COMBINED WRITTEN TESTIMONY
and
SUBMITTED POST-HEARING COMMENTS
Proposed Revision of Minnesota Department of Health Newborn Screening Rule 4615

Twila Brase, President
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Overview

The newborn screening rule lacks sufficient information-sharing requirements to fully inform parents about their dissent rights and options. Our testimony on the Minnesota Department of Health’s proposed revision of the newborn screening rule covers the following four points:

1. Background of the statute and the procedure known as newborn screening
2. Ethical issues surrounding newborn screening
3. Objections to the substance of the proposed rule
4. Requested revisions to the proposed rule

Background

The blood of Minnesota babies was first tested in 1965, when the phenylketonuria test (PKU) was mandated by law to prevent the mental retardation of children. Parents were allowed to claim a religious exemption to the testing. In 1988, testing was broadened by statute to include hemoglobinopathies, such as sickle cell disease. In 1991, all statutory references to mental retardation were eliminated. In 1994, the legislature removed the religious exemption, forcing all children to be tested. By 2001, newborn babies born in Minnesota were being tested for 5 conditions.

In 2003, the Minnesota Department of Health came to the legislature explaining tandem mass spectrometry which allows newborns to be tested for a long list of conditions—and requesting an increase in the laboratory fee charged for each newborn tested.

They also asked that the commissioner of health be authorized to expand the number of conditions for which children are tested ad infinitum without the public’s knowledge—citizens are unaware of the State Register—and without specific legislative authority.
Our organization testified on the provision, informing members of the House health policy committee that newborn screening is in fact genetic testing. This was a surprise to committee members. But as the HHS Secretary’s Advisory Committee on Heritable Disorders and Genetic Disease in Newborns and Children noted at their first meeting:

Committee members then discussed the meaning of “genetic test” and the fact that many people don’t view newborn screening as genetic testing, when in reality, newborn screening is by far the most common type of genetic testing done in this country. (Minutes, June 7-8, 2004 Meeting, Washington, D.C.)

According to the book Genomics and Disease Prevention, which is published on the website of the CDC, “[N]ewborn screening is the largest genetic testing effort in the nation and is primarily performed by state public health laboratories.” Or as an article in the 1997 American Journal of Public Health states, “Newborn screening is the most widely utilized form of genetic testing in the United States.” (“Public Participation in Medical Policy-Making and the Status of Consumer Autonomy: The Example of Newborn-Screening Programs in the United States,” Aug 1997) Or finally, as the University of Minnesota’s Center for Bioethics says, “Genetic screening is the application of genetic testing to an entire population. The most common form of genetic screening is newborn screening, which began in 1962 and is now used in every state to test nearly 4 million babies per year in the U.S.” (“Genetic Testing and Screening,” accessed online 1/18/07)

We asked the 2003 legislature to require informed parent consent, and we asked for parents to be allowed to request that only the PKU be done, but the health department opposed these requests. In the course of legislative negotiations, we were only able to obtain a requirement for parent dissent. Thus the law requires that parents be informed that they have two options: 1) to refuse all testing by the state’s newborn screening program, or 2) to have the testing done by the State, but request that the infant’s test results and blood specimen be destroyed within 2 years. Today, four years later, the Minnesota Department of Health tests newborns for 53 conditions—48 more than in 2003—but few parents know about the dissent options.

Although the health department proceeded to develop parent opt-out forms and a parent brochure, they failed to notify hospitals that the law requires them to inform parents of their two dissent options. They further failed to change the Minnesota Rule that hospitals are required to follow. Thus, our organization began hearing from parents that knew about the change in law, but couldn’t convince their hospitals that they had opt-out options regarding newborn screening. In fact, one mother called us from the hospital post-delivery and asked us to fax the department’s forms to the hospital so she could exercise her options.

On September 9, 2005, an ad hoc genetic advisory group organized by the data practices division of the Minnesota Department of Administration began meeting to propose legislation on genetic privacy. Our organization, as well as legislators concerned about genetic privacy, was in attendance. Representatives of the health department were there as well. At most of the group’s meetings, the department’s lack of implementation and enforcement of the 2003 the law came up various times.
Perhaps in an attempt to avoid legislative action on the issue, MDH began to change the rule shortly thereafter. According to the SONAR, the department began working on potential revisions sometime in October, and requested comments on December 12, 2005. However, in February 2006, legislators introduced a bill called “Parents’ Right to Say No” to give parents the right of consent in newborn genetic testing. In other words, the newborn screening program would not be able to take the blood of the child or do genetic testing unless parents first gave their permission. The health department opposed providing parents with consent rights, instead promising they’d do a better job of telling hospitals about the 2003 law and the need to inform parents about their dissent rights.

Legislators accepted their promise. They also added a few provisions regarding a citizen’s destruction request. A separate form for adults to request destruction of their own newborn blood specimens is now required, the department must comply with the parent’s or adult’s request for destruction in 45 days, and the department must notify parents that the tissue and the blood sample are destroyed.

Meanwhile, because the department did not implement the 2003 law, as was their statutory duty, approximately 250,000 children have been genetically tested without their parents being advised of their legal dissent rights or given the ability and information to exercise them. These parents and children were deprived of their legal rights.

As Mr. McCann said in response to a concerned questioner at the Jan 23, 2007 hearing, the department has been operating as though the law was an “implied consent” law, rather than an informed dissent law. If the parents didn’t dissent, for whatever reason, including failure of the department to implement the law, the department considered lack of parent dissent to be parent consent.

The department’s failure to implement and enforce the 2003 law is a serious violation of state law, and displays what appears to a departmental disregard for the rule of law and the rights of citizens. Our organization does not want the newborn screening rule to extend the department’s violation or exacerbate the disregard.

**Ethical Issues Surrounding Newborn Screening**

According to a 2005 study (“California Newborn Screening Program Review”), the number of conditions for which babies are tested is rapidly expanding across the country. At that time nearly one-half of the states tested for 25 conditions or more. Wisconsin now tests for 47 conditions, Minnesota for 53 conditions, and California for 86 conditions.

As newborn genetic testing has expanded so have the concerns of physicians, researchers, genetic organizations, and ethicists. The Committee on Bioethics of the American Academy of Pediatrics summarizes the concerns in a 2001 article in the peer-reviewed journal PEDIATRICS:
First, genetic information is familial. Thus, the test results of one person have
direct health implications for others who are genetically related. Second, the risks
of genetic testing may not be obvious because the primary risks are psychological,
social, and financial. The psychosocial risks include guilt, anxiety, impaired self-
esteem, social stigma, and insurance and employment discrimination. Third,
genetic information often has limited predictive power. Our genes interact with
our environments in complex ways, often making predictions impossible about
whether disease will develop or the severity of its manifestations. Finally, many
genetic conditions remain difficult to treat or prevent, meaning the value of
 genetic information may be limited for altering the clinical care of the
person…Given these concerns, detailed counseling, informed consent, and
confidentiality should be key aspects of the genetic testing process, particularly
when the benefits are uncertain. Because young children are unable to discern the
value of genetic information for their own lives, particular care must be exercised
by parents and pediatricians when making decisions about genetic testing for
children. (“Ethical Issues with Genetic Testing in Pediatrics” June 2001)

Five examples of ethical issues:

1. The rising rate of false-positive results has lingering negative impact on parents
   and the parent-child relationship. In June 2006, researchers from Children’s
   Hospital Boston (Elizabeth Gurian, et. al, “Expanded Newborn Screening for Biochemical Disorders:
The Effect of a False-Positive Result”) reported “false-positive results cause considerable
   parental stress, even when the baby proves negative on retesting.” Mothers whose
   children had a false-positive were more worried about their child, said their child
   needed more care, scored higher on the parent stress index, including in the
   parent-child dysfunction subscale and the difficult child subscale. According to
   one study (T. Zytkovicz, 2001) there are 12 false-positives for every true case
diagnosed. Another study puts the ratio at at least 50:1 (C. Kwon, 2000). The Boston
   study concluded that false-positive screening results can increase parental stress
   and affect the parent-child relationship. The researchers also noted that “the stress
could be alleviated by better education” of the parents about the process of
   newborn screening.

2. Parents of newborns with abnormal testing results can be targeted for testing with
   unexpected and unpleasant results for the parents. In 1982, a study carried out by
   the New York Newborn Screening Program (Ranjeet Grover, et. al. “Newborn Screening for
Hemoglobinopathies: The Benefit beyond the Target”, Am J Public Health 1986) noti-
   fied parents of positive results for the sickle cell disease or trait in their infants, and offered
   testing to the parents. About half the parents agreed. Of those who did agree,
some unexpected, perhaps life-shattering, results occurred such as the discovery
of probable non-paternity in nearly 2% of those tested. Were parents informed
about this possibility prior to testing?

3. Predictive DNA testing looms on the horizon. According to a speaker at a
   University of Minnesota forum held last fall on newborn screening, New York
state is involved in a pilot project that tests the baby’s DNA at the bedside, and provides parents with a DNA chip to take home. He mentioned that newborn screening will someday be used to screen babies for their propensity to develop diabetes, or become obese. Thus, as DNA research and technology advances, newborn screening shifts closer to being newborn diagnosis of a lifetime of potential disease conditions. Here are a few citations to emphasize the point:

- **Expansion of testing:** “msms today…DNA tomorrow” ("Newborn Screening in New York," (PDF) accessed online 1/29/07) **Note:** “msms” means Tandem Mass Spectrometry, a method to test for multiple conditions at one time.

- **Federal funding to test expansion of screening to predict diabetes:** The National Center for Environmental Health’s Division of Laboratory Sciences has funded the Pacific Northwest Research Institute’s partnership with the Washington State Public Health Laboratory in a study of screening newborns for Type I Diabetes. The study “aims to show that population-based prospective prediction of T1DM by HLA genotype screening followed by autoantibody surveillance can be performed within the public health infrastructure.” (Population-wide Infant Screening for HLA-Based Type 1 Diabetes Risk via Dried Blood Spots from the Public Health Infrastructure” Annals of the New York Academy of Sciences, November 2003) These parents were asked for consent for the study, but there is little doubt that researchers intend to show that it is possible to screen for diabetes predisposition—the first step to requiring it as a part of the newborn screening mandate. (“Screening and Surveillance for Type 1 Diabetes,” Robert Vogt, CDC)

- **Why some advocate for expanded newborn testing:** “‘[O]nce you pass the newborn nursery, there is no good venue to get 100 percent of the population screened.’” (Edward McCabe, MD, PhD, Genetic Medicine Specialist, UCLA, “Genes, Screens and a Healthy Future,” Facts of Life, Vol 11, No 6, June 2006)

Newborn screening is clearly moving toward predictive testing for adult onset diseases and conditions. Are parents prepared to handle getting the news? Do they want it? Will they wish they’d been better informed prior to testing? Shouldn’t they be? Will they and their child rue the day that genetic results were added to their baby’s permanent medical record…and their own? Unlike genetic testing done beyond the newborn stage, newborn genetic testing is usually done with little discussion, and no genetic counseling. Once it’s done, there no going back.

4. **Newborn blood contains the complete DNA of newborn babies.** Minnesota began retaining the blood of newborns 10 years ago. That means state government holds the blood of nearly three-quarters of a million children. During that time, the department has received various requests from researchers for access to the blood spots, and we know the Mayo Clinic has been given permission to conduct genetic research on them. As we learned at the hearing on 1/23/07, the department has received three requests for access to the blood specimens, and permission has been granted all three times. We do not however know how many children’s
blood specimens have been accessed. It could be all 750,000 of them; it could be
only a few of them.

What we do know is the department has sole discretion over the distribution of
the genetic material of children born in Minnesota. In addition, we know that it’s
highly unlikely that any of the parents of those children even know 1) the State
has the blood, 2) the State can distribute and/or sell the genetic material of its
citizens, or 3) whether the blood of their children has been used for research.

It is a basic human right, confirmed through the Nuremberg Code, that research
goals should never supercede the parent’s and the child’s rights to not be a
research subject, which is the primary purpose of blood spot retention (see #5
below). Here are a few key considerations:

MDH Policy

 Despite assertions by MDH at the 1/23/07 hearing that their policy is to
anonymize the data, the department’s policy is just that. A policy, not a
law, not a rule. The public has not seen the policy, and the Office of
Administrative Hearings has not seen the policy. It’s the word of the
department alone.

 Even if the department’s policy is as MDH claims, the policy can be
changed at the department’s discretion, as it was when the department
chose to begin retaining test results, and later blood spots. The public was
neither notified nor consulted.

 Furthermore, we do not know the department’s definition for, or process
for making blood samples “anonymized.” Is the data associated with the
blood spot still linked, coded, encrypted? In addition, the terms
“anonymous” and “anonymized” do not necessarily mean the same thing.

 Finally, the department stated at the hearing that after two years, the Mayo
Clinic has to destroy the two blood spots from each child they receive
from MDH. Since they likely receive blood spots daily from MDH
Monday – Friday, one could presume that Mayo is daily destroying blood
spots. This may or may not be true. In addition, it is not clear whether
Mayo is required to also destroy all punches of blood they have taken
from the blood spots, all DNA they may have extracted from the punches,
and all the data they have collected and created on each child from the
blood spots.

“Anonymized”

 The public wants control. In a poll of 504 individuals, 65.8% want consent
to be required for research on tissue samples obtained through clinical
care, and 27.3% want that consent even if samples are anonymized. (“The
Debate Over Research on Stored Biological Samples,” Wendler and Emmanuel, Arch Intern med 2002)
In 2005, Ann Cavoukian, Ph.D., Information & Privacy Commissioner for Ontario, gave a presentation at the University of Toronto Law School. The PowerPoint presentation notes: “It is impossible to completely anonymize DNA since there is always a means to identifying the tissue or the sample (Nuffield Trust).”

Gene Watch (UK) writes in an online response to a 2000 document published by the Human Genetics Commission: “given that an individual's DNA is unique to themselves, ensuring that a bio-collection entry is completely anonymous is technically impossible. In addition to the DNA itself, the linking with biographical data and medical records narrows the concept of anonymity still further. For biographical data to be useful, it will need to be more than a 'one-off-snapshot'. This means follow-up checks will need to be undertaken with individuals which will involve keeping two-way channels of communication open.”

5. The use of newborn blood for medical and genetic research without the knowledge or consent of parents or the subject of the specimen.

Gallup Poll – 86% of respondents said doctors should first obtain permission to run genetic tests, and 93% said researchers should first obtain permission to study genetic information. (“Public Attitudes Toward Medical Privacy” 2000)

Potential sale of blood spots, sale of blood punches, or sale of access to the genetic material of citizens. We do not know, and MDH has not explained, the monetary or contractual arrangements made with those entities that have already accessed Minnesota’s newborn blood for research or other purposes. Nor do we know the plans or contractual details for future access.

“What is singularly lacking in provisions for informed consent is explicit permission for future use of samples that are stored away after newborn testing is complete.” (Mary Z. Pelias, PhD, JD, (now professor of genetics) presenting at the Council of Regional Networks for Genetic Services, Feb 16-17, 1996)

Yet…in a May 2006 PEDIATRICS article (“Status of Newborn Screening Programs in the United States”), Braford Therrell et. al. notes:

i. “These specimens, although collected initially for immediate preventive health purposes, have the potential to be useful in other studies that may have significant health impact, because they provide a ready source of biological material containing DNA for essentially the entire population of newborns.”

ii. The article notes that 5.3 million specimens were received by U.S. screening programs in 2001, and that “the DNA contained in the
specimen seems to be stable indefinitely…it is agreed generally that specimens stored for long periods are of interest primarily for their potential research use.”

iii. Finally, the authors note that because most screening programs do not need to obtain consent for testing… “the use of specimens beyond the newborn screening procedure itself raises various legal and ethical questions.”

iv. The authors point out that the potential for research is “extensive.” In fact in September of 2001, the CDC and the Association of Public Health Laboratories (APHL) held a working conference to discuss combining the newborn specimens from all the programs to create a large collection of specimens for research purposes.

Our organization is not alone in calling for parents to be fully informed about the process and risks of newborn genetic testing. Genetic Drift, a publication of the Mountain States Genetics Network calls for hospitals and others to fully inform parents that the blood test is not just for PKU, and to let them know the breadth of the screen. The American Academy of Pediatrics’ Committee on Bioethics writes, “Attention should be given to the education of women and couples about newborn screening before the immediate postpartum period.”

Studies using focus groups find that parents have limited awareness of newborn screening, are unfamiliar with the term “newborn screening,” do not know about the state’s involvement, and want to be informed prenatally. Statements from mothers in the focus groups include:

- “The hospital visit was a fog; the only thing I wanted to know was ‘is the baby ok?’” (“Informing Parents About Newborn Screening: Hidden Problems, Practical Solutions,” PPT, Terry Davis, PhD, LA State University Health Sciences Center-Shreveport, April 21, 2005)

- “I just kept trying to figure out how the health department got my name and knew I had just had a baby.” (Ibid)

- “You’re so out of it after you give birth. I remember them talking about PKU and coming in to prick her heel and take blood…but I was really out of it. I’m sure they tried (to explain the test to me). But I just gave birth and then had all that drugs and stuff. I wasn’t really coherent.” (“A Regional Project to Determine Attitudes about the Ethical, Legal, and Social Issues Surrounding Current and Future Newborn Screening for Diseases” PPT, Lianne Hasegawa, M.S., STAR-G Project, no date, accessed online 1/29/07)

The lack of parent information appears to be long-standing in newborn screening programs. The August 1997 edition of the American Journal of Public Health states the following, “In…states where parental refusal is permitted in theory, there are no legal or
regulatory assurances that parents will be given adequate opportunity to refuse screening, or even that they will be made aware of its existence.” (Public Participation in Medical Policy-Making and the Status of Consumer Autonomy: The Example of Newborn-Screening Programs in the United States, August 1997).

But as Ellen Wright Clayton, MD, JD, Rosalind E. Franklin Professor and Director of the Center for Genetics and Health Policy, Vanderbilt University, notes in a presentation on the ethics of newborn screening, “No physician would dream of doing a test like this in the clinic without talking with parents.” (“Talking with Parents – What are the Issues?” June 30, 2004)

While our organization is pleased that we were able in 2003 to get the law changed to require parent dissent—and that the rule is finally being revised nearly 4 years later—we are not pleased with the substance of the rule.

**Key objections to the substance of the rule**

**Section 4615.0600**

While the department has developed a parent brochure, as well as online information, the rule does not specify the elements of information the department must provide to “responsible parties” to fully inform parents. Current department information for parents is remarkably inadequate, and without the information requirements being listed in the rule, there is no guarantee that parents will ever be adequately informed about genetic testing before it’s done to their child.

*Brochure* – The department’s “One simple test…” brochure is not an informational piece for parents. It’s a lovely, but misleading marketing piece meant to sell newborn screening to parents without ever telling them what else they’re buying. Genetic testing is controversial. The department acknowledges in the proposed rule that they are conducting genetic testing, but the brochure doesn’t mention it,

The department’s brochure has a list of conditions, but doesn’t provide parents with a list of risks associated with genetic testing or with the risks associated with providing their child’s most detailed genetic information to state government.

The brochure doesn’t connect the dots for parents. It mentions that a few drops of blood are put on a card, it says the baby’s blood will be tested, it mentioned that the “card” will be stored, but it doesn’t tell parents that the baby’s blood will be stored. Most parents would not imagine that the card would still have blood after the testing. The brochure also does not mention that the baby’s blood may be given to researchers without the parents’ consent or knowledge.

The brochure hides the full extent of government involvement. It doesn’t tell parents that the State of Minnesota—state government—could be contacting them about their test results before they ever hear from their doctor, or that state government will be annually contacting the parents to collect medical data on the child if the test is abnormal.
The brochure hides the parent’s dissent options. The dissent options are mentioned in passing, and buried on the fourth page. They are under a heading “Newborn screening helps protect every baby’s health,” making it easy for parents to think that any dissent might endanger their child. Furthermore, the brochure mentions that a refusal must by “in writing,” as though the parents had to write a letter. It doesn’t tell parents there’s a State form available online or from health care professionals.

The Minnesota Department of Health’s own Patients’ Bill of Rights (accessed off the Abbott Northwestern Hospital website) says:

> Patients shall be given by their physicians complete and current information concerning their diagnosis, treatment, alternatives, risks and prognosis as required by the physician’s legal duty to disclose. This information shall be in terms and language the patients can reasonably be expected to understand…This information shall include the likely medical or major psychological results of the treatment and its alternatives.” (Minnesota Patients’ Bill of Rights, accessed online 1/30/07)

One wonders then why there is nothing in the proposed rule to require such “complete and current information” to be given to parents regarding the department’s own genetic testing program.

In short, the brochure obfuscates the realities of newborn genetic testing, and does next to nothing to prepare parents to make a truly informed decision when the hospital staff member says they have two options.

Thus, the newborn screening rule must be explicit about the specific information that will, and must, be provided to parents by the department and the “responsible parties.”

**Dissent Forms** - The department dissent forms emphasize the supposed risks of not being screened and the supposed risks of not allowing the health department to retain the results and the blood. The forms appear to have been made specifically to engender fear in parents. As the American Association of Pediatrics says in the instruction sheet for the AAP’s “Refusal to Vaccinate” form,

> “The use of this or a similar form…focusing the parent’s attention on the unnecessary risk for which they are accepting responsibility may in some instances induce a wavering parent to accept your recommendations.”

This type of implicit pressure is not informed dissent. This is a subtle form of coercion. Parents are tired, protective, and assuming the best. The form not only gives them insufficient information in which to make a thoughtful decision about how to best protect their babies, it also uses their vulnerable state against them. Parents are presented by a biased set of information and are thus prevented from thoughtful consideration of both sides of the issue (testing/no testing, storage/no storage)
Unless they are properly informed, parents will have no idea that their decision not to sign the form could lead to genetic exploitation of their child and family. Not signing could have lifelong life-changing negative consequences. Nor do they know that this is the only time they will be given an opportunity to both know and take action. Later action will require not only becoming informed about that which has not been disclosed, but also finding the appropriate forms and the necessary co-signer to change that decision. By that time, their baby’s blood could have been accessed and used for genetic research.

**Section 4615.0550**

The following information, all part of the Minnesota newborn screening program, are not yet required by the proposed rule, and thus may or may not be provided or approved by the department as stated in 4615.0550.

1. **List of Tests:** There is no requirement that a complete list of conditions be published for the parents or the public to see, leaving everyone in the dark as testing expands at the sole discretion of the commissioner of health. Without a regulatory requirement, the department can choose to publish a partial list, a list hidden online, or no list at all.

2. **Not Just PKU:** There is no requirement that parents be told the test is not just the PKU, or that they be given a list of all the conditions their child will be tested for.

3. **State Testing:** There is no requirement that parents be told that state government, not the hospital is doing the tests, and that the baby’s blood is sent to the State of Minnesota and to the Mayo clinic.

4. **Genetic Tests:** There is no requirement that parents be told that newborn screening is genetic testing.

5. **Genetic Counseling:** There is no requirement that parents be offered genetic counseling before the testing.

6. **State Database:** There is no requirement that parents be told that the baby’s test results go into a government database.

7. **State Property:** There is no requirement that parents be told the blood is considered property of state government, accessible at the State’s discretion.

8. **Researcher Access:** There is no requirement that parents be told that MDH can provide the baby’s blood to researchers and others without the consent or knowledge of parents.

9. **Always Identifiable:** There is no requirement that parents be told the child’s blood has their complete DNA and there is always a risk of identifiability.

10. **Blood Kept Forever:** There is no requirement that parents be told that the baby’s blood is kept indefinitely, perhaps far into the adulthood of the child, perhaps through their child’s lifetime and beyond.

11. **Future Uses:** There is no requirement that parents be told the baby’s blood and genetic information are susceptible to the legislative actions and decisions of future legislators, including the creation of state or national DNA databases.

12. **Child Profiles:** There is no requirement that parents be told that the State of Minnesota is in the process of linking the database of newborn genetic test results...
with other electronic state databases maintained by the Minnesota Department of Health on children (immunization registry, birth certificates, etc).

13. **False-Positives:** There is no requirement that parents be told false-positives have a negative impact on parents and the parent-child relationship.

14. **State Tracking:** There is no requirement that parents be told that if there is an abnormal test result, the State of Minnesota contacts a specialist, sets up an appointment, and maintains follow-up with their doctor without their knowledge.

15. **State Registry:** There is no requirement that parents be told that the State of Minnesota keeps a list of every baby born with an abnormal result.

16. **Future Impact:** There is no requirement that parents be told that the results of the tests become part of the baby’s permanent medical record, potentially exposing the child to discrimination and impacting future life, insurance and employment options...even if the child only has a trait, or an asymptomatic condition.

17. **Parent Privacy at Risk:** There is no requirement that parents be told the baby’s test results inform government, doctors, and insurers about the genetic make-up of the parents and siblings.

18. **Private Testing:** There is no requirement that the department provide to hospitals a list of private testing options to be given to parents.

The only protection for parents, children and the general public is explicit inclusion in the newborn screening rule of information requirements related to the preceding 18 items, all of which is necessary for parents to make a truly informed decision when told of their right to refuse testing or have the child’s test results and blood specimen destroyed.

**Requested Revisions to the Proposed Rule**

We make this request in two parts: rules as written, and current department procedures and forms.

**Rules as written:**

- Under 4615.0400, we request that the definition of “infant” be confined to infants 28 days old or younger as in statute. The department should not use its regulatory authority to pursue testing of children older than the statutory limits of 28 days.

- Under 4615.0550, we request that “responsible parties” be required to provide the department’s list of private testing options to parents.

- Under 4615.0550 (D), we request that “and send a copy of the signed form to the commissioner” be struck. The statute only requires that the form be placed in the child’s medical record, not sent to the department.

- Under 4615.0550, we request that the hospital be required to post a notice about the upcoming newborn testing decision in each patient room where laboring
mothers are admitted, so that parents have the opportunity ask for or find the materials and the dissent forms on newborn genetic testing in advance of the decision.

- Under 4615.0550, we request that responsible parties be required to distribute and verbally discuss MDH information about newborn screening’s risk and benefits prior to the mother’s hospital admission, such as during prenatal clinic visits.

- Under 4615.0550, we request that responsible parties not only provide parents with “an explanation for the reasons for the screening, the parent’s right to refuse the screening, and the information in M.S. 144.125, subd. 3,” but also with an explanation of the process of the screening program, the risks of genetic testing, the risks of not having private testing, and the risks of government retention of the baby’s test results and blood specimen. Besides disclosure of the risks inherent to genetic testing, the information that should be explicitly disclosed to parents is listed below in our proposed rule change to incorporate a Tennessen warning. It’s also noted above in our list of 18 parent information items that are not yet required in the rule but are necessary for parents to be fully informed for the purpose of deciding whether to refuse testing or choose to have the testing done but require the destruction of the child’s test results and blood specimen.

- Under 4615.0550, we request that “responsible parties” be required to provide parents with a Tennessen warning. The Tennessen warning in M.S. 13.04 sub 2 requires that the public be given notice to make an informed decision as to whether they will or will not provide the government with personal data.

  - The Tennessen warning informs citizens, in this case parents, whether they are required to provide private and confidential data, if they provide it, how it will be used, and if they provide it, who else will have access to the data. In the case of newborn screening, hospitals are essentially acting in the stead of the Minnesota Department of Health. They are collecting the private tissues and data of citizens for direct transmission to state government.

  - The risk to children, parents, families and citizens in this situation is extraordinarily high. Not only are the parents in a vulnerable physical and emotional state post-delivery of their child, the data they are being asked to provide is the most sensitive data ever generated on individuals. The use of it can affect the insurability and employment of their child and themselves. It can impact life itself. It can open up the door to outside meddling in the life decisions of couples regarding children. It also exposes the parents, indeed the entire family line, to genetic exploitation and surreptitious analysis of the baby’s DNA by outsiders. Furthermore, government ownership of citizen DNA exposes citizens to the political decisions of future legislatures, including the possible creation of a national or state DNA database for law enforcement or other purposes.
Thus, the rules should require the Department to develop (4615.0600), and the “responsible parties” to provide (4615.0550), a Tennessen warning to parents, along with a list of all the information parents need to know to make an informed decision. A proposed rule change to incorporate a Tennessen warning for parents can be found at the end of this testimony.

The Tennessen warning should not be tucked away in the large stack of papers that parents are given on admission to the hospital. The rules should require that it be made available and distributed along with other prenatal information in prenatal classes and by practitioners caring for expectant mothers. Responsible parties in the hospital should be required to hand the warning directly to the parents as a separate notice at least several hours before they are asked to make the decision about testing. Parents should be provided plenty of time to read the Tennessen warning, read the dissent forms, and make a decision.

- Under 4615.0600 generally, we request that the department be required to maintain an updated list of all the conditions for which children are tested. The list of conditions should be in layman’s terms to the extent possible as well as medical terms—including referring to newborn screening as genetic testing—and it should be handed to every parent so they can make a decision about whether to submit their child to government testing, forego testing altogether, or obtain private testing for PKU only or for a more limited or expansive set of conditions.

- Under 4615.0600, the department should be required to make the list of tested conditions available online, with a link to newborn genetic testing on the homepage. Without a list readily available to the public, citizens will be left in the dark as the Commissioner expands genetic testing. Right now parents do not know that the Department is involved in the testing. Once the department’s involvement becomes common knowledge, many more parents can be expected to visit the department’s website. Therefore, this critical information should not be hidden or difficult for parents to find.

- Under 4615.0600 (F), we request that the department add requirements that follow the 2006 law requiring a separate form for minors and adults who request destruction of their results and blood specimen, compliance with the destruction request in 45 days, and notification of requesting parents, and adults tested as minors, that their data and blood specimen have been destroyed.

- Under 4615.0600, we request that the department make the department policy on retention and use of test results and blood specimens readily available to the public, including maintaining an updated policy online.
Under 4615.0600, we request that the department provide a list of private testing options to the “responsible parties” for distribution to parents at the hospital and prenatally.

Under 4615.0760, we request that the original language “because of a lack of available income” be retained. The SONAR does not explain its deletion, and it appears to broaden department activities (and spend financial resources) where Minnesota statute does not broaden or require them.

Under 4615.0750, we request that the words “of diagnosed cases” not be deleted as it is unclear why the department should be expending state resources to provide financial information for treatment in the case of no diagnosis. It is not clear that statute allows this broader interpretation.

Under 4615.0750, 4615.0755 and 4615.0760, we request that there be a clear distinction between the baby diagnosed with an actual symptomatic condition in need of treatment and the baby diagnosed with an asymptomatic condition or a trait with no need for treatment. We are unsure that the statute authorizes the ongoing annual follow-up the department is currently engaged in, however we do not believe that the statute gives the department authority to do follow-up and annual tracking of those babies that have mild asymptomatic conditions or only a trait.

Under 4615.0760, we would ask that the department clarify “other available services” and in subp. 4, that the rule limit contact with parents to children up to the age of 17 rather than age 21. At age 18, a child becomes an adult with the right to decide whether or not he or she will share private information with the department.

Current department procedures and forms:

We request that the department’s newborn screening brochure and poster be revised to provide accurate, complete, and unbiased data to parents. The revision should begin with the title. Rather than “One simple test can make a difference for your child,” perhaps something truly informative, such as, “Newborn Genetic Testing: You must decide for your baby.” The poster does mention that health care providers and the department “can answer your questions about the benefits of newborn screening and parents’ rights to decline testing” but it should also say that providers and MDH can answer questions about “the risks of genetic testing, long-term storage of newborn blood, and genetic research” and about “parents’ right to require the Department of Health to destroy the baby’s test results and blood specimen.”

We request that the Department of Health be required to revise their dissent forms in at least three ways:
First, the law does not require the department to obtain anything more than the parent’s signature on a form in order for parents to exercise their legal right to dissent. The forms, however, require parents to get the signature of a witness. The form requesting destruction requires notary or a witness. This is prohibitive. At the hospital, parents could find themselves having to argue with a medical professional that is resistant to the parent’s decision. Or the parent may find professionals unwilling to sign, thus making it difficult to exercise their right of dissent. This is a significant barrier to a tired, frazzled, overwhelmed parent. **Thus, we ask you to require the department to drop the secondary signature requirements of the form.**

Second, the law merely says that the dissent must be on a form. It need not be long. As previously noted, the forms appear intended to invoke fear. The forms act as tools to dissuade parents from dissenting. The language is biased and skewed, and the form to request destruction of test results and blood specimen is a very long 3 pages that on its face is prohibitive to even read. **Thus, we ask you to require the department to use a simple unbiased form for the request, or a form that provides parents with a concise description both the risks and benefits of genetic testing, government testing, government retention of data and blood, and genetic research.**

Third, the department’s opt-out forms are misleading. *The form for parents to refuse testing* does not mention genetic testing in its first sentence. And its statements do not explain the risks of testing, only the risks of not testing. *The form for parents to request destruction of data* also doesn’t tell the whole story:

- It starts off with a false statement about who can access the baby’s blood specimen and results. Only if the tired parent manages to make it to the second page, will they learn that the child’s data actually can be shared.
- The form says the child’s identifying information is removed, but fails to mention that the child’s blood is always identifiable...through DNA.
- The form says the department will provide a “permanent record” as though the child’s medical record is not a permanent record.
- The form says that the sample will be destroyed and unable to be used for identification purposes in the future. However, one need only go to the pillow of the child to find another piece of the child’s DNA (hair sample) for identification purposes.
- The form’s statement regarding duplicative testing disregards the fact that the specimen does not give a result that is confirmatory of a diagnosis, just presumptive, with many, many false-positives reported, and a second confirmatory test required.

**Thus, we ask you to require the department to delete these misleading and coercive statements meant to keep parents uninformed and unable to properly consider whether to make use of their right to refuse testing or have their child’s results and blood specimen destroyed.**
Parents should feel free to make a decision about newborn genetic testing without hospital pressure or government coercion. They have a legal right to do so. Thank you.

**Proposed Rule Change to Incorporate Tennessen Warning – Informed Dissent**

4615.0600. The Department will provide hospitals with the following information as part of a Tennessen warning, and 4615.0550, hospitals will provide the warning to parents as noted above:

- Notice that newborn screening program is a government screening and data collection program.
- Notice of the parent’s right to refuse participation in newborn screening, or have the test results and blood specimen destroyed after the test is conducted.
- Notice that once the parent agrees to testing, even if he or she requests the test results and blood specimen are destroyed, the form requesting destruction of the data is maintained, producing a government record on the child and parent.
- Clarification that the newborn screening blood test is not just a test for PKU.
- A list of all the conditions for which an infant will be tested.
- Notice that newborn screening is genetic testing.
- Notice about availability of genetic counseling prior to a decision about testing.
- Notice regarding where the blood is sent and who conducts the testing.
- Notice regarding the entry of test results into a state government database.
- Notice that the infant’s blood is considered property of the State of Minnesota unless the parent requests it be destroyed.
- Notice that the department and others can conduct research using the blood specimen without notification or consent of the parent.
- Notice that the baby’s blood is never unidentifiable, or anonymous because it contains the baby’s DNA.
- Notice that newborn blood is kept indefinitely unless parents request destruction.
- Notice that the baby’s blood are available and susceptible to the policy decisions and legislative actions of future legislators.
- Notice that MDH plans to create child profiles by linking the a child’s newborn screening information with their birth record, their immunization record, the newborn hearing screening database, and other state databases maintained by the department.
- Notice that studies show a lingering negative impact on parents and parent-child interactions when the baby receives a false-positive test result.
- Notice that the state of Minnesota will do follow-up with the child’s physician, coordinate services and annually track the child with a genetic condition.
- Notice that the State of Minnesota maintains a registry of all babies with conditions detected by the newborn screening program.
- Notice that all newborn screening test results become part of the baby’s permanent medical record, potentially impacting future life, insurance and employment options.
- Notice that the test results inform government, doctors, and insurers about the genetic make-up of the baby’s parents and other family members.
- Notice that private testing is available.

ATTACHMENTS

MDH - Mayo Clinic contract ("state property")
MDH Opt-out forms
2006 law – 3 provisions
Refusal to Vaccinate – AAP form and Guidance
2007 MIIC – linking of state databases
American Journal of Public Health – page 1 (newborn screening is genetic testing)
Tenessen Warning – M.S. 13.04
MDH Brochure
Clinical Chemistry – article on use of research using blood spots provided by MDH and Mayo
Screening and Surveillance for Type 1 Diabetes