

In December 2008 Susannah Baruch of the Genetics and Public Policy Center, Karen Pollitz of the Georgetown Health Policy Institute, and Jeremy Gruber of the National Workrights Institute answered questions about GINA's implementation, the recent Request for Information on GINA from the Departments of Labor, HHS, and Treasury, and recently-published model comments (<http://www.dnapolicy.org/resources/RFlanalysis.pdf>).

An edited transcript of the question and answer session – part of a webinar that was hosted by Genetic Alliance and presented in part by the Coalition for Genetic Fairness – follows. Final federal regulations will clarify many of the issues discussed in this document – our answers represent our best understanding of the law. Please contact us at ginainfo@jhu.edu with any questions.

HIPAA AND GINA

Q: What are the current protections against genetic discrimination in group health plans as provided by HIPAA? Could you also comment on a larger scale -- what are the limitations of HIPAA with regard to the impact of genetics and technology on health care? How does GINA seek to fill in these gaps?

A: Before GINA passed, and until GINA is in effect, HIPAA has provided some protection from genetic discrimination in the group health insurance market, and certainly HIPAA's protections were something of a model in drafting GINA. The intent in drafting the protections in GINA was to extend the protections to the individual market make sure that folks in all types of health insurance had the same protections. The GINA protections also seek to fill some (fairly technical) gaps that were left that to make sure, again, that everyone had the same protections, but not to go much further than HIPAA went, so that compliance would not be a huge burden. During the course of GINA negotiations it became clear that it was important to a lot of stakeholders and members of Congress alike that GINA be consistent with other related laws, whether they are health insurance laws or civil rights laws.

One of the primary tenants of HIPAA is that there is some privacy to your health information, but to the extent that your health insurer needs that information for underwriting, they could have it; underwriting was a permitted use of health information under HIPAA. This was not a genetic specific issue; t his was true in general. What GINA does is say that while that may be true of most health information, it is prohibited for health insurers to collect or to use your genetic health information as defined by GINA for underwriting.

Underwriting is actually defined now in GINA, which is a plus for federal law, and it draws on the definitions of underwriting that had been included in the HIPAA privacy regulations, so it's a

very broad definition. Underwriting in general is just evaluating the risk of a health plan participant or applicant for all kinds of purposes, such as for purposes of establishing eligibility for health insurance. This happens all the time when you are buying an individual policy. “Re-underwriting” is a process for determining continued eligibility — you may have heard about insurance rescissions where underwriters worry that they made a mistake and they admitted someone to a policy and they want to go back and “re-underwrite” and take the policy away. For purposes of setting a premium for a policy, for purposes of determining whether something is excluded as preexisting condition — all of those activities are included in the definition of medical underwriting and they had all been permitted uses of health information under HIPAA privacy rules for most health information. But now under GINA, if it’s genetic information, it cannot be used for underwriting purposes ever. I think that is a really important change in the law, and we wanted to make sure that the regulations clarify the definition of underwriting as broadly under GINA regulations as they had previously been interpreted under HIPAA privacy regulations.

Q. Does the issue of GINA provide an opportunity to discuss how HIPAA fits within the rapidly changing field of genetics and technology? Are there other areas, directly or indirectly related to GINA, that need to be discussed with regard to HIPAA’s protections?

A. Many issues related to HIPAA and technology, including genetics and privacy and the role of electronic medical records, do remain. Those issues are beyond the scope of this Q and A session, but we must be mindful of them as GINA regulations move forward.

Claims and Payment

Q: Can you provide some clarification about how family history can be used as justification for payment with health insurers?

A: Let me give an example because I think it’s useful to think about a case here.

Let’s say that I have a family history of breast cancer, and I want to know if I’m at increased risk. So, the first issue is that my family history of breast cancer is itself genetic information that is protected by GINA. If I want my insurance company to pay for a genetic test to look for one of the BRCA mutations, they may ask me to justify the request for them to pay for that test. To justify it, I have to come up with a particular reason for them to pay for it because they are not going to pay for it for everybody. I could tell them that I have a family history of breast cancer; I could tell them if my ethnic background puts me at increased risk. There are a couple of different arguments, but it may be that the strongest one in that case is revealing my family history.

However, let’s say that I decide that, instead of revealing my family history to my insurance company, I’m going to pay for the genetic test myself and what ends up happening is that I get a positive test result. I’m contemplating prophylactic surgery to reduce my risk and I want my health insurer to pay for this surgery because I don’t want to pay out of pocket. So, my health

insurer will want to know why somebody -- who from their perspective is not at increased risk -- is going to have prophylactic surgery, and why they should pay for it. So, again, I need to come up with an explanation for why they should pay for my prophylactic surgery. In my personal knowledge, I have both my family history and my test results that I could offer, both of which are genetic information, and if I don't want to reveal that information, I don't have to. However, without offering one or the other at least, I'm going to have a hard time making the case for them to pay for that surgery. Having said that, insurers are required to take the minimum necessary information, so I might make the argument that the family history information is enough if I am more comfortable revealing that than a genetic test result.

Q. Could you clarify whether or not health insurers are able to ask for family health history information in making coverage determinations about a specific claim, as well as the measures health insurers must take to treat the information supplied by the participant or beneficiary as protected genetic information? What is the likelihood of a health insurer asking for family health history information as opposed to requesting that an individual undergo genetic testing?

A. Health insurers may only ask for minimum information necessary to justify payment of a claim. What constitutes minimum necessary information will depend on the service for which a claim is made.

For example, a patient who has had breast cancer and tested positive for a BRCA mutation is at heightened risk for ovarian cancer. She may seek a prophylactic oophorectomy and be asked to justify the medical necessity of the surgery. The patient may reveal the positive BRCA test result, or she and her doctor may argue that her own history of breast cancer puts her at heightened risk and is thus enough to prove medical necessity.

Another patient may have no personal history of breast and ovarian cancer, no positive BRCA genetic testing, but a very strong family history of breast and ovarian cancer. She may seek prophylactic surgery based on her family history (which is itself her genetic information) and the insurer may determine whether that information meets its standards for medical necessity. The insurer may not request or require that she take a genetic test as a condition of payment.

Wellness Programs

Q. GINA does not ask for the elimination of the collection of family health history information for wellness programs, correct? Do you have a sense of how effective wellness programs are at alerting individuals to potential familial risks that could lead to improved preventative measures?

A. GINA does not prohibit collection of family health history information by wellness programs in all circumstances. However, under Title I, if wellness programs are considered to be part of an employer group health plan (as defined under ERISA), then we believe the wellness program will be subject to all limitations on collection of genetic information that otherwise apply to group health plans. This means a wellness program could not collect any genetic information

(including family history) prior to enrollment. Once a person is enrolled in a wellness program that is part of a group health plan, the wellness program also could not collect or use genetic information (including family history) for underwriting purposes. Underwriting is broadly defined to include determination of eligibility or continued eligibility for benefits, rating or premium contributions, and other activities. The question about the effectiveness of wellness programs at alerting people to family risks is an important one, but we do not have any current data on that issue. We expect that federal regulations will clarify the rules for wellness programs.

Manifest Disease

Q. Can you comment on the role, if any, of GINA when the diagnosis of a manifest condition hinges on a genetic test, and even more so, when the genetic test result is tied to a prognosis? Does GINA cover the specific result of the genetic test, such as a mutation or chromosomal abnormality, but not the actual diagnosis and manifested symptoms? An example could be an individual who is experiencing nosebleeds and skin telangiectases, but who has not yet undergone genetic testing for Hereditary Hemorrhagic Telangiectasia (HHT) and does not yet carry a diagnosis.

A. When a patient has manifest disease (i.e., signs and symptoms) and a specific diagnosis is made that incorporates the results of a genetic test, GINA does not prohibit underwriting (raising premiums, dropping coverage, etc.) based on the manifest symptoms or the diagnosed disease. The genetic test result itself is covered by GINA -- although that may not help the patient much.

However, as our comments emphasize, a genetic test result alone, without signs and symptoms, should not be considered a manifest disease. In this example, the HHT test, along with signs and symptoms, establishes a diagnosis. Before the test occurs, GINA would not prohibit underwriting on the basis of the symptoms alone. After the test occurs, GINA does not prohibit underwriting on the basis of the diagnosed and manifest disease.

Q. Can you please clarify whether, if an individual with breast cancer undergoes testing for the BRCA1/BRCA2 and is found to test positive and be at an increased risk for ovarian cancer, the increased risk for ovarian cancer can be used for underwriting purposes, if the individual has breast cancer as a manifest condition?

A. In this scenario, the woman would have both a manifested disease (breast cancer) and genetic information about her risk for future disease (ovarian cancer, as well as a second breast cancer). GINA does not regulate discrimination based on manifested disease; this is subject to current state law (which, for example, permits at least some degree of health insurance discrimination based on health status in most state individual markets) and current, pre-GINA federal law (which, for example, prohibits most discrimination based on health status under employer-sponsored group health plans).

However, GINA does protect this woman from health insurance discrimination based on her genetic information. To the extent she might be vulnerable to two penalties (for example, a pre-existing condition exclusion for her current breast cancer and a premium rate increase based on her future risk of ovarian cancer), GINA would prohibit the second penalty.

Q. Can you explain how a young adult with a genetic disorder or disease is protected from genetic discrimination in health insurance and employment upon looking for their first job? For example, if an individual who has been diagnosed with a genetic condition has been under their parents' health insurance throughout high school and college, and is joining either a large business or a small business with fewer than 15 employees, can you provide us with their current protections (before GINA is in effect) for both scenarios? Will GINA change this at all?

A. Prior to GINA's effective date, current federal law prohibits most discrimination based on genetic information in group health plans:

- Group health plans may not discriminate against members of the group based on health status, including genetic information. This means a group plan participant's eligibility for benefits or premium contributions cannot be based on health status.
- Group health plans may not apply a pre-existing condition exclusion period based on genetic information.

However, prior to GINA's effective date, current federal law does not prohibit health insurance companies from charging a higher premium for the entire group based on the genetic information of a group member.

Further, current federal law does not limit collection of genetic information by group health plans and insurers. Nor does it prohibit group health plans and insurers from requesting or requiring individuals to take a genetic test.

In the scenario described above, if a young adult with genetic information joined a small employer health plan prior to GINA's effective date, the insurer who writes the small group coverage might ask the young adult for health information, including genetic information, prior to enrollment. As a result of this individual's genetic information, the small employer might be charged a higher premium for the entire group. Genetic services received by the young adult (for example, preventive therapies to reduce the risk of future disease) might be subject to a pre-existing condition exclusion or lead to further premium increases for the employer.

None of these actions would be allowed once GINA takes effect.

The Research Exception

Q. For the research exception, how much information must the health insurer supply to the plan participants or beneficiaries about the purpose of the research and what will be done with

the information? Will the regulations be able to include such requirements for use of the research exception?

A. Please see our discussion of the research exception in our comments on the recent RFI (<http://www.dnapolicy.org/gina/>) at p. 14. We recommend that regulators require such research to comply with either 45 CFR 46 (for federally funded research), or the substantially equivalent regulations that must be met for research leading to FDA-approved products. Such research would need IRB approval and participants would need to provide written, voluntary, informed consent, which means patients would receive information about the risks and benefits of participation.

DTC and the \$1000 Genome

Q. In your opinion, how does GINA impact the direct-to-consumer (DTC) genetic testing market? Does GINA apply here? How will GINA impact the \$1,000 genome? Is the information from whole-genome sequencing covered by GINA?

A. GINA provides reassurance to individuals considering all forms of genetic testing (including whole-genome sequencing and DTC genetic testing), that the use of their information by health insurers and employers for discriminatory purposes is now illegal. This may increase the number of individuals interested in pursuing genetic testing overall. On the other hand, DTC genetic testing sometimes has been promoted as a way to obtain a genetic test without the results becoming part of the patient's official medical record – a strategy that makes some individuals feel less vulnerable to discrimination. Thus, GINA may reassure some patients that genetic testing through a health care provider is less risky, lessening interest in DTC.

GINA Enforcement – Federal and State

Q: Could you clarify how the federal law will be implemented at the state level, or more specifically, how the Departments of Labor (DOL) and Health and Human Services (HHS) will enforce the federal baseline of protections at the state level?

A. HHS has what is called “fallback” enforcement authority. In the event that a state does not adopt and enforce any one of GINA's provisions, the Secretary of HHS will directly enforce that protection against health insurers in that state. HHS can levy civil money fines against non-complying insurers in the amount of \$100 per day per affected individual.

DOL, by contrast, has direct enforcement authority over group health plans sponsored by employers. In addition, DOL has direct enforcement authority for GINA regulations pertaining to private health insurance companies that sell group policies to employers. DOL can also levy civil money fines against non-complying group health plans and group health insurance companies in the amount of \$100 per day per affected individual. DOL enforcement powers are not dependent on state action. Therefore, for example, if a group health insurance company were to surcharge a small employer's group health plan premium based on genetic information

of an employee, the insurer might be subject to both state enforcement and enforcement by DOL.

Q. How can I get detailed information about my state's current protections against genetic discrimination in health insurance? The National Council for State Legislatures provides just a general grid, and I find my state Web sites to be hard to navigate. Is there a better way to find that information?

A. Try the following site, maintained by the National Human Genome Research Institute:
<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

You may also find useful this article by Karen Pollitz and colleagues for an additional summary of state laws that is somewhat more specific to GINA provisions:

K. Pollitz, B. Peshkin, E. Bangit, and K. Lucia, "Genetic Discrimination in Health Insurance: Current Legal Protections and Industry Practices," *Inquiry*, 44: 350-368 (Fall 2007).

Q. The RFI mentions two different places to submit complaints of GINA violations, HHS and DOL. Will these two methods for submitting complaints be tied together? How are they different? Is there any opportunity for inter-departmental communication and information sharing?

A. The health insurance requirements in GINA are drafted in three places in the federal law. DOL and the Department of the Treasury/IRS work on everything related to group health plans and health insurance sold to group health plans. HHS deals with all plans: group health insurance, individual health insurance, Medigap supplemental insurance, and also the HIPAA privacy component. In order to be thorough, you can submit to all three agencies, but my understanding is that they work together and if you just want to send a general form to one of them, they will all see it.

In recent years, HHS has not maintained a way for consumers to register complaints about violation of federally guaranteed protections in private health insurance. DOL, by contrast, can accept and investigate complaints regarding group health plans. GINA implementation presents federal agencies with an important opportunity to strengthen capacity and procedures for health insurance oversight, complaints, investigations, and information sharing.

Q. Have there been any discussions regarding penalties against health insurers and issuers for violating GINA?

A. The penalty for violation is \$100 per day per affected person. Each of the federal agencies (HHS, DOL, Treasury/IRS) has authority to levy this penalty for violation of GINA protections.

Q. How will state and federal laws intermingle with regard to GINA's enforcement? You may speak generally or more specifically about the issues raised in the RFI about HHS's enforcement on the states with regard to state genetic discrimination laws in health insurance.

A. Most states, at this point, have some kind of genetic nondiscrimination law for their private health insurance market. No state has a law that completely matches up with GINA. Under GINA, these federal standards for health insurance rule and states may enforce equivalent or better protections, but if they don't the federal government is supposed to step in and enforce the federal rules. That is on a provision-by-provision basis, so "close enough for government work" is not an adequate standard for states. States will all need to go back, look at their state laws, and make the needed changes. No state definition of genetic information matches exactly what is in GINA. Many states don't include family history in the definition of genetic information. Many states don't prohibit collection of genetic information by insurers. I'm not aware of any states that have a prohibition on insurers requiring you to take a genetic test. So, states are going to need to look at their laws and conform them to GINA.

What we suggested is that the federal government needs to take responsibility for checking whether states have done this. They are supposed to under current HIPAA regulations, but they haven't for the last eight years. They have done nothing; the office that is authorized to do that has been reorganized out of existence. There is nobody at HHS whose job it is to do this. So, we suggested that HHS will have to be much more careful about going and checking on what states are doing. There should be a process where people can complain if they feel they are not getting their rights under state law; there ought to be an easy and obvious way for HHS to receive complaints about that and other kinds of monitoring processes. The final thing we would note is that there is a change in GINA that gives authority for the Secretary of Labor to directly regulate group health insurers, not just the plan that the employer sponsors, but actually the insurance company that they buy the policy from. DOL has new authority to directly enforce GINA protections. If the states are enforcing against Blue Cross for screwing up on a group policy, that doesn't prevent DOL from doing so as well. There is new, ongoing permanent authority for DOL to directly enforce against group health insurance companies when there are GINA violations. There are stiff fines- it's \$100 per person per day, so if a group health plan has 1,000 people in it, that's \$100,000/day fine. We suggested that there needs to be oversight and enforcement capacity restored in the federal government and there has to be outreach to the states by the federal government so that it is clear what they need to do to conform their laws to these important new federal standards.

Q. Will the process for the writing of regulations for the employment provisions of GINA be similar to this RFI process for health insurance provisions of the bill? What can we expect?

A. We're expecting a proposed rule related to Title II of GINA. It is in the works, but may not be published for comment until the winter or early spring.

Q. In discussions about GINA, and especially through the articulation of concerns in response to the RFI, there is an interesting balance between avoiding the collection of genetic information

by health insurers and ensuring that health insurers are aware that they cannot use this information for underwriting purposes. With GINA's protections in place, why shouldn't individuals feel more comfortable giving complete health information to their insurers, or even employers if relevant, knowing that GINA prohibits the misuse of this information?

A. Individuals should, indeed, feel assured that their genetic information is not supposed to be misused by insurers or employers. However, public education about GINA will also be important so that individuals understand its protections and can recognize situations in which their genetic information may be inappropriately collected or misused. In addition, regulators must take steps to educate insurers and employers about their new responsibilities under GINA. Strong oversight will also be key to ensuring that GINA protections are meaningful in practice.