

Questions and Answers with Kim Monk

DR. McCABE: Questions, comments from the Committee?

MR. DANNENFELSER: Martin Dannenfesler from the Administration for Children and Families at HHS.

Could an insurer require certain tests, even if they did not acquire the information? For instance, could they have a policy that all women 35 years and older who are pregnant have to undergo amniocentesis, even if the insurance company does not acquire that information?

MS. MONK: That's a good question. It was my bad not to mention that provision.

We do have a ban in the bill that says an insurance company can never require you to take a test, request or require somebody to take a test. We do have an exception that says an insurance company can, however, as part of a bona fide wellness program, which is defined in statute now, can offer or make available information that, oh, you know, genetic tests are available for this or that through health care professionals.

So because we do know that insurers offer wellness services, quite a range of them, we don't want to curtail those types of activities, but the insurance company can never request or require somebody to take a genetic test. It's just a flat-out ban.

MS. MASNY: Thank you very much for such a comprehensive overview and the history that went into it and we can see all the work that went into it as well.

I have a question regarding, you mentioned that there will be a ban that genetic information cannot be used for underwriting purposes. Does that cover as well or apply to life insurance?

MS. MONK: No. The bill that we approved in Committee applies to employment and health insurance, and to my knowledge, nobody's really thought through the life insurance issue yet. It's a very different product than health insurance. The game of life insurance is figuring out what life expectancy is, and I think before anybody got into that, they'd have to have a better sense of what the implications are, but it's just health insurance.

DR. McCABE: Some of the agencies were mentioned, Labor, Civil Rights, EEOC. Anyone from those agencies wish to comment?

DR. ZURAWSKI: Hi, Kim. I have a question about the HIPAA changes.

Does the civil penalties only apply for violations regarding genetic information and not other HIPAA type of protections?

MS. MONK: That's correct. While we built on the existing HIPAA nondiscrimination provision, the changes that we made were -- and that is the clarification of your right to injunctive relief, clarification of reinstatement of your coverage, and I guess the discretion of the court to award the HIPAA penalty to the individual which doesn't exist now. We only did that for the genetic piece, and it was really a political

reason for that, which was we didn't want to open up everything that was already out there and make it a much bigger bill, but that's obviously something that will come up and will be questions that you'll get in terms of enforcement.

MR. MARGUS: Just to clarify, I'm a neophyte in all this, but is there any difference at all in what the new law is as far as penalties for denying coverage versus just raising premiums?

MS. MONK: It treats them as the same violation.

MR. MARGUS: The same, regardless.

MS. MONK: Yes. Either way, it's discrimination.

MR. MARGUS: The second part of that is, I'm more familiar with what happens with individuals, but with the groups, my understanding is a company could be denied or charged atrocious premiums for group insurance if one of its employees has a preexisting condition of a serious disease, like even a genetic disease.

So in this case, it will now be impossible for that carrier to deny or overcharge for or to use genetic information to do that but not for a genetic disease, is that right? It's kind of like what you hope is that there are no symptoms yet. That's basically what happens, right?

MS. MONK: Well, this whole bill was drafted and we really actually did try to draw a line because the current law does deal with people who are currently sick, symptomatic, what have you. So we really did try to draft this bill so that it just deals with the genetic predisposition of healthy people, but even then you may have a family coverage and you may have dependents who are needing health care services here now. So you could get discrimination based on your family policy or what have you based on somebody in your policy, but I think you had several questions there.

To answer your question, yes, we do have a provision that prevents discrimination against the group as a whole. It's a little bit of a strange provision because you have self-funded group health plans out there. So to say you can't discriminate against a group is saying to the employer you can't discriminate against yourself. That doesn't really make sense.

But it could make sense where you have somebody buying a group health plan or employer, more likely to be a smaller employer buying a fully-insured product in which case you'd have an insurance company issuing a rate or issuing coverage, and in that case our prohibition does say you can't discriminate against the group as a whole on genetic information and genetic information is defined to include -- I'd just basically refer you to the summary, but it's not intended to get to current health status, but I think it is intended to get to the four corners of what would be considered genetic information.

MR. MARGUS: And this is new as far as protection?

MS. MONK: Well, under HIPAA, when HIPAA was passed in '96, there was a nondiscrimination provision, health status nondiscrimination provision, that said you can't discriminate against individuals in a group and that's premiums or eligibility under the plan based on health status, and health status was defined as like five different things -- evidence of insurability, claims history, receipt of care -- and genetic information was one of those.

So technically, genetic information has been out there for group health plans since 1996, but it hasn't been very fleshed out in terms of what is genetic information. So there are real questions about what it is and

what it isn't and how it differs from health status items, and as I said before, that law only deals with discrimination against individuals in a group, and we took it a step further for genetics, just for genetics, and said you can't charge the whole group higher premiums because one person in there has the cystic fibrosis gene.

MR. MARGUS: Thanks, and thanks for your effort.

MS. MONK: Sure.

MR. MARGUS: I can only imagine what it takes to push something like this through.

MS. MONK: It's fun.

DR. FELIX-AARON: Kay Felix-Aaron, the Agency for Healthcare Research and Quality.

My question has to do with the use of genetic information when people leave the health plan. What happens to that information, and does the regulation address the use of that information, not people currently in the plan but what if people wanted to reenter that plan, can that information be used? One.

The second is insurance companies also engage in research activities, and does the genetic HIPAA regulation affect the use of genetic information in research by insurance companies?

MS. MONK: Two very good questions. The question regarding how do the protections work when you come and go from insurance plans and between insurance plans. The answer is they're meant to follow you and your information. So underwriting is a process that occurs when you first try to get into a health plan. It's most likely to occur when you first try to get into a health plan, particularly in the individual market. They may say what illnesses do you already have or what's your family history, now we're banning the family history, but that may occur also on an annual basis when they take a look at your rate and reassess you every year.

I think the important thing to remember is regardless of which health plan you're in, whether you're moving from one health plan to another, we basically apply the protection to the underwriting function. So it's protected at every possible point. Basically whenever somebody may try to use it for underwriting, we banned that. So whether you're coming or going or staying in the plan, it's covered.

Then to answer your other question on research, we were very careful and very concerned about not putting in restrictions that don't exist for other health care information that would inhibit research or quality activities or patient safety activities. So the short answer is the rules that apply, the privacy rules that apply to all health information really govern the genetic information, and I don't think we've done anything in our additional restrictions on insurers around their underwriting practices or business practices that would interfere with that.

Now, if the insurers say that the existing privacy rules interfere with research, then that would also be true for genetics, but I think there are still some questions about the research provisions under the privacy rules that are still being sorted out.

DR. FROHBOESE: And on that note, I'm Robinsue Frohboese from the Office for Civil Rights, and as you noted, we are the ones that are --

MS. MONK: I'm glad I didn't know you all were here when I was explaining this. I'd be very nervous.

DR. FROHBOESE: Well, we certainly, knowing what the Department went through in developing and then subsequently modifying the rule before it took effect, we are very pleased that this bill takes the approach of basically adopting the privacy rule and giving to the Office for Civil Rights the responsibility for enforcement.

The one thing that I did want to clarify, you had mentioned at the outset that one departure in this bill is giving an individual a private cause of action or being able to get penalties for violations under Title 1 if the health plan discriminates against the individual.

Under the privacy rule, there is no private right of action and individuals do not get monetary penalties, and I just wanted to clarify whether in this structure, are there any penalties that individuals can get under the privacy rule or is it adopting the same enforcement structure?

MS. MONK: It is the latter. It's adopting the same enforcement structure. The penalties that I was describing, the clarifications of current law and sort of the new rights, that is for the insurance nondiscrimination provisions. That's why we broke it up. So that is, if an insurance company says we're going to charge you more because you have the BRCA gene or we're just not letting you in the plan because your kid has spina bifida or the gene for it, that's the new or clarification of penalties are only for the nondiscrimination provisions.

For the privacy provisions, the use, disclosure, collection pieces, that does fall within the enforcement framework of the privacy rules, and obviously you would know better than I, but there's obviously, I think, a question under the privacy rules, which were regulations and did not create a new private right of action.

The states have passed laws. So some people may have the ability to enforce their state law privacy rights under a state law private right of action and this is something that's still very much, I think, in a state of gray in terms of who has what rights, depending on what kind of entity they're under and questions of when federal law preempts state law. That's very much a gray area, and we did include some language in the agreement that said we are not interfering with that framework. We're not taking away any of those rights and we're not interfering with those rights. So there's a general statement that we're respecting the preemption framework around remedies that goes with the privacy rules and not trying to put our thumb to tilt the balance one way or the other.

MS. MONK: You should look at that language.

MR. LESHAN: My name is Tim Leshan. I'm filling in for Dr. Collins as the representative for the NIH and NHGRI.

I wasn't going to say anything, but I know that I'd be remiss if I didn't just pass on his gratitude and thanks to you and the Senator for your extraordinarily hard work on this issue, and I know there's still more work to go, and we look forward to working with you on it, but we just want to express our gratitude for this piece of legislation because we think it's really a step in the right direction.

MS. MONK: Great. Thanks, Tim. You guys were a great help throughout the process and we appreciate it.

DR. ZURAWSKI: Just a follow-up to one of Brad's questions about preexisting conditions, that there is an existing HIPAA protection and sort of HIPAA rights around preexisting conditions that will no longer

be exactly like the genetic information type of violation, assuming this bill becomes law, but I think there are already some federal protections there.

DR. McCABE: Any other questions or comments for Kim? Yes, Martin?

MR. DANNENFELSER: Just a very quick follow-up. On the issue of requiring tests, is that current law now or would this be new, what you're doing?

MS. MONK: It's new. To my knowledge, Paul, there's nothing like that now. So this is new.

MR. DANNENFELSER: Thank you.

DR. WINN-DEEN: I just wondered if you might speculate a little bit on when this might move through the House and actually become law. I mean, you've made tremendous progress in getting it to the point that it's at, but it really doesn't help the community until it becomes law.

MS. MONK: Yes. Well, you know, usually people in the Senate are the last to know what's going on in the House. We have to hear it from you guys, but one complicating factor in the House is that there are two Committees of jurisdiction, and we had the beauty of having one and that was complicated enough. Actually, three. Well, technically, we had two in the Senate, but we only ever worked on it once. Technically, they have three in the House and it appears that two are interested and engaged and that's Ed and Workforce and Commerce. Ed and Workforce has the employment title and then they have the group health plan, ERISA stuff, and Commerce would have the all-important individual insurance market, and both Committees are interested in the issue and have looked at it.

Another kind of -- I don't know if it's a complicating factor, but it certainly is something that plays into how it's moved or not moved so far in the House is that in the Senate, we have always had a Republican bill and a Democratic bill, and so we've always had that tension between, on the one hand, both sides wanted to get it done, and we've had differences in agreement about policy about how to get it done, but I think that's really helped the momentum.

On the House side, they've only had the Slaughter bill. There hasn't been any competition, and I think that there are efforts underway to either negotiate with her and/or put a bill out that either looks like the Senate bill or the Republican alternative. It's a little hard for me to get a handle on, but I don't think there is the same kind of momentum over there, and so I am concerned. I'm primarily concerned that I know we spent 15 months on definitions alone, and when I talked to my House counterparts and they asked me questions, I'd think, wow, those are the kinds of naive questions I was asking a year and a half ago, and we don't have a year and a half for you to learn the way I had to learn.

So there really is a bit of a learning curve and just timing in that they're starting very late. So whenever I go talk about this, I urge people to really get in there and work with the House folks. I know many of you are not in lobbying positions, but certainly, hopefully when we pass it in the Senate, we'll get some really strong feedback from the White House and that will help create some momentum.

DR. McCABE: And just to comment, we had invited Christine Fitzgerald from the House Education and Labor Committee and she just could not come today, but we can try and continue to have contact with her.

DR. LEONARD: Does this blanketly apply to anyone with or obtaining health insurance or are there carveouts, like for groups with less than 50 members, that we still need to be concerned about?

MS. MONK: That's a good question. Again, ask an easy question, get a complicated answer.

On the discrimination provisions, there are no carveouts. The way HIPAA works now is the carveouts are actually -- well, again I'm using HIPAA very broadly. There are different parts of HIPAA. You have the portability piece, you have the women's breast cancer rights, you have the mental health parity, COBRA. They all have different exceptions, but the nondiscrimination pieces of HIPAA out there today have an exception for what I call tiny group health plans, which are groups of one, and for retiree-onlys. So where you only have retirees in the plan, and we did not retain that exception. So that means there are no exceptions for the nondiscrimination ban, the ban on the testing and what have you.

Now, on the privacy side, we had to kind of rethink that because the privacy rules are obviously very comprehensive and there are some exceptions under the privacy rules and those exceptions are for groups of less than 50 that self-administer. There may be 10 or fewer of those in the country, but I'm sure there's a couple. Usually when they're small, they use a third-party administrator insurance company. What that means is those groups out there today don't have to put in that whole privacy framework. They don't have to have a privacy officer. They don't have to get their files and systems and investments in place to comply with the privacy rules. They don't have to sign business associate contracts and all that stuff.

So we felt that we really needed to pick up on that scope. Otherwise, we would be putting really tiny businesses, fewer than 50, who self-administer. So again, it's much narrower than the universe of 50 or fewer because it's only those who actually use their own employees to process claims, which is very rare. I don't know if you all might have data on that, but it's very rare. Because if we didn't have that exception for privacy, we'd be basically telling these really tiny employers in order to comply with these kind of several genetic use and disclosure restrictions which are really just icing on the cake on top of the base privacy rules, that now in order to do that, they'd have to have a privacy officer and they'd have to invest a lot of money in systems. So we'd kind of basically be back-in be forcing them to fall within the scope of the privacy rules, which we did not feel was fair.

So when it comes to privacy, it's the scope of the privacy rules. When it comes to discrimination, it applies to everybody.

DR. McCABE: Kim, I want to thank you very much for coming.

MS. MONK: Thank you.

DR. McCABE: And hopefully you will continue to remain in communication with us through the process and let us know if we can be of any assistance in moving this forward, though, of course, we work with the Administration side, so we'd have to work through the Secretary. But we do want to applaud you for making such progress.

I think, given the time and where we are in the agenda right now, we're going to take a 15-minute break. We will resume at 10:30 and proceed with the agenda from there.

Thank you.

MS. MONK: Thank you.

(Applause.)