

Sen. Hann's Floor Statements on Newborn Screening & Baby DNA Parent Consent Amendments to HF 2967

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Transcribed by Sam Larson 5/24/12

Senator Michelle Fischbach: President of the Minnesota Senate

Senator David Hann: Chair of the Health and Human Service Committee

Cal Ludeman: Secretary of the Senate

Introduction

Fischbach: Further discussion on the A9 amendment. Senator Hann.

Hann: Thank you Madam President. I would like to offer the A10 amendment to the Robling Amendment.

Fischbach: Senator Hann offers the A10 amendment the Secretary will report the amendment.

Ludeman: Senator Hann moves to amend the Robling amendment to House File number 2967 as follows, on page 1 after line 6 insert this is the A10 amendment.

Fischbach: To the amendment, Senator Hann.

Hann: Thank you Madam President and members this is an amendment that puts onto the Senator Robling amendment, a provision dealing with newborn screening. I have talked to Senator Robling about this and she has agreed to accept the amendment. So, she is friendly to it and members you may be familiar with this issue we have in and have had in our state, the process to do newborn screening which has proved to be beneficial. But there were controversies raised about the retention of the data that was collected from screening.

There was a lawsuit, the people bringing the lawsuit prevailed and the result of that is that right now the Department of Health really doesn't have firm guidelines with respect to the continuation of the newborn screening program. So, with this amendment, the A10 does is take into consideration the things the court decided in that lawsuit and puts those provisions into place so that the Department does have direction and a process by which they can continue to do newborn screening in Minnesota.

'Get Out of Court' Provision

And I do want to take a brief couple of minutes and go through some of the provisions so that people understand. There is section, section one of the amendment that in effect holds harmless

for a period of one year the Department in case there are any other issues that may come up with respect to this lawsuit. It's sort of giving them an opportunity to kind of not have to face continuing litigation on something. So, that's what that provision does, it was put in at the request of the Department.

Full Disclosure to Parents and Opt-Out

The next part of the bill is section 4 subdivision 3 in the amendment this talks about the process by which the newborn screening is going to take place it does put in place a requirement that this screening that there's full information provided to parents so that they understand what the screening is involved and gives them the opportunity before, actually before they get to the hospital to understand what the newborn screening test is and gives them full opportunity to understand that.

There's also in section 5 of the amendment subdivision 4 an opportunity for parents who do not wish to have their child receive the screening it does have a process that allows them to opt-out, if you will. And we currently have that in law or it has been in law in the past.

This does provide, in addition if a parent does opt-out that becomes a part of the child's medical record. Section 6 of the amendment the A10 amendment talks about, defines what the newborn screening program operations are. And it just is a list of the things that need to be done to conduct newborn screening.

And it does specify that there is no research that is done on the material as a result of the operation of newborn screening. Section 7 of the amendment talks about, defines the standard retention period for samples and test results, 71 days. This is language that was put in the bill as result of the court case. These were provisions in the court case of the lawsuit that was brought that these were agreed to by the court.

Parental Option for Extended Storage and Revoking Consent

Section 8 of the amendment speaks to the parental option for extended storage and use, which was the heart of the controversy originally. This puts a provision into law that defines if a parent, if a mom, or a family decides that they want to have the material that is collected at the time the screening is done if they want to allow the Department to continue to use that information for further research that provides the process by which that permission is granted it does use the understanding of the informed consent that we have had in statute for sometime. And members this was really the heart of the dispute that led to the lawsuit that was decided last December.

There is also subdivision 10 or section 11, subdivision 10 the A10 amendment talks about a process for revoking consent so if a individual does give consent for the newborn screening data that is collected to be used for research at sometime in the future if they want to revoke that consent, there is a process to find here how to do that.

In addition, section 12 of the bill talks about the duties of the Commissioner and they're the pertinent part of this in paragraph B that says nothing in this new provision in law exempts the Commissioner from the requirements of the Genetic Privacy Act that is in section 13.386 or from the penalties that are in place in that section of law that are provided as if there is a violation of that act.

Input from Department and Enactment Dates

There is also a section that requires a report from the Commissioner. This is section 24 of the amendment report from the Commissioner of Health. They are going to look at other provisions, other things that they are currently doing that may need consent for which they are not currently perhaps it's uncertain that they are actually getting the consent that's required. So, they are going to evaluate the other things they are doing and then make a recommendation to the legislature, by January 2013, of what other things that may need to have legislative attention to make sure that they are in compliance with genetic privacy and informed consent.

There are different effective dates in the bill. There's a provision section 25 that speaks to that, sections 4 and then 8 through 11 in the amendment are effective August 1st of 2012. The sections 5 through 7 in the amendment are effective the day following the enactment. And there's also a provision in the effective date section that says nothing in this amendment would effect or limit any pending legal actions that are going on with respect to this process.

And then there are some things, as I understand some things still not settled in court. And that is in this bill to make it clear that there is nothing in this bill that is going to effect or it can be implied to effect any of those current disputes that are in court.

I apologize for the brevity here it is not I believe, overly complex it is a fair relatively short provision I think it's about six pages in its entirety. But this was at one point a bill that was brought to us by the department, but by the time we received the bill it was rather late in the process we did not have time to work through all the changes that needed to be made. We did have a hearing in the HHS committee we had some testimony and then we tabled the bill and that's where the original bill remains. So, this is a little bit different from the original bill this does reflect some compromise that was reached with folks who were involved in the original lawsuit that had concerns for the way the original bill that was brought to the legislature was crafted.

This amendment as it stands has been vetted with parties, it is acceptable to both the Department and to the others involved and so I would certainly be happy to answer any questions on this provision, but would urge your support, thank you.

NOTE: H.F. 2967 WAS SIGNED INTO LAW MAY 10, 2012.