Q&A: ASHG's Boughman on Insurers' Successes and Challenges in Implementing GINA's Title I

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The Genetic Information Nondiscrimination Act marked an implementation milestone last week, as insurers were required to meet a May 21 deadline to incorporate policies that protect people from discrimination based on their genetic information.

Under Title I of GINA, which was signed into law in May 2008, healthcare insurance providers had one year to enact regulations against deciding coverage or setting premiums for enrollees based on genetic data. Under the law, insurers are also restricted from requesting genetic screening or testing for applicants who are applying for healthcare coverage [see PGx Reporter 05-07-2008].

GINA not only makes it illegal for health insurance providers to discriminate based on genetic information. Title II of the act discusses the circumstances under which employers are restricted from requesting genetic information and using that information to make hiring, firing, and salary decisions. Employers have until Nov. 21 to come into compliance with Title II of GINA.

Joann Boughman, the executive VP of the American Society of Human Genetics, recently discussed with Pharmacogenomics Reporter the positive advancements insurers are making and the challenges they face in complying with the new law.

For example, there are some complexities of GINA Title I related to manifest diseases that could be the source of confusion for insurers and lead to unintentional non-compliance with the law, Boughman said.

"Certainly the genetics community and healthcare providers have learned a lot" in the 13 years it took to get GINA passed, Boughman said. "It's a happy time for us when we can connect the science to the implementation."

ASHG is a professional organization representing more than 8,000 scientific researchers, physicians, laboratory scientists, and genetic counselors who are actively engaged in the genetics field. Boughman represented the ASHG in the Executive Committee for the Coalition for Genetic Fairness, a group of scientists, patients, advocacy groups, and industry representatives that worked for the passage of the GINA legislation.

Below is an edited transcript of the interview.

A lot of state insurers have protections for genetic information on the local level. How does GINA fit in with those existing regulations? Where is the most work needed for state insurers in coming in line with the national law?

The tricky part here is that the federal law doesn't pre-empt state law. So, anyone who has a tougher law will continue with their own law anyway. But the federal legislation really sets the floor, if you will, of protections. Some states will be looking to other states, to see how others have been dealing with this over time. In some respects, on the health insurance side, it's not going to turn things on their heads.

But GINA is certainly going to affect some states more than others.

New York and California are the states with the most regulations around all kinds of regulatory testing. So, they are kind of the lead states out there. Every state has had newborn screening in place for a long time, so … every state has been doing genetic testing in some form for a long time. The gap that GINA addresses is really the group where we would be testing individuals who would have increased risk for developing a disorder later, not actually diagnosing the disorder.

It took us 13 years to get [GINA passed] through Congress. The turning point in my mind, the point at which the conversation changed on Capitol Hill, was when people really began to understand the BRCA1 and BRCA2 issues. They all knew someone with breast cancer. Then they understood you could test for the gene, but it only related to an increased risk and not having the disease itself. So, it was really that change in conversation around 2002, where things really changed.

Some private payors, such as Aetna, also have regulations around genetic information protections. To what extent do you think private payors have policies that are sufficient under GINA?

I don't think there has to be a massive change in their processes. That's the bad news and the good news about this having taken 13 years. When you take a step back and think about it, depending on what you wanted the outcome to be, the fact that we did get some changes and now that [the deadline for implementation] is here, it's fine that there won't be any major changes.

We made our point. We have achieved the goal, which is to have genetic information be protected, so it could be used and utilized, rather than misused. So, it's okay that we're not going to have these sweeping changes and turning the insurance industry on its head.

So, could you discuss how the law doesn't extend to pre-existing genetic conditions?

Right, and this will apply to the employment side [Title II], as well. Anybody that has what we call manifest disease is already covered under other laws, such as the Americans With Disabilities Act. So, GINA doesn't move into space that already had protections associated with it.

Do you foresee any potential for confusion for states and private insurers in implementing GINA?

Let me talk about manifest disease for just a minute. If I am an individual with a manifest disease, GINA doesn't affect me related to that disease. But, with breast cancer, for example, GINA does protect information about my mother having breast cancer. So, GINA does cover the history of manifest disease and relatives. I think that becomes a little confusing depending on how the sentence [in the law] is worded. Someone else's disease is not my disease; it's only information about me. It affects my risk, but it doesn't say whether I have the disease or not. It's just a risk factor.

So, in the regulations, we've tried very hard to word it so people understand that, but I'm sure there will be some confusion around that.

One aspect of GINA is that there will need to be additional resources spent on educating patients …

And physicians. Especially the primary care physicians will need education. Genetics is everywhere and it's nowhere with regard to the actual practice of personalized medicine. This is going to be a huge learning curve on all aspects of genetic information. We're getting there a little bit. In medical school, the recent graduates are much better prepared. But it's the physicians who have been out there for a while, who might not be quite up on this stuff. … It's going to be a continuous learning process out there.

Our hope is we can utilize this, so people will engage in getting and using this information in a

proactive and pre-emptive way. So, we can use this to bring down some health costs, because we may prevent some serious disease out there.

Are you aware of any private payors and managed care organizations who have invested in educating their physicians about protecting genetic information since the passage of GINA?

They are. Kaiser Permanente is one of the big ones. And I've seen in passing some of their information … and they have been doing a tremendous amount of [educational] work. However, I think it's going to be those individual physicians out there, not related to large practices, who will be the greatest challenges in terms of education.

One of the main areas of concern, prior to the passage of GINA, was that people were apprehensive about participating in genetic studies without assurance that their genetic data could be protected. Have you noted an increase in clinical trial participation following GINA's passage?

Yes, certainly in the areas of basic science and translational science, there has been an improvement in two ways. [Prior to the passage of GINA,] geneticists and genetic counselors felt obligated during the session to say that patients' genetic information was not legally protected at the time. Now we won't have to have that conversation. My hope is that in fact we simply delete that conversation, so we won't further confuse people by giving them too much information. There may be times where, if a question is asked, we may say, 'A year ago, your information was not protected, and now you are.' But, I don't think we have to have that conversation in every genetic counseling situation that we have. That actually is going to save around five minutes out of every 45-minute counseling session that goes on. That, in and of itself, is saving a little money.

Genetic counseling is still not reimbursed. Are there any efforts in this regard to get this part of the process covered?

There are a few states where counselors can become a certified group and legitimate practitioners in and of themselves. On the national front, we're trying to get the CPT codes changed in such a way that counseling activities themselves can be billed differently. Right now, it comes under a complex interaction with doctor and other staff. That's just not the most efficient way to do this.