Scope of Coverage Comparison and Preemption Analysis

NCCUSL Uniform Act on Misuse of Genetic Information in Employment and Insurance
2007 Annual Meeting Draft
and
Genetic Information Nondiscrimination Act of 2007 (GINA), H.R. 493
(passed House: April 25, 2007; placed on Senate calendar: April 30, 2007)

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I. EMPLOYMENT

A. Coverage Analysis (see also comparison table at end of memo)

The NCCUSL draft and the GINA bill cover very similar employment entities. The primary difference is that employers under GINA are defined by the 1964 Civil Rights Act as those with 15 or more employees, while the NCCUSL provisions apply if there is even one employee. There is also a minor difference in that the federal bill covers "training programs" while the NCCUSL draft covers "licensing authorities."

The information that would be affected by the two pieces of legislation is very similar. The definitions have different scopes, but the "genetic information" plus "family medical history" covered in the NCCUSL draft are essentially equivalent to "genetic information" in GINA. The primary difference is that the federal bill specifically includes genetic information of a fetus or embryo in its definition of "genetic information."

The NCCUSL draft sets restrictions on genetic testing by employers. GINA has no comparable provision.

Both texts prohibit employers from accessing genetic information with exceptions. The common denominator for those exceptions is employer access to aggregate data on genetic monitoring, but the federal bill limits this exception to genetic monitoring required by state or federal law.

The NCCUSL draft includes an exception that would permit an employer to defend a legal claim brought by an employee, but this is missing from GINA. There are also several exceptions in GINA that are not found in the NCCUSL draft. (See comparison table.)

In terms of use, GINA prohibits "discrimination" while the NCCUSL draft prohibits adverse employment action. The NCCUSL draft has an exception for protecting the health and safety of others from a direct threat that is not included in GINA. The NCCUSL draft also permits uses that may or may not be prohibited by GINA's discrimination clause, such as reducing workplace exposure for a susceptible individual.

Confidentiality and disclosure provisions are similar except that the NCCUSL draft gives employees the capability to authorize disclosure and GINA includes research provisions and the

Family Medical Leave Act. In addition, entities covered by the HIPPA privacy regulations are not affected by GINA's use and disclosure provisions.

There are major differences in remedies and enforcement. The federal bill couples enforcement by the EEOC or Attorney General with a private right of action that has a 180-day statute of limitations. Significantly, this cause of action may not be based on disparate impact, and so would be available only to redress intentional discrimination. The NCCUSL draft relies on a private right of action with a statute of limitation of two years. Relief is more limited under the federal bill and is subject to caps based on the number of employees.

B. Preemption Analysis

The federal bill provides that Title II, which covers employment, shall not be construed to limit the rights or protections of an individual under any Federal or State statute that provides equal or greater protections. (§ 209) Therefore, this legislation would not preempt NCCUSL employment provisions that supplement it or are more stringent.

In some cases, the NCCUSL provisions could be construed as providing less protection for employees. This is probably limited to NCCUSL provisions that create exceptions to prohibitions, such as the exception for employer access to defend a legal claim, and NCCUSL's broader genetic monitoring authorization.

Another relevant federal statute is the Health Insurance Portability and Accountability Act (HIPAA), because some employers (primarily health care providers) are covered by the use and disclosure provisions of the HIPPA privacy regulations. GINA provides that it is superceded by the HIPPA privacy regulations for those employers which are subject to them. The NCCUSL draft privacy protections are not, however, preempted by HIPPA because it explicitly permits more stringent state privacy rules. It is possible that a few of the exceptions to the NCCUSL prohibition on disclosures could be preempted if they are interpreted as more lenient than the HIPPA rule.

II. HEALTH INSURANCE

A. Coverage Analysis

Title I of H.R. 493, which covers Health Insurance, amends the Employment Retirement Income Security Act (ERISA), the Public Service Health Act, the Internal Revenue Code and Title XVIII of the Social Security Act relating to Medigap. Each act, as it would be amended, is compared to the NCCUSL draft.

1. ERISA

The NCCUSL draft covers more entities than ERISA, which is limited to group health insurance plans covering 50 or more individuals. The NCCUSL draft covers all individual and group health insurance plans.

GINA would strengthen ERISA by prohibiting group health plans from requesting or requiring genetic testing, subject to requests to participate in research. The NCCUSL draft does not contain the research exception.

In terms of access to information, both texts prohibit collecting genetic information for underwriting. (We are not sure, however, whether "collecting" as used in ERISA means just "testing" or also "accessing" in other ways.)

The NCCUSL draft prohibits use of genetic information for eligibility determinations and underwriting but permits billing and therapeutic uses. In contrast, the ERISA amendments would prohibit group-based discrimination on the basis of genetic information.

2. Public Health Service Act

The Public Health Service Act ("PHSA") is a United States federal law enacted in 1946. The full act is captured under Title 42 of the United States Code "The Public Health and Welfare", Chapter 6A "Public Health Service." The portion of the Public Health Service Act that is devoted to health insurance coverage is set forth at 42 U.S.C. §300gg. The Public Health Service Act governs health insurance provided to federal employees, as well as certain federally qualified health centers ("FQHCs") that are created under PHSA Section 330 federal grant funding, such as Community Health Centers, Migrant Health Centers, Health Care for the Homeless Programs, and Public Housing Primary Care Programs.

The PHSA already contains limitations on exclusions for preexisting conditions, which specifically prohibit treating genetic information as a preexisting condition in the absence of a diagnosis of the condition related to such information. 42 U.S.C. § 300gg(b)(1)(B). The PHSA also prohibits discrimination against individual participants in group health plans based on health status, including prohibiting use of genetic information when determining enrollment eligibility. 42 U.S.C. § 300gg-1(a)(1)(F). The PHSA prohibits group health plans and health insurance issuers from requiring any individual to pay a premium higher than a similarly situated individual enrolled in the plan on the basis of any health status-related factor. 42 U.S.C. § 300gg-1(b)(1). GINA would strengthen this PHSA "premium contribution" provision at § 300gg-1(b) by adding a prohibition for group health plans and health insurance issuers from using genetic information to adjust premium or contributions amounts. All of the PHSA provisions relating to health insurance contain "preemption" sections allowing States to establish more protective standards. The PHSA adopts the definition of "group health plan" used by ERISA (see 42 U.S.C. §300gg-91(a)), and adds a new definition of "family member" at 42 U.S.C. §300gg-91(d)(15) to include first, second, third, and fourth degree relatives, and to add a definition of "genetic information" at 42 U.S.C. §300gg-91(d)(16) to mean any information about such individual's genetic tests, the genetic tests of family members, and the manifestation of disease or disorder in family members. Lastly, GINA adds in definitions of "genetic tests," "genetic services," and "underwriting purposes" to 42 U.S.C. §300gg-91(d)(17-(19), respectively.

The PHSA also applies to health insurance offered in the individual market, at 42 U.S.C. §300gg-51 et seq. The PHSA requirements relating to the individual market are intended to

provide access to health benefits for individuals in the individual market within States. States are allowed funding for providing individual market reforms for the uninsured, as long as they meet certain criteria set forth at 42 C.F.R. §300gg-44, such as high risk pools. GINA would add a new section at the end of 42 U.S.C. § 300gg-51 prohibiting use of genetic information as a condition of eligibility in the individual market, and prohibiting use of genetic information in setting premiums in the individual market, and prohibiting use of genetic information as a preexisting condition in the individual market.

In sum, GINA would strengthen PHSA by prohibiting health insurers subject to PHSA from requesting or requiring genetic testing, subject to requests to participate in research. The NCCUSL draft does not contain the research exception.

The NCCUSL draft prohibits use of genetic information for eligibility determinations and underwriting but permits billing and therapeutic uses. In contrast, the PHSA amendments would prohibit discrimination on the basis of genetic information in group health plans or on the individual market.

3. Internal Revenue Code

GINA would amend subsection (b) of section 9802 of the Internal Revenue Code so as to prohibit group health plans from adjusting premium or contribution amounts for the group covered under such plan on the basis of genetic information. In addition, new subsections to section 9802 would prohibit a group health plan from requesting or requiring an individual or family member of such individual to undergo a genetic test, except in connection with requests to participate in research. (The NCCUSL draft does not contain the research exceptions) Also, subsection (d) of section 9802 would prohibit group health plans from requesting, requiring, or purchasing genetic information for underwriting purposes, and from requesting, requiring, or purchasing genetic information with respect to any individual prior to such individual's enrollment under the plan.

4. Title XVIII of the Social Security Act (Medicare) relating to Medigap

Both Medicare Parts A and B have deductible and coinsurance cost sharing provisions, and there are also a number of services and items that are not covered under either Medicare Parts A or B, such as custodial nursing home care, dental care, and eyeglasses. Medicare beneficiaries may either pay the amounts that are not covered under Medicare Parts A and B "out-of-pocket," or may choose to individually purchase private "Medigap" insurance to help cover the gaps and pay these costs. Approximately 75% of all Medicare beneficiaries have some type of private supplemental health insurance coverage, which may include Medigap policies, employer-sponsored health plans, as weel as limited benefit plans such as indemnity policies for specified disease coverage and long-term care policies. NAIC Model Standards, as revised in 1992, prescribed 10 standardized Medigap benefit packages, designated "A" through "J." More recently, as a result of the Medicare Modernization Act of 2003 (Pub. L. 108-173), the NAIC has designated two standardized Medigap benefit packages ("K" and "L") which eliminate first dollar coverage for most Medicare cost-sharing and have annual out-of-pocket limits. Once the annual out-of-pocket limit is reached, the policy covers 100% of all cost-sharing under Medicare

Parts A and B for the balance of the calendar year. For 2006, the out-of-pocket limit for Plan K was $4,000, and for Plan L was $2,000.

Congress has granted the Secretary of Health and Human Services with the authority to establish procedures to certify Medicare supplemental health insurance "Medigap" policies. 42 C.F.R. § 1395ss. The current version of 42 C.F.R. § 1395ss(s) sets forth coverage of preexisting conditions at (s)(1), and (s)(2) currently prohibits Medigap issues from denying or conditioning issuance, or discrimination in pricing of policy, because of health status, claims experience, receipt of health care, or medical conditions. GINA amends 42 U.S.C. 1395ss(s)(2) to specifically prohibit genetic discrimination in Medigap as it pertains to issuance and pricing. GINA also creates a new section at the end of 42 U.S.C. §1395ss(s), limiting requesting or requiring genetic testing by Medigap issuers, and prohibiting collection of genetic information for underwriting purposes, and prohibiting Medigap issuers from collecting genetic information prior to enrollment.

These policies would also be covered under the terms of the NCCUSL draft.

GINA would prohibit Medigap health insurers from requesting or requiring genetic testing, subject to requests to participate in research. The NCCUSL draft does not contain the research exception.

Instead of a discrimination provision, the Medigap amendments prohibit insurers from using genetic information to deny or condition issuance of policies, exclude benefits or affect pricing. The NCCUSL draft similarly prohibits use of genetic information for eligibility determinations and underwriting.

5. HIPAA

GINA Section 105 directs the Secretary of HHS to amend HIPAA privacy regulations so as to prohibit "use" of genetic information for underwriting purposes. This is consistent with the prohibitions of section 302 in the NCCUSL draft, which prohibits a medical insurer from considering genetic information in setting rates, terms, and conditions.

B. Preemption Analysis

H.R. 493 does not include any preemption provisions for health insurance, so this analysis considers preemption under the statutes that would be amended by the federal bill.

1. ERISA

2. PHSA – all PHSA sections relevant to health insurance contain preemption clauses which state that PHSA will not be construed to supersede any provision of State law with establishes standards or requirements for health insurance except to the extent that such standards or requirements prevent application of PHSA. In other words, PHSA does not preempt more stringent state requirements.

3. IRS

4. Medigap – According to 42 U.S.C. § 1395ss(j), "Nothing in this section shall be construed so as to affect the right of any State to regulate medicare supplemental [Medigap] policies which, under the provisions of this section, are considered to be issued in another State."

5. HIPAA – Again, to the extent state privacy rules are more stringent, they will not be preempted by any eventual changes to the HIPAA privacy regulations.

III. LIFE, DISABILITY-INCOME, AND LONG-TERM-CARE INSURANCE

A. Coverage

H.R. 493 does not include any provisions on life insurance or disability-income insurance. Our preliminary conclusion is that it also does not appear to affect long-term care insurance.

B. Preemption

The provisions of Article IV of the NCCUSL draft on life and disability-income insurance would not be preempted by H.R. 493 because the bill has no coverage in this area.

IV. PRIVACY

A. Coverage

HR 493 Section 105 requires the HHS Secretary to revise the HIPAA privacy regulations to treat genetic information as health information.

The revised regulations must prohibit disclosure of genetic information by covered entities for underwriting purposes under a group health plan's health insurance coverage or Medicare supplemental policies.

B. Preemption

Again, to the extent state privacy rules are more stringent, they will not be preempted by any eventual changes to the HIPAA privacy regulations.

In addition, one interesting provision of HR 493 (Section 106) requires the Secretary of Health and Human Services (which promulgates HIPAA regs) to coordinate with the Secretary of Labor and Secretary of Treasury under an interagency memorandum of understanding so that all regulations, rulings, and interpretations over which two or more Secretaries have responsibility will be administered so as to have the same effect. This Coordination provision may bolster an argument that none of the regulations issued under GINA (or at least those governing privacy)

preempt more stringent state laws because they must be administered consistently with the HIPAA regulations.

I. Employment Provisions *(differences are italicized)*

NCCUSL Draft	H.R. 493
<u>Entities Covered</u> Employee = works for compensation or applicant; Employer of at least *1 employee*; Employment agency; Labor organization; *Licensing authority*	<u>Entities Covered</u> Employee includes applicant; Employer defined by 1964 Civil Rights Act = *15+ employees* plus government employers; Employment agency; Labor organization; *Training program*
<u>Information affected</u> Genetic information = tests + use of genetic service Family medical history	<u>Information affected</u> Genetic information = tests + use of genetic service + disease in family members Definitions are similar to NCCUSL, EXCEPT that genetic information includes genetic information of a fetus or embryo.
<u>Restrictions on genetic testing</u> *Prohibits offering or providing testing EXCEPT:* *– genetic screening for predisposing characteristics that create susceptibility to harm in workplace;* *– genetic monitoring program;* *– preventative health program* *(all require employee authorization).*	<u>Restrictions on genetic testing</u> *No comparable provision.*
<u>Restrictions on access and use</u> Prohibits knowingly obtaining genetic information & family medical history. *May not inquire, request, or require but employee may submit voluntarily.* EXCEPT: – Genetic monitoring program (aggregate information only); *– Court order if employee has placed health at issue in judicial proceeding and employer demonstrates compelling need.*	<u>Restrictions on access and use</u> Prohibits acquisition of genetic information. EXCEPT: – Inadvertent requests; *– For health services provided by employer (aggregate information only);* *– Family & Medical Leave Act purposes;* *– Purchase of published materials;* – Genetic monitoring, but *only if required by federal or state law & complies with monitoring regulations* (aggregate information only);

– For employer use as quality control in forensic laboratory.

Prohibits adverse employment action based on genetic information or family medical history.
EXCEPT:
– to protect health & safety of others from direct threat created by employee genetic characteristic.

Permitted uses:
– genetic monitoring program;
– defend legal claim;
– reduce workplace exposure for susceptible individual.

Discrimination prohibited in hiring, discharge, compensation, terms, conditions or privileges, or classification based on genetic information.

<u>Confidentiality and Disclosure</u>

Genetic information = confidential record to be retained separately from personnel files.

Disclosure prohibited EXCEPT:
– to employee;
– by employee authorization;
– by court order;
– genetic monitoring program (aggregate form).

<u>Confidentiality and Disclosure</u>

Genetic information to be treated as a confidential medical record.

Disclosure prohibited EXCEPT:
– to employee;
– to researcher under 45 CFR part 46;
– by court order
– investigation of compliance with GINA;
– Family Medical Leave Act.

Covered entities under HIPAA permitted to use and disclose genetic information as allowed by HIPAA regulations.

Remedies and Enforcement

No enforcement provision

Private right of action;
Two-year statute of limitations.

Relief may include:
compensatory damages, *back pay, front pay, reassignment, reinstatement, injunctive relief,* punitive damages

Attorney's fees and costs awarded to prevailing plaintiff.

Remedies and Enforcement

Enforcement by EEOC or Attorney General under Civil Rights Act, 42 U.S.C. § 2000e-5;

Private right of action after 180 days or right to sue letter;
180-day statute of limitations

Relief for private cause of action = compensatory and punitive damages *subject to caps based on number of employees under 42 U.S.C. § 1981a.*

Court has discretion to award attorney's fees to prevailing party under 42 U.S.C. § 1988.

No cause of action based on disparate impact; Commission shall be established in 6 years to recommend whether or not to extend relief beyond intentional discrimination.