



*Protecting, maintaining and improving the health of all Minnesotans*

January 12, 2007

The Honorable Barbara L. Neilson  
Administrative Law Judge  
Office of Administrative Hearings  
100 Washington Square, Suite 1700  
Minneapolis, Minnesota 55401

Dear Judge Neilson:

Re: In the Matter of Proposed Modifications to the Newborn Screening Rules, Minnesota Rules, Chapter 4615; Rulemaking Docket Number 11-0900-17586-1; Governor's Tracking Number AR232

The Minnesota Department of Health (MDH) is writing to respond to comments on the proposed modifications to the Newborn Screening Rules. These comments were submitted either during the comment period, or made orally or in writing at the January 23, 2007 hearing. We thank you for holding the hearing and also wish to acknowledge all those who participated in this rulemaking process.

I. **Need and Reasonableness:** The Minnesota Department of Health ("department") has met its burden to show that the proposed modifications to the rules are necessary and reasonable.

Minnesota Statutes, section 14.14, subdivision 2, requires the department to "make an affirmative presentation of facts establishing the need for and reasonableness of the proposed rule . . ." In making its affirmative presentation, the Department must show that its action has a rational basis. See G. Beck, M. Gossman, and L. Nehl-Trueeman, *Minnesota Administrative Procedure* 325 (1998). The department submits its Statement of Need and Reasonableness ("SONAR") as such an affirmative presentation and relies on its SONAR to establish the need for and reasonableness of the proposed modifications to the rules. The department contends that its evidence clearly meets the rational basis standard and compels one to conclude that the proposed rules of the Department of Health are needed and reasonable.

II. **Response to Comments:** The proposed modifications to the department's rules for newborn screening generated written comments and hearing testimony. These comments are summarized below. The department's response follows each comment or issue.

**General Comment**

First, the department points to the focus of this proceeding: revising the existing rules. Many issues raised in the comments are tangential but warrant our response. Second, the department reiterates the beacon of the newborn screening mandate: finding all one hundred babies born each year in Minnesota with a treatable heritable or congenital disorder and following through with appropriate health care to prevent the severe disabilities or death that would otherwise strike these babies.

**Comment 1:** At the January 23, 2007, newborn screening rules hearing, Representative Mary Liz Holberg testified that she was surprised that when the House of Representatives was having hearings in April and May, the newborn screening brochure was never brought up. (Page 34, Transcript of Hearing Proceedings, January 23, 2007.)

Response:

After the January 23 hearing, newborn screening staff reviewed their legislative testimony and the hearing dates from the previous April and May to which Representative Holberg referred. We found no record of relevant April or May hearings, but did find a record of a hearing held on March 23, 2007. MDH staff, however, did not have the opportunity to speak at the House Health and Human Services Finance Committee on that date. In addition, the Senate hearing on newborn screening was on March 30, 2007. Both hearing dates preceded completion of the newborn screening brochure. MDH staff did speak about the new brochure at the Senate hearing.

**Comment 2:** A number of written comments requesting a hearing objected to the entire newborn screening rules, not just the modifications, on privacy grounds.

Response:

Existing newborn screening law and the corresponding rules already require newborn screening of infants in Minnesota unless their parents exercise their opt-out rights.

Since the legislature mandated newborn screening, objections to the newborn screening rules as a whole do not address the proposed rule changes. MDH recognizes and respects that citizens' privacy concerns are important. The public health interests at stake, however, pertain to its mandate to protect all Minnesota citizens, especially the most vulnerable. Furthermore, the legislature heard these privacy arguments in 2003 and again in 2006.

The Minnesota Government Data Practices Act balances privacy interests and protection of public health. Under the Act, health data on individuals are private.<sup>1</sup> MDH can only release such data pursuant to Minnesota Statutes, sections 13.04 (release to the subject of the data) and 13.3805 (disclosure approved by the Commissioner for certain public health purposes). The protection of privacy is essential to public health. Individuals rely on public health to protect them and public health relies on individuals for accurate and timely data.

The fact that testing bloodspots for metabolic and heritable disorders is standard medical practice is reflected throughout the United States. Moreover, the proposed changes to newborn screening rules delineate current standard medical practice in Minnesota.

**Comment 3:** Many comments concerned the storage and use of residual dried blood spots. Some testifiers recommended that all blood spots should be destroyed as they are being kept illegally.

Response:

MDH believes these arguments do not address the proposed rule changes and cites Minnesota Rules, part 1400.2100 (the standards of review that a judge uses when approving or disapproving a rule). MDH takes the issue of privacy very seriously as mentioned in the previous comment. The legislature has considered these concerns twice before.

**Comment 4:** Ms. Twila Brase testified that after the 2003 legislative changes, the department failed to change the rules or notify hospitals that the law now requires them to inform parents of their options. (Page 44, Transcript of Hearing Proceedings, January 23, 2007 and page 2 of Combined Written Testimony and Submitted Post-Hearing Comments submitted by Twila Brase on January 31, 2007)

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<sup>1</sup> Minnesota Statutes, section 13.3805, subdivision 1, paragraph (b), clause (1).

Response:

MDH disputes Ms. Brase's contention that it "failed" to change the rules, which it is now doing. Many factors affect the timing of any rule change. Here, MDH waited for the American College of Medical Genetics (ACMG) to issue their new uniform screening panel recommendations to accommodate the changing dynamics of emerging technology and changing landscape of newborn screening. We sought to write rules that would be reasonable and consistent with national standards and believed that writing rules that could be potentially obsolete within a year would not be a wise use of resources.

We are uncertain where Ms. Brase received her information about hospitals and providers not being timely notified about the 2003 rule changes because MDH conducted a variety of activities to notify them. The department immediately modified its existing newborn screening brochure to reflect the 2003 legislative changes allowing parents to opt out of screening or have their child's blood spots destroyed (see attachment A) while simultaneously sending out a mailing to all birthing hospitals with the changes. Moreover, MDH divided the state into four quadrants and had staff visit over 60 hospitals, reflecting ~90% of the birthing population, to inform them of the new changes and newborn screening in general. In addition the smaller hospitals that MDH staff were unable to visit received mailings and phone calls.

**Comment 5:** In Ms. Brase submitted "COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS" from January 31, 2007 on page 3, she writes, that Mr. McCann said in response to a questioner at the hearing that "the department has been operating as though the law was an 'implied consent' law, rather than an informed dissent law."

Response: Ms. Brase misinterpreted the hearing testimony. The questioner asked the department if this was an "assumed consent" law. Even though, it was a confusing series of questions, Mr. McCann reiterated the department's newborn screening legislative mandate that all newborns are screened unless the parents opt out.

**Comment 6:** In Ms. Brase submitted "COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS" from January 31, 2007 on page 5, She writes, "As we learned at the hearing on 1/23/07, the department has received three requests for access to the residual dried blood specimen's and permission has been granted all three times.

Response: The department's testimony was not clear. The department has actually had four requests for access to data but approved only three. The three that the department approved did not identify individuals because they used de-identified dried blood spots to research new tests for newborn screening.

**Comment 7:** In Ms. Brase submitted "COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS" from January 31, 2007 on page 6, she refers to the department's use of anonymized data and implies that this is just a policy.

Response: The Minnesota Department of Health complies with the Minnesota Data Practices Act in Minnesota Statutes, Chapter 13. Specifically, Minnesota Statutes, section 13.3805 states that Health data are private data on individuals, which means that identifiable health data cannot be released without the consent of the patient/guardian.

**Comment 8:** Several people commented that they worried about what will happen in the future with the information stored at MDH. Some believe the government and/or insurance companies may use this information to deny people insurance or certain jobs.

Response:

These arguments do not address the proposed rule changes under consideration here. *See* Minnesota Rules, part 1400.2100.

However, the department wants to make the public aware that Minnesota Statutes, section 72A.139 prohibits insurance companies from discrimination based on genetic testing. Also, the Genetic Information Nondiscrimination Act is actively being discussed on the Federal level. For more information go to <http://www.geneticfairness.org/act.html>.

**Comment 9:** Many of the comments and testifiers at the hearing felt that parents were not receiving all the information needed to make an informed decision and that parents were not receiving “balanced” information.

Response:

Again, this comment does not relate to the proposed rule changes. Nevertheless, the department restates its guiding principle: the “balance” falls overwhelmingly on the side of testing babies for treatable conditions that are either disabling or deadly. Since screening itself poses no real health risks to babies, it is easy to choose the benefits of early detection. While the odds are in favor of the vast majority of the 73,000 born in Minnesota each year, these approximately one hundred babies cannot be found in a timely fashion without screening. The department operates the newborn screening program to help those one hundred.

The department firmly believes that the health education message parents are receiving adequately informs them of their decision on screening. This is evidenced in the department’s parent education brochure (Hearing Exhibit O) and its aggressive distribution since April 2006. Newborn Screening as a health education activity is in its early stages throughout the United States, including Minnesota. However, in this new endeavor, Minnesota is considered a leader in the parent education of newborn screening.

**Comment 10:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 7, Ms. Brase implies that MDH may have a monetary interest in the potential sale of blood spots and that the public does not know the plans or contractual details for future access.

Response: The department does not sell dried blood spots. The purpose of newborn screening is to screen infants for potentially debilitating and sometimes deadly congenital disorders and to ensure that all infants have access early diagnosis and treatment for these disorders. Moreover, as stated in Mr. McCann’s testimony at the January 23, 2007, hearing, any researcher requesting dried blood spots goes through a vigorous institutional review board (IRB) process. Finally, MDH is subject to both state and federal privacy laws on any data collected.

**Comment 11 Suggested Rule Changes.** Ms. Brase made a number of suggested rule changes in her hearing and written testimony. She divided these into two areas: 1) rules as written and 2) current department procedures and form. They are addressed below.

**Rules as written**

**Suggested Change:** Ms. Brase stated, “we really don’t feel the word infant should be defined as up to the age of one. In the statute, it’s up to only 28 days and we don’t really want to expand the

department's regulatory authority to test children beyond what the statute allows. (Page 61 Transcript of Hearing Proceedings, January 23, 2007, also see combined written testimony of January 31, 2007, page 12)

Response: The current law does not define the term "infant." It only addresses the initial testing being done by the responsible party before an infant is 28 days,<sup>2</sup> which is the case in almost all situations. Later tests are conducted if the specimen was unsatisfactory or follow-up is needed.

See Response #2 to Allina comments (submitted as Hearing Exhibit I) for further discussion of this issue. As we stated in our response to Allina, "the Legislature contemplated that screening would be followed up when it imposed duties beyond testing in Minn. Stat. § 144.128. This statute requires that the Commissioner follow up with the primary care provider after testing and the newborn leaves the hospital. Minn. Stat. § 144.125, subd. 1 further directs the Commissioner to collect the newborn screening fees that "approximate the costs of conducting the tests and implementing and *maintaining a system to follow-up infants* with heritable or congenital disorders."

Because of the need for retesting of unsatisfactory specimens and the need to conduct follow-up, MDH contends that it is necessary and reasonable to define infant as up to one year in the proposed rules. The proposed rule changes submitted at the January 23, 2007 hearing define "newborn" as up to 28 days of life.

**Suggested Change:** In Ms. Brase submitted "COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS" from January 31, 2007 on page 12, she requests that "Under 4615.0550 (D) the department strike the following part "and send a copy of the signed form to the commissioner."

Response: Minnesota Rules, part 4615.0550 (d) addresses the destruction of an infant's blood sample and results. The department proposed this measure to add procedural detail consistent with the 2003 legislative changes in Minnesota Statutes, section 144.125 subd. 3, which require this request to be in writing (See SONAR page 14). Even though the statute does not expressly require the form be sent to the department, this is the only logical method to carry it out. The department cannot destroy the blood sample or the results without written parental consent. As Mr. McCann stated in his testimony at the January 23, 2007 hearing, the form requires a parental signature and witness to "establish parental identity." The department maintains that this is necessary and reasonable to require the responsible party to send the department this form.

**Suggested Change:** In Ms. Brase submitted "COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS" from January 31, 2007 on page 14, Ms. Brase requests that the department be required to maintain an updated list of all the conditions for which children are tested." She also requested that the list be available on line.

Response: The newborn screening brochure (hearing exhibit O) lists all 53 disorders for which the department screens. Moreover, the conditions are all listed on the department's current web site at: <http://www.health.state.mn.us/divs/fh/mcshn/nbsdis.htm>. Finally, in response to a statement by Representative Mary Liz Holberg on listing all the tested disorders on the newborn screening Web site, Mark McCann, Supervisor of the Newborn Screening Program at MDH, testified that MDH will be redesigning its Web site this spring or summer. He stated the redesign "will do a much better job . . . [of] balancing many of the comments that Mary Liz has stated."

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2 Minn. Stat. § 144.125, subd. 1

(Pages 36-37 Transcript of Hearing Proceedings, January 23, 2007.) In addition, Minnesota Statutes, section 144.125, subdivision 2 states, “the list of tests to be performed may be revised if the changes are recommended by the advisory committee established under section 144.1255, approved by the commissioner, and published in the State Register.”

The department believes that the current proposed changes regarding the duties of the responsible party are reasonable and should not be modified.

**Suggested Change:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 14, Ms. Brase requests that the department add requirements to the rule that follow the 2006 law.

Response: The 2006 legislative changes in Minnesota Statutes, section 144.128 clearly outline the commissioner’s responsibilities. Because the commissioner’s duties are clearly delineated, restating the statute is needless repetition. The department contends that no further elaboration is required.

**Suggested Changes:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 14, Ms. Brase requests that the department make the department policy on retention and use of test results ... readily available to the public.

Response: This information is currently easily accessible on the departments Web site at: <http://www.health.state.mn.us/divs/fh/mcshn/nbsfaq.htm>. Moreover, as Mr. McCann stated in his testimony at the January 23, 2007 hearing, the department is currently working on a redesign of the newborn screening Web site and will have an area that specifically addresses this issue.

**Suggested Change:** In both her written and oral testimony, Ms. Brase requested that the department should provide to hospitals a list of private testing options to be given to parents.

Response: The department’s newborn screening parent education brochure (exhibit O) already clearly indicates that a parent can arrange for private testing. The department believes that this is reasonable practice.

**Suggested Changes:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 15, Ms Brase requests that the original language “because of a lack of available income be retained.”

Response: The department removed this language because it duplicates the statement earlier in that sentence that says, “when the patient is uninsured or is unable to pay the cost of treatment.” Deleting this phrase does not broaden the department’s activities, but merely eliminates an unnecessary phrase.

**Suggested Change:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 15, Ms Brase requests 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.

Response: The department removed this language because it is repetitive and unnecessary. The term treatment already implies diagnosis.

**Suggested Change:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 15, Ms Brase requests that “there be a clear distinction between the baby diagnosed with an actual symptomatic condition and a baby diagnosed with an asymptomatic condition. We are unsure that the statute authorizes the ongoing follow-up the department is currently engaged in, however we do not believe 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.”

Response: First, under Minnesota Statutes, section 144.128 subdivision the commissioner has the duty to follow-up on cases. Specifically, Minn. Stat. § 144.128 (3) states: The commissioner shall:

(3) maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services;

Whether a condition is symptomatic or asymptomatic is a pediatric subspecialty decision, independent of the department. Our role is to provide treatment information and provide follow-up on cases of heritable and congenital disorders detected by the screening program.

**Suggested Change:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 15, Ms Brase requests that the age limit be changed to “children up to the age of 17 rather than 21, under proposed Part 4615.0760, subpart 4.

Response: The registry maintains a list of patients diagnosed with a disorder. Many of these affected children are still eligible for services, such as special education, until they are 21. Ensuring that these children are getting the care they need and for which they are eligible is reasonable. Moreover, even though 18 is the age of majority, it is important to remember that people 18 to 21 years old are just making the transition to adulthood. We need to ensure that members of this fragile group are receiving appropriate services. Often, the parent is the one who knows where the child is living. In addition, there are children who are over 18 years old but remain on their parent’s health insurance while at college.

**Suggested Changes:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007, she made other requests to the rules as written that addressed other duties the responsible party should be required to do. These included, providing a list of private testing options, distribute and verbally discuss newborn screening before prenatal visits, and requiring posting a notice about newborn screening in the patient’s birthing room.

Response: These comments concern business practice decisions that should not be part of the rule and thus are not included in the proposed rule changes. The department appreciates Ms. Brase’s thoughtful comments and will consider them when developing future health education materials.

**Current department procedures and forms:**

**Suggested Change:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 15, Ms. Brase requests that the newborn screening brochure and poster should be revised.”

Response: Based on standards in Minnesota Rules, part 1400.1200, the department believes these comments do not address the proposed rule changes. The department believes that the current newborn screening brochure and poster contain the information necessary for a parent to make an informed choice and are not misleading.

**Suggested Change:** In Ms. Brase submitted “COMBINED WRITTEN TESTIMONY and SUBMITTED POST-HEARING COMMENTS” from January 31, 2007 on page 15, Ms. Brase requests that the department revise their dissent forms.

Response: Based on standards in Minnesota Rules, part 1400.1200, the department believes these comments do not address the proposed rule changes. The department believes that the current dissent forms contain the information necessary for a parent to make an informed choice and are not misleading.

**Suggested Change:** In both her written (page 17) and oral testimony (page 63 of written transcript), Ms. Brase stated that her organization felt the rules should require the department to develop and the responsible parties to provide a Tennessee Warning to parents along with a list of all the information parents need to know to make an informed decision.”.

Response: First, the Tennessee Warning, in Minnesota Statutes, section 13.04, applies to government units only. It does not apply to private or non-profit hospitals.

Even if, as Ms. Brase states, “hospitals are essentially acting in the stead of the Minnesota Department of Health, a government agency,” the department asserts that the requirements of the Tennessee warning are essentially contained in its current newborn screening brochure given to new parents. (Hearing Exhibit O)

After carefully considering all public comments, the department believes that the rule changes as proposed by the department are necessary and reasonable and balance the need for testing with the public’s right to know and without placing an undue burden on healthcare providers. As we highlighted in both our SONAR and Mr. McCann’s testimony, *the newborn screening rulemaking advisory group thoroughly reviewed and discussed the proposed rules to ensure this balance was achieved.*

In conclusion, MDH believes the proposed amendments to the reporting rules are necessary, reasonable, and in accordance with law. We urge your recommendation to adopt these rules.

Respectfully submitted,



Mark McCann  
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Newborn Screening Program  
Minnesota Department of Health

February 12, 2007

Date



Patricia Segal Freeman  
Policy Analyst/Rule Writer  
Minnesota Department of Health

February 12, 2007

Date