scope of GINA. Specifically, the Senate HELP Committee Report for S. 358 states:

"Long-term care insurance is not intended to be subject to section 104. Since benefits for long-term care insurance are 'excepted benefits' ... it has never been the intent of the bill to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services. "Excepted benefits," including benefits for long-term care, are not subject to the provisions of sections 101 or 102 which track the HIPAA framework that exempts "excepted benefits" from its substantive provisions. Accordingly, long-term care insurance is not subject to section 104."[25]

S. 358 did not include modifications to the Internal Revenue Code (found at § 103 of GINA), so § 104 of S. 358 tracks with § 105 of GINA.

In addition, it was widely accepted and reported throughout the policy community that GINA excluded life insurance, disability insurance and long-term care insurance.[26] Not only does this interpretation comport with the referenced definitions in GINA Secs. 101-103 (see analysis below), it also accurately reflects political circumstances which favored passage of a more narrowly crafted piece of legislation.

Internal Statutory Consistency

Differential Scope of GINA Sec. 105 vs. Secs. 101- 103

The applicability of the prohibitions established in Secs. 101-103 of GINA are limited to group health plans and health insurance issuers, as defined at ERISA Section 732(c)(2)(B); PHSA Section 2791(c)(2)(B); and IRC Section 9832(c)(2)(B). Specifically, PHSA Section 2763(a) states that "[T]he requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in section 2791(c)(1)." Section 2791(c) (2) defines "excepted benefits" to include, where offered separately, "[B]enefits for long term care, nursing home care, home health care, community-based care, or any combination thereof."

This creates a situation whereby the prohibitions established in Secs. 101-103 of GINA do not apply to long-term care insurance, whereas the prohibition on the use and disclosure of protected health information, that is genetic information, for purposes of underwriting established in § 105 of GINA and implemented in the HHS proposed rule, would apply to long-term care insurance. It might be desirable, from a policy perspective, to have the prohibitions established in Title I of GINA apply uniformly.

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[25] S. Rept. No. 110-48, p. 27, 110th Cong. 1st Session (2007).

[26] National Human Genome Research Institute. "The Genetic Information Nondiscrimination Act of 2008, Information for Researchers and Health Care Professionals." Accessed at: [http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf].

Long-term Care Insurance vs. Group Health Plans/Health Insurance Issuers

The HHS proposed rule would also create differential requirements on long-term care insurance carriers and group health plans/health insurance issuers. Specifically, while Secs. 101-103 place limits on both the collection and the use of genetic information, § 105, and its required modification of the HIPAA Privacy Rule, would place restrictions on the disclosure of genetic information, as well as seemingly redundant prohibitions on the use of the information for underwriting purposes. This would result in a situation whereby long-term care insurance carriers would not have prohibitions on the collection of genetic information, but would on its use and disclosure. This would be in contrast to group health plans and health insurance issuers, who would have prohibitions on the collection, use and disclosure of genetic information.

Requirements for Written Authorization

The HHS proposed rule would remove the ability of the individual to control the release of his or her protected health information, that is genetic information, through written authorization for the purposes of use in underwriting. In other words, under the HHS proposed rule, the individual could provide written authorization for the release of his information, and the health insurance issuer or group health plan would still not be permitted to use such information for underwriting purposes.

This aspect of the HHS proposed rule is in contrast with processes established under Title II of GINA as they relate to employers, employees, and wellness program Specifically, Secs. 202- 205 of Title II of GINA establish that employers are permitted to request, require, or purchase genetic information with respect to an individual or family member where the employer offers health or genetic services, including as part of a wellness program. Under these sections of GINA, employers are permitted to acquire genetic information (that is, individuals are able to release their information) if certain statutorily defined requirements are met, one of which is the provision of prior, knowing and voluntary written authorization on the part of the employee.

It may be argued that the use of genetic information by an employer in the context of a wellness program could be beneficial to the employee, and therefore that it is logical to allow the individual to control release of this information to his employer in this particular context. In contrast, it is unclear if releasing protected health information, that is genetic information, to a covered entity per the HIPAA Privacy Rule may ever be beneficial to the individual; however, removing the individual's control over release of his or her own information in this way may be viewed by some as paternalistic.