Clarifications of SF3138, Newborn Screening

Significant misinformation is being used in an effort to cripple the newborn screening program. Here are the facts.

- The Commissioner of Health has not acted illegally or surreptitiously. The Commissioner and her predecessors have professionally followed the duties imposed on them to protect the health of infants born in our state.
- The ALJ said the Commissioner can collect newborn screening samples. The ALJ said the statute did not clearly state that the newly collected samples could be stored after the genetic information statute became law.
- Parents have been notified of the newborn screening process through literature prepared by the Department of Health and delivered by hospitals and clinics.
- The bill does not violate parent rights, privacy rights, patient rights or DNA property rights. It strikes a balance in allowing limited use of personal information about a newborn for the specific benefit of the infant and the potential benefit of all children through improved testing.

To fairly evaluate the debate on SF3138, it is important to understand the history of the newborn screening law and the 2006 statute on genetic information.

Newborn Screening Mandate

The Commissioner has had a clear mandate since 1965 to test infants and children for inborn genetic defects (previously called inborn errors of metabolism). The first testing was for a single genetic defect leading to a condition that causes severe mental retardation. (Laws 1965 c 205 s 1) Over the years additional tests were added and in 1988 the Legislature authorized the Commissioner of Health to add additional tests to the screening panel and removed the requirement that the screening was only for conditions causing mental retardation. (Laws 1988 c 689 art 2 s 31) The legislature's appreciation of the value of and confidence in this program was demonstrated in 1994 when the right of parents to object to genetic testing on the basis of a religious exemption was removed (Laws 1994 c 636 art 2 s 2). In 1997 the Commissioner was required to develop a program to follow-up infants with positive test results. (Laws 1997 c 203 art 2 s 11)

It was only in 2003 that the legislature decided there should be a notice to parents. (Laws 1Sp2003 c 14 art 7 s 26) In addition to establishing the notification requirement the Commissioner was also directed to convene an advisory committee to assist in deciding which conditions should be screened and to study and develop new tests.

Use of Genetic Information Law

It is not true that the Commissioner has performed any illegal act under this statute. Prior to August 1, 2006 there was no Minnesota law on the use of genetic information. Because this language was added as a floor amendment to the omnibus data practices bill late in the session, and there were no committee hearings on the language, there is ambiguity over the effect of this statute. In addition the 2006 legislation authorized a work group on genetic information to be convened by the Commissioner of Administration. This work group began meeting in September 2007 and will make its

- Clearly defines the limited public health studies and research that can be done using the newborn blood samples.

It is appropriate to have a full debate about the appropriate scope of government programs. The newborn screening law has been the subject of decades of legislative interest and oversight. It is only in the last 18 months that a vocal group of advocates has attempted to thwart this important public health program. SF 3138 is a common sense and measured approach to balancing competing interests.

Newborn Screening Education and Communication

Type	Current Activities	Future Activities
Family / Medical Education and Outreach	Parents are routinely educated at birthing facilities (Over 6,500 brochures per month) regarding newborn screening and parental rights. Presentations are made to professional audiences, including physicians, nurses, and laboratorians regarding issues in screening newborns for serious genetic disorders and parental rights.	Educational outreach will include prenatal care providers and birthing educators to address the importance of communicating about newborn screening and parental rights in the prenatal period. Increased site visits are planned. Also, the development of hearing screening provider training material is planned to help improve hearing screening for all Minnesota babies.
Medical Provider Manuals	Manuals are provided for professionals involved with all aspects of newborn screening. The manuals outline requirements, procedures, and other information related to newborn screening.	Significant revisions are planned to include more in-depth information for screening administration as well as new information on mandatory hearing screening. A specialty manual for NICU providers is also planned.
Fact sheets	Fact sheets provide information on the disorders screened and are available for both parents and medical providers. This includes a parent fact sheet on storage and use of the residual dried blood spot specimens.	New parent fact sheets will be developed to focus on parental anxiety surrounding a positive newborn screen rather than delving into the disease itself. New provider fact sheets will focus on action required to appropriately follow-up on positive results.
Website	Current website provides easy access to all aspects of newborn screening. Nationally, this has been praised by other public health educators.	Enhanced, even easier to use, website revisions are underway to provide user friendly access to all aspects of newborn screening up through confirmatory diagnosis.
Brochures	As one of MDH's largest public health outreach efforts, the Newborn Screening Program's brochures which are available in English, Spanish and even a version for the Amish are routinely distributed and used by birthing care providers. (Over 85,000 per year.)	Update written Spanish translation and Amish version of brochure. Exploring the option of recording translations of the brochure into other languages on the website so the recordings can be accessed by speakers of other languages as well as those with low reading skills.

Newborn Screening Program

HF3438 / SF3138

Newborn Screening Program

- Approximately 73,000 infants are born in Minnesota each year
- Shortly after birth, infants are screened for 53 rare and serious medical conditions
    - If not detected and treated early, these conditions can lead to chronic illness, physical disability, mental retardation, developmental problems, or infant death.

Background

- There is a conflict between the newborn screening statute (M.S. § 144.125) and the genetic privacy statute (M.S. § 13.386).
- Currently, M.S. § 144.125 requires that all infants be tested for rare and serious conditions.
- However, parents must be informed that:
    - They have the right to decline to have the tests;
    - Blood samples used to perform testing may be retained by MDH
    - They have the right to have the tests *and* require that all blood samples and records of test results be destroyed within 24 months of the testing.

Proposed Statutory Changes

- Clarify that M.S. §§ 144.125 to 144.128 govern MDH's collection, storage, use, and dissemination of genetic information and specimens for testing infants for heritable and congenital disorders (Lines 1.21 to 1.23);
- Clarify that residual samples and results may be used for quality assurance, development of new test methods, and for the purposes of public health practice and related research (Lines 2.23 to 2.27);
- Provide parents with additional options, including the right to have the tests, but to decline to have the test results and samples used for newborn public health studies and related research (Lines 2.10 to 2.13);
- Require MDH to provide parents with additional information regarding what data may be collected as the result of testing and how samples and data will be stored and utilized (Lines 2.3 to 2.27); and
- Require MDH to report to the Legislature on efforts to ensure that parents of newborns are fully informed of rights and options regarding newborn screening (Lines 2.28 to 2.34).

Use of Blood Samples in Newborn Screening Process

Blood samples obtained through newborn screening are used for three critical purposes:

1. Testing Infants

- Small samples are collected from each newborn and sent to MDH for screening
- MDH partners with the Mayo Medical Laboratories to test these specimens
- The Mayo laboratory screens for 42 disorders and the MDH laboratory screens for 11 disorders
    - For children identified as having one of these disorders, confirmatory testing and specialty medical services are provided by the Mayo Clinic, Children's Hospital and Clinics of Minnesota or the University of Minnesota.

2. Quality Assurance and New NBS Tests

- After all testing is completed the specimen is stored at MDH indefinitely, unless otherwise directed in writing by the child's parent
- These stored blood specimens are used to perform the quality assurance and instrument calibration activities required by the federal Clinical Laboratory Improvement Act (CLIA) and for the evaluation of new screening tests to benefit newborns and their families.

3. Method Development and Public-Health Related Research

- Residual dried blood specimens are used by MDH, in collaboration with the Mayo Clinic and the University of Minnesota to conduct research essential for the development of additional tests of importance to public health
- Residual specimens could also be used for other research studies designed to answer questions of public health significance.
    - Whenever the specimens are used in this way, **the following protections would be applied:**
        - Individual identifying information would be removed
        - Specimens will not be used in any way that could identify the individual who provided the specimen
        - All research be reviewed by an Institutional Review Board

Newborn Screening Advisory Committee

MDH program staff meets regularly with a broad-based Newborn Screening Advisory Committee established in statute.

- The Newborn Screening (NBS) Advisory Committee is made up of parents of affected children, primary care physicians, genetic and metabolic specialists, as well as advocacy groups such as the March of Dimes.
- The NBS Advisory Committee assists MDH in rulemaking by providing advice and guidance on proposed rules.

Minnesota Department of Health fact sheet March 2008

Newborn Screening Program

HF3438 / SF3138

Newborn Screening Program

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- **Shortly after birth, infants are screened for 53 rare and serious medical conditions**
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Background

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- Currently, M.S. § 144.125 **requires that all infants be tested** for rare and serious conditions.
- However, **parents must be informed** that:
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  - **blood samples** used to perform testing **may be retained** by MDH
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Proposed Statutory Changes

- **Clarify that M.S. §§ 144.125 to 144.128 govern** MDH's collection, storage, use, and dissemination of **genetic information** and **specimens for testing infants** for heritable and congenital disorders **(Lines 1.21 to 1.23);**
- **Clarify that residual samples and results may be used** for quality assurance, development of new test methods, and for the purposes of public health practice and related research **(Lines 2.23 to 2.27)**;
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MINNESOTA MDH DEPARTMENT of HEALTH
Public Health Laboratory
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(651) 201-5256

Newborn Screening Program

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- The NBS Advisory Committee assists MDH in rulemaking by providing advice and guidance on proposed rules.

KL Copy

Subd. 3. **Right of parents to object.** (a) The parent or legal guardian of an infant otherwise subject to testing under this section may object to any of the following procedures:

(1) the testing itself;

(2) the maintenance of the infant's blood samples and test result records for a period longer than 24 months; and

(3) the use of the infant's blood samples and test result records for public health studies and research.

(b) An objection under this subdivision must be made in writing and recorded on a form that is signed by the parent or legal guardian. The signed form must be made part of the infant's medical record. The signature of a parent or legal guardian shall be sufficient to establish a valid objection. No witness to that signature, photo identification, or notarization may be required.

(c) If a parent or legal guardian objects to the maintenance of an infant's blood samples and test result records for a period longer than 24 months, the department of health must treat the objection as a request for destruction of the samples and test results after 24 months. The department must notify the parent or legal guardian of the infant upon destruction of the samples and test results.

(d) The requirements of subdivision 1 and section 144.128 shall not apply with respect to an infant whose parent or legal guardian has objected to testing pursuant to this subdivision.

Subd. 4. **Notification of parental rights.** (a) Prior to collecting a sample, persons with a duty to perform testing under subdivision 1 must provide the parent or legal guardian of the infant with a form explaining:

(1) that the blood samples used to perform testing and the results of the testing may be retained by the department of health;

(2) the benefit of retaining the blood sample;

(3) the data that will be collected as a result of the testing;

(4) the consequences of the decision to provide or object to provide a sample;

(5) the consequences of the decision to permit or decline testing;

(6) the consequences of the decision to permit or decline to have the test results used for public health studies and research;

(7) the ways in which the samples and ~~date~~ data? collected will be stored and used at the Department of Health and elsewhere; and

(8) that the parent or legal guardian may choose any of the following alternatives with respect to the testing: (i) to decline to have the tests; (ii) to require that any blood samples and records of test results be destroyed within 24 months of testing; and (iii) to decline to have the test results and samples used for public health studies and research.

(b) The form must be made in duplicate, and contain a space for the parent or legal guardian to acknowledge receipt of the form by providing their signature. The parent or legal guardian must sign the form prior to collection of the infant's blood sample. The duplicate copy of the form must be provided to the parent or legal guardian, and the original must be placed in the infant's medical record.

NO

Subd. 5. **Public health studies and research.** For purposes of this section, "public health studies and research" includes calibrating newborn screening equipment, evaluating existing newborn screening tests to reduce the number of false positive and false negative results, studying the development of new newborn screening tests for heritable and congenital disorders, and other population-based health studies.

Judiciary

Suicide – cost to genetic test
who pays
she had cancer estrogen

Nikki

① testing
② data base

780K
very rare.
Wendy's responders
in the 780K.

object to no consent
today consent is required
under CMS MDH has
not followed the law for 18 months
could require more by having to notify
all parents.
Tennessee is stream through act.

Mona – worst case scenario fallout?
– individuals decisions made according to their genetics.

My dept of health going to parents.
and parents pregnant & chose
to abort babies if not even being
sure.

Susan Berry

purpose of the test is not to gather genic information

School supports the bill

What path did the hosp. public interest bill
2004 take?

Advisory Committee on Heritable and Congenital Disorders

Name	District	Senator	Representative	U.S. Representative
Jan Larson	19A	Koch	Anderson, B.	Bachmann
Louis Mertz	19B	Koch	Emmer	Bachmann
Dietrich Mattern	30A	Lynch	Liebling	Walz
Piero Rinaldo	30A	Lynch	Liebling	Walz
Sandra Davenport	41B	Michel	Peterson, N.	Ramstad
Marianne Keuhn	41B	Michel	Peterson, N.	Ramstad
Ann Allen	42A	Hann	Ruud	Ramstad
Kathy Stagni	43A	Bonoff	Anderson, S.	Ramstad
Kristin Benson	43B	Bonoff	Benson	Ramstad
Lisa Schimmenti	59B	Pogemiller	Kahn	Ellison
Dorothy Markowitz	59B	Pogemiller	Kahn	Ellison
Susan Berry	59B	Pogemiller	Kahn	Ellison
Kyriakie Sarafoglou	59B	Pogemiller	Kahn	Ellison
Anthony Killeen	59B	Pogemiller	Kahn	Ellison
Steven Johnson	60A	Dibble	Kelliher	Ellison
Richard Lussky	60A	Dibble	Kelliher	Ellison
Stephen Nelson	61A	Berglin	Clark	Ellison
M. Kathryn Teufert	61A	Berglin	Clark	Ellison
Diane Madlon-Kay	61A	Berglin	Clark	Ellison
Michael Pryor	61A	Berglin	Clark	Ellison
Carol Wilson	61A	Berglin	Clark	Ellison
Candace Lindow-Davies	65A	Pappas	Thao	McCollum
Kevin Sheridan	65A	Pappas	Thao	McCollum
Julie Thompson Larson	65B	Pappas	Mariani	McCollum
Tania Daniels	66B	Anderson, E.	Hausman	McCollum

Kristin Loncorich - FW: newborn screening bill

From: Frank Iossi
To: "Krowka, Michael J." , "Meyerle, Kathleen A., J.D." , "Simmons, Patricia S." , "Rinaldo, Piero, M.D." , Dave Renner , Sara Noznesky , Phil Griffin , Kristin Loncorich
Date: 5/8/2008 8:40 AM
Subject: FW: newborn screening bill

Terrific, Scott, thank you.
Frank

------ Forwarded Message
From: "Wright, R Scott, M.D." <wright.scott@mayo.edu>
Date: Wed, 7 May 2008 22:57:38 -0500
To: <carolyn.jones@state.mn.us>
Cc: "Iossi, Franklin W." <fiossi@mayo.edu>
Subject: newborn screening bill

Carolyn:

I am writing to encourage Governor Pawlenty to sign the newborn screening bill. It is a rare opportunity when public policy can be enacted that will improve health and transform health care delivery. This is one example. As you are well aware, Mayo, MDH and the U have been working in a collaborative to screen newborns for genetic and biochemical diseases where early treatment and intervention can effect a cure or stop further progression. We should foster further research and development of these tests to enhance the health of newborns. The bill as written provides parents the options of declining participation, declining the storage of blood beyond initial testing and the option of keeping blood on file but opting out on further testing unless they change their mind. I realize some are concerned about privacy but I believe this legislation attempts to strike a fair balance between practicality and honoring parental consent.

I have spent 12+ years doing medical research in Rochester as part of my work at the Mayo Clinic. I have a great deal of respect for proper informed consent and protecting patients' privacy. It seems to me this bill safeguards both issues in an appropriate and societally responsible way. The only way we can advance medicine is to advance the science of medicine.

Feel free to share my recommendation that he sign the Bill with Governor Pawlenty.

My best personal regards to you and the Governor.

Sincerely,

Scott Wright, MD

------ End of Forwarded Message

Kristin Loncorich - Update on Newborn Screening Rules Vis-À-Vis the Genetic Privacy Statute, MS 13.386

From: David Orren
To: Chris Everson; Louise Liao; Mark McCann; Norman Crouch; Patricia Winget; Patricia.Segal Freeman
Date: 4/25/2007 10:17 AM
Subject: Update on Newborn Screening Rules Vis-À-Vis the Genetic Privacy Statute, MS 13.386
CC: Kristin Loncorich; Leanna Schell; Margaret Kelly; Scott Leitz

FYI

Mark McCann, Kristen Loncorich, and I will be meeting at 1:00 p.m. today with Representatives Phyllis Kahn, Steve Simon, Mary Liz Holberg, and Shelley Madore to discuss the newborn screening rules. We will discuss MDH concerns about how the ALJ interpreted MS 13.386 as requiring parental opt in for MDH to store newborn blood spots and results.

Rep Kahn and I have exchanged a number of voice messages about this.

In a voice message from last Friday, Rep Kahn said that Rep Holberg had wanted to do an amendment to the newborn screening statute to require a total opt in provision, but that Rep Kahn had talked Rep Holberg out of it. Rep Kahn added that we are all going to have to get together and decide what to do. Rep Kahn said that Rep Holberg will agree with a fully informed opt out, but that some language was needed to do that. She said that the place to do it is Rep Simon's bill, HF1360.

In a voice message from yesterday (Tuesday), Rep Kahn said that a meeting today at one o'clock would work for her. I called to confirm and spoke with her. She said that the meeting would be in Representative Simon's office and that Representatives Holberg and Madore would attend.

Representative Kahn's phone number is 651/296-4257. Her legislative assistant is Krysta at 651-296-7173.

DaveO

Dave Orren, Chief Legal Counsel
Minnesota Department of Health
625 North Robert Street
P.O. Box 64975
St. Paul, MN 55164-0975
Ph: 651/201-5742 Fx: 651/201-4986
Email: david.orren@health.state.mn.us

Kristin Loncorich - Re: Fwd: Infant Genetic Disorder Testing Amendment

From: David Orren
To: Matt Gehring
Date: 4/18/2007 10:13 AM
Subject: Re: Fwd: Infant Genetic Disorder Testing Amendment
CC: Kristin Loncorich

Matt,

Thanks for getting this back to me quickly. If you are open to some minor wordsmithing suggestions, please consider the following:

=> for the subdivision added to section 13.3806: "Data and specimens collected for testing infants for heritable and congenital disorders are governed by sections 144.125 to 144.128."

=> for the amendment to section 13.386: "Notwithstanding this subdivision, the Department of Health's collection, storage, use, and dissemination of genetic information and specimens for testing infants for heritable and congenital disorders are governed by sections 144.125 to 144.128."

One other thing - I sent you the mail yesterday with a copy of the ALJ report for our newborn screening rules. Later, I received a notice that the delivery failed. Did you get the email? If not, you still want an electronic copy of the ALJ report?

Thank you,
DaveO

Dave Orren, Chief Legal Counsel
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St. Paul, MN 55164-0975
Ph: 651/201-5742 Fx: 651/201-4986
Email: david.orren@health.state.mn.us

>>> "Matt Gehring" <Matt.Gehring@house.mn> 4/17/2007 3:57 PM >>>
Dave - looks like I mistyped your email address when I first sent this message; the amendment attached has gone to Rep. Kahn, but let me know if you have any questions or concerns about the way it is drafted- sorry for the delay.

Matt Gehring

>>> Matt Gehring <matt.gehring@house.mn> 04/17/07 3:42 PM >>>
Representative Kahn (via Dave Orren) requested an amendment to clarify the intent of section 13.386, related to the use and storage of genetic information and specimens resulting from the testing of infants for disorders.

The attached amendment adds a cross reference in two places: Section 13.3806 is the general "cross references" section of the data practices act for medical-related data. Also, I have added a new paragraph to subdivision 3 of section 13.386, clarifying that sections 144.125 to 144.128 governs the use, collection, storage, and dissemination of genetic information and specimens collected for infant testing purposes. As a result, the

opt-out process will apply to these specimens, as described in those sections of chapter 144, rather than the opt-in process otherwise established in this section of chapter 13.

There are two versions of the amendment attached to this email; the amendment to SF 1997 amends the omnibus state government finance bill. The amendment to HF 1360 amends the omnibus data practices bill. We also discussed drafting this amendment to the Health and Human Services bill - the current engrossment is not yet available, so the amendment will be prepared for that bill as soon as it is possible to do so.

Feel free to let me know if you have any questions-

Matt Gehring

Kristin Loncorich - Re: If You Want to Discuss My Newborn Screening Email

From: David Orren
To: Phyllis Kahn
Date: 5/10/2007 5:56 PM
Subject: Re: If You Want to Discuss My Newborn Screening Email
CC: Kristin Loncorich; Margaret Kelly; Mark McCann; MaryLiz Holberg; Paul Thissen; Scott Leitz; Shelley Madore; Steve Simon

Representative Kahn,

Please clarify what you want rewritten. Is this a rewrite of the last part of the amendment to MS144.125, subd3? Or is this the last part of our newborn screening opt-out form that tells parents what their rights are? Or the last part of our educational materials? Or something else?

When do you want it? To give you a fully informed response, I need to check with the director of the newborn screening program and others who are much more knowledgeable then I am about the program. To get a fully informed response from these people, it will take at least much of Friday, May 11, IF the right people are available.

We agree with you in concept that parents should be able to make a fully informed choice about each step of the process. But we are not writing concept here, we are amending statute. Changes we make in a hurry might appear innocuous on their face, but I fear they could have far-reaching negative consequences.

ALL WE ASKED FOR was a clarification that the genetic privacy statute (MS13.386) was not intended to apply to the existing newborn screening program. The newborn screening statute (MS144.125-144.128) has been worked out and hammered out over the years through policy committee hearings and many other deliberations. We do not want to have to make changes to the statute in a hurry, when being in a hurry only serves opponents of the program.

Notwithstanding what Representative Holberg has stated, the Minnesota Department of Health has worked in good faith and has put a great deal of resources and effort into enhancing the information to be given to parents. And we will continue to work hard on this in good faith, with Representative Holberg and any other people who care about this.

If the concepts you want incorporated in the newborn screening program are right (and I think they are), then there should be time to do this right in policy committee hearings next session.

Having said all that, we will still bust our backsides to get you what you want now. However, please consider just clarifying MS13.386 now and leaving substantive changes to the newborn screening statute to next session when we can take the time to do it right.

Thank you,
Dave O

Dave Orren, Chief Legal Counsel
Minnesota Department of Health
625 North Robert Street
P.O. Box 64975

St. Paul, MN 55164-0975
Ph: 651/201-5742 Fx: 651/201-4986
Email: david.orren@health.state.mn.us

>>> "Phyllis Kahn" <rep.phyllis.kahn@house.mn> 5/10/2007 4:19 PM >>>
Please, very quickly send us a rewritten last part, so we can get the final form done. We want a clear informed opt out provision, outlining a chance at each step. testing, saving, purposes and ability to destroy samples at some point.

HOUSE RESEARCH

Bill Summary

FILE NUMBER: S.F. 596
Version: Side-By-Side Comparison

DATE: May 15, 2007

STATUS: Conference Committee

Authors: Simon and others

Subject: Data Practices Omnibus Bill

Analyst: Matt Gehring, 651-296-5052

Overview

This summary outlines both the substantive and technical differences between the house and senate versions of the omnibus data practices bill. Where differences exist, a complete summary is given of the house language; the differences are explained, in *italics*, below the summary. Except where otherwise specified, the section references are to the section numbers as incorporated in the house version of the bill.

House Section Number	
1	***Identical Language***
2	***Identical Language***
3	**Judicial Branch Data.** Specifies that the "traveling data" provisions apply to the judicial branch. If the judicial branch disseminates judicial branch data to a government entity, the existing classification of the new government-entity-controlled data remains unchanged. *This section is not included in the senate's bill.*
4-7	***Identical Language***
8	**Damages.** Increases the penalty for a willful violation of the data practices act. Provides that a government entity is liable for exemplary damages of between $5,000 and $50,000 for each violation. Current law sets the penalty range between $100 and $10,000 per violation.

Section	
	with the term "government entity." This section also specifies that a "public official" includes executive or administrative heads of departments, bureaus, divisions, or institutions that are within state government. *The senate language does not make the "within state government" specification related to public officials.*
28-29	***Identical Language***
30	**Peer Counseling Debriefing Data.** Replaces the term "agency" with "entity" *The senate language replaces the term "agency" with "government entity."*
31-36	***Identical Language***
37-39	***Identical Language*** *These sections, related to Benefit Data, are combined into one section in the senate version of the bill, rather than three separate sections as in the house bill. The difference is entirely technical.*
40	***Identical Language***
(S.F. § 34)	**Homestead Applications.** Establishes a cross reference to a newly created subdivision established later in the bill, related to property tax classifications of homesteads. *This provision is NOT included in the house language.*
41-42	***Identical Language***
43	**Grants.** Adds a new section to address the status of data relating to grants. Key points include: ▸ Data created by a granting agency (defined as the government entity providing the grant) to create a request for proposal is nonpublic until the request for proposal is published. ▸ Responses submitted by a grantee are not public until opened. Once opened, the name and address of the grantee and the amount requested is public. After the government agency's evaluation process is complete, all other data in the response is public, except for trade secret data. If all responses are rejected, data that is not made public at the initial opening remains private until the evaluation process is completed or the grant is abandoned. Data that a government agency maintains as part of the evaluation process are not public until completion of the evaluation process. *This section is not included in the senate's bill.*

Section	
	Subd. 3. Bureau Responsibilities. Requires the Bureau of Criminal Apprehension to provide a listing of all law enforcement agencies with ISS access and information for individual data subjects on how to challenge the accuracy or completeness of data. This information must be provided on a public internet site. *The senate's language contains some technical differences in drafting, including using the term "Integrated Search Service" rather than "Crimnet." The senate's subdivision 2 also specifies that an individual who is the subject of data may access the ISS only as provided in this section. This specification is not included in the house language.*
53	**Landowner's Rights.** Directs the Department of Natural Resources to share a real estate appraisal with the landowner prior to an offer. Eliminates the requirement that a landowner be given a resume of the state's certified appraisal, and instead requires the landowner be informed of the value of the land as determined by the commissioner. This provision makes the law consistent with other requirements in the data practices act. *The senate's bill also includes technical changes to formalize the language used in this section.*
54	**High School Coaching Data.** Corrects a technical error; specifies that a school board hearing on the renewal of a coaching contract may be closed to discuss private data, rather than nonpublic data. Data is classified as "private" when it concerns an individual; it is classified as "nonpublic" when the data does not concern a particular individual. *The senate's bill specifies that meetings may be closed to discuss data that are "not public" rather than only "private data" as specified in the house language. The "not public" specification is broader under the data practices act, and includes private, confidential, nonpublic, and protected nonpublic data.*
55	**Newborn Screening Procedures.** Modifies the procedures and requirements for the testing of infants for genetic and heritable diseases. Persons with a duty to perform testing are required to provide parents with a document explaining specified procedures and rights of the parent, as well as the parents' ability to opt-out of any aspect of the testing or subsequent data and blood or tissue sample storage or use. *This section is not included in the senate's bill.*
56	**Drivers License Photos.** Permits criminal justice agencies and public defenders to access driver's license photos for specified purposes. A criminal justice agency may use photos to investigate and prosecute crimes, serve process, locate missing persons, supervise offenders, and prepare for court cases. A public defender may use the photos for preparation of criminal, juvenile, and traffic court cases. *The senate language also permits use of the photos by criminal justice agencies for the purpose of enforcing a no contact order.*
57	**Unemployment Data.** Permits data related to unemployment insurance to be disseminated to the department of corrections to conduct postconfinement employment tracking of

Section	
	requesting the number has a legally permissible reason to need to obtain a consumer report on the individual under the federal Fair Credit Reporting Act, the person requesting the number is required or authorized by law to obtain the number, the business has a reasonable basis to believe the person is using a false identity or documents, the business transaction cannot be completed without the number, or the request is consistent with the purposes of the federal Gramm-Leach-Bliley Act.. Eliminates current language that is shown below the new clause (9) that permits a Social Security number on certain mailed applications and other forms, but does not permit putting it on the outside of the mailing or in a bulk mailing of credit card solicitations. Eliminates the existing paragraph (c), which provides that this entire section of existing law, other than subdivision 2 (not shown in this bill, and repealed below), is effective July 1, 2007. *This section is not included in the senate's bill.*
64	**Social Security Numbers; Other Law and Exclusions.** Specifies that the regulations on the use of social security numbers as described above do not prevent the collection, use, or release of social security numbers as required: (1) by federal or other state law, including the federal Fair Credit Reporting Act, and the Gramm-Leach-Bliley Act; (2) for civil or criminal claims or settlement administrat6ion, law enforcement, government, or public safety purposes; (3) where reasonably necessary for fraud prevention or identify verification and another method would be impractical; (4) for internal verification and administration of specified compensation plans or benefits; or (5) to approve, maintain, administer, or serve an account, loan, or mortgage at the transaction's origination, transfer, or for review or management of the account, loan, or mortgage, provided that the social security number is incidental to the transaction and another method would be impractical. A definition of "account" is provided. *This section is not included in the senate's bill.*
65	**Penalties and Remedies.** Provides that a violation of the social security number regulations established in the bill, subjects the violator to section 8.31. That section permits the Attorney General to enforce the law and also permits a private right of action under section 8.31, subdivision 3a. Current law does not specify an enforcement method or penalty for violations, so by default a violation under current law is a misdemeanor under section 645.241. *This section is not included in the senate's bill.*

Kristin Loncorich - Email Sent to Rep Kahn - Fwd: Newborn Screening Amendments to Address All Concerns

From: David Orren
To: Chris Everson; Louise Liao; Mark McCann; Norman Crouch; Patricia Winget; Patricia.Segal Freeman
Date: 5/8/2007 10:50 AM
Subject: Email Sent to Rep Kahn - Fwd: Newborn Screening Amendments to Address All Concerns
CC: Kristin Loncorich; Leanna Schell; Margaret Kelly; Scott Leitz
Attachments: Kristin Loncorich; Leanna Schell; Margaret Kelly; Scott Leitz

Here is the email sent yesterday to Rep Kahn, copy to Mark McCann and to Matt Gehring (of House Research). Rep Kahn forwarded it to Rep Holberg and others.
You might want to first read the 5/7/2007 email from me at the end of this email, and then read the next paragraphs with Rep Holberg's reply and my thoughts.
Rep Holberg's reply to Kahn and me was:
"Thank you Rep. Kahn for including me in the discussion. The language lacks an option for opting out of all research if the parents consent to the testing. In addition, there is no lanuguage that addresses the need to present information on options and rights to parent(s) prior to testing taking place. I believe that there should be little to no cost to providing a one page document that can be down loaded by the hospitals. I believe that the proposed language falls very short of what we discussed last week and in fact errodes the rights of parents that were affirmed during the rule making process. ML"

DaveO's thoughts about Rep Holberg's reply: I think I should first ask Rep Holberg for a clarification on what she means by "research." Does she mean the quality control, quality improvement, and program improvement aspects of the newborn screening programs? If yes, then to tell her we consider these part of the newborn screening program and not research.

Suggestions?

Dave O

Dave Orren, Chief Legal Counsel
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>>> David Orren 5/7/2007 12:07 PM >>>
Representative Kahn,

Attached is amended language that will address MDH's concerns caused by the Administrative Law Judge's Report regarding our Newborn Screening Rules. The document also has amended language that should address Representative Holberg's concerns.

=> The first amended section is MS13.3806, which adds a reference to the language in MS13.386.

=> The second amended section is MS13.386, which clarifies that MDH's collection, storage, use, and dissemination of genetic information and specimens are governed by the newborn screening statutes; namely,

MS144.125 to 144.128.

=> The third amended section is MS144.125, subdivision 3, which would require that parents of infants be advised of the ways MDH might use the samples and results and that for parents who do not object to testing, the fact of advising the parents of their rights must be made part of the infant's medical record.

Also, we have drafted some language that will be included in the information that parents will be given regarding newborn screening. At first, this information will be added to our web site for newborn screening. Then, when our current printing of the newborn screening brochures runs out (which we expect to be in about March 2008), we will add something to the following effect:
"MDH will use the sample to test your baby for heritable or congenital disorders. MDH might also use some samples for anonymous testing for quality control (calibrating testing equipment), quality improvement (improving the accuracy of our testing), and program improvement (to find tests for other rare disorders and other studies related to newborn health). MDH will not ask for individual consent when using samples for anonymous tests. MDH will ask for individual consent before using identifiable samples for newborn health studies."
[*Please note that this is a preliminary draft of language. MDH will revise this when we do a wholesale edit of the brochure for the next printing cycle.]

I copied Matt Gehring on this email because we worked with him to prepare the first draft of the changes to 13.3806 and 13.386.

Let me know if you would like to discuss these proposed changes with Mark McCann and me. Also, if these changes are acceptable to you, please confirm to me the bill they end up in (likely omnibus data practices bill, HF1360) so we can follow the bill and advocate for the changes.

I did not cc this email to Representatives Steve Simon, Shelley Madore, and Mary Liz Holberg. Please let me know if you will share this with them or if I need to do more follow up with them.

Thank you very much for your help in addressing our concerns.
Dave O

Dave Orren, Chief Legal Counsel
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Newborn Screening Rules
Administrative Steps After ALJ Rejection of Reconsideration

A. Review of Proceedings

1. In her March 23, 2007 report, Judge Barbara Nielson approved some portions of the rules as written and found defects in other portions. She recommended changes to fix the defects. (*See attachment A of June 27, 2007 letter to the Chief ALJ)*
2. MDH accepted most of her recommended changes but asked for reconsideration of Finding 67. (*See June 27 letter*)
3. Chief Judge Raymond Krause denied reconsideration of Finding 67 (*See July 3, 2007 letter from Chief ALJ)*

B. Information on Next Steps in the Rules Process

1. The Notice of Adoption must be published in the state register within 180 days after the ALJ Report is issued or the rules are automatically withdrawn. The 180 days does NOT include days needed for review by the Chief ALJ or the LCC or because the Legislature delayed option of the rules.
   - ALJ did not release original report until March 27 (4 days)
   - ALJ reconsideration June 27-July 3 (7 days)
   - Must Publish Date: September 30, 2007

2. General Administrative Steps (*when there are no complicating issues*)
   - Contact the Revisor to make the appropriate changes and finalize the rules. (5 to 7 days)
   - Send an ALJ copy of new revised rules and ask for approval of changes
   - Get final Governor's approval on direction MDH is taking
   - Draft an Order Adopting Rules and get the commissioner's signature and send the signed Order to the Office of Administrative Hearings (OAH). The OAH will then request certified copies from the Revisor. Once they are received, the OAH will file them with the Secretary of State. The OAH should notify us when they are filed
   - Once the Secretary of State makes them official with her stamp, she'll send a copy to the Revisor, the Governor, and MDH. Once the Revisor receives the filed copy, the Revisor will prepare the Notice of Adoption and send MDH three copies. (Note. The Governor has 14 days from receiving the rules to veto them.)
   - MDH will then send the Notice of Adoption to the State Register for publication. (Usually 12 days between submission to publication) The rules become effective five days after publication.

3. Options:
   - Draft and submit an Order Adopting Rules accepting all the ALJ's revisions.
   - Ask Chief Judge Krause to reconsider his "denial of reconsideration" base on other information.
   - Draft and submit an Order Adopting Rules with new changes (1400.2240, subd. 5).
   - MDH formally withdraws parts of the proposed rule changes and Submits an Order Adopting Rules accepting the other changes.
   - MDH formally withdraws the entire proposed rule changes.
   - Do nothing and proposed rules are automatically withdrawn. Must inform LCC, other appropriate committees, and the governor its failure to adopt and reasons for failure.

no —

C. Future Legislative Action/Initiatives

Mark McCann - Fwd: Newborn Screening - Feedback Needed

From: Susan Berry <berry002@umn.edu>
To: Mark McCann <Mark.Mccann@state.mn.us>
Date: 1/29/2008 5:00 PM
Subject: Fwd: Newborn Screening - Feedback Needed
Attachments: Newborn Screening 2007 A6 Amendment.pdf

this is note I had from sara

Begin forwarded message:

> **From:** "Sara Noznesky" <SNoznesky@mnmed.org>
> **Date:** January 15, 2008 2:10:39 PM CST
> **To:** <berry002@umn.edu>, "Megan Jennings, MD" <mjenning@pipstop.com>
> **Subject: Newborn Screening - Feedback Needed**
>
> Hi Sue and Megan,
> I am meeting with Mayo and March of Dimes representatives tomorrow morning to discuss the newborn screening issue. Could the chapter support the language as attached?
>
> ---
>
> **From:** Sara Noznesky
> **Sent:** Thursday, January 03, 2008 3:13 PM
> **To:** 'Susan Berry'; Megan Jennings, MD; 'Anne Edwards'
> **Subject:** Newborn Screening language
>
> Hi Sue,
> At the end of the session last year, the Department of Health offered the attached amendment to attempt to define research for the purposes of the newborn screening program as part of efforts to address the Administrative Law Judge ruling.
>
> Since the draft rules were pulled, the Department is expected to offer policy language this coming session.
>
> It would be helpful to hear your thoughts and specific concerns with the language in the attached amendment (the language that is underlined is proposed as new language). I have information that leads me to believe this old amendment will be the starting point for the Department's new language. We have a better chance at influencing MDH if we weigh in with the Chapter's concerns prior to the bill being introduced.
>
> The Mayo Clinic and March of Dimes are interested in coordinating with us again this year. If our positions remain aligned I recommend we continue to do so. If you could get back to me within the next week or two that would be great.
>
> Thanks,
> Sara
>
> Sara Noznesky
> Minnesota Medical Association
> Manager, Legislative Affairs
> snoznesky@mnmed.org
> (m) 612-202-2827