

COPY OF OTHER COMMENTS RECEIVED

The agency's response is included



Protecting, maintaining and improving the health of all Minnesotans

Jacqueline M. Moen
Assistant General Counsel
Allina Law Department
2925 Chicago Ave. S
MR 10905
Minneapolis, MN 55407-1321

January 11, 2007

Dear Ms. Moen:

This letter responds to the written comments that you faxed to the Minnesota Department of Health (MDH) on December 29, 2006 regarding the proposed changes to the newborn screening rules. I will respond to your comments in the order they were presented.

Comment 1. The statute imposes duties with respect to infants who are age 28 days or less. The proposed rule, however, defines “newborns” as infant “from birth through the first month of life” and imposes duties with respect to such newborns. This definition sets up potential ambiguity when infants are 29 to 31 days old defining “newborns as infants up to 28 days of age would be consistent with the statute and less confusing.

Response 1: After reviewing your comment with newborn screening program staff, we agree. Changing the definition of newborn to “up to 28 days” would be consistent with the statute, is appropriate, and will not affect the proposed changes in a substantial way. We will submit the change at the administrative hearing on January 23, 2007.

Comment 2: The proposed rule, both in defining responsible parties and throughout, assigns responsibility to primary medical care providers (“PMCPs”), defined by the rule as physicians or clinics whom parents identify. This class of person, however, is not among the persons having statutory duty to arrange testing, except perhaps where such PMCPs are already required to register the birth of the child under § 144.215 because they were present at the time of a birth occurring outside an institution. Therefore, the rule imposes a duty on persons who do not have a duty under the authorizing statute.

Response 2: For MDH’s forty-one years in newborn screening, Minnesota’s physicians have zealously participated in ensuring that the very few infants born with metabolic or other heritable disorders receive immediate intervention. The PMCP’s continue the care, including further testing and communicating with MDH. Our system works well because the providers are already doing this work. This proposed rule merely spells out the current standard of care, in place since 1965, to ensure that all newborns are screened, diagnosed, and receive treatment for these potentially debilitating and deadly disorders.

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 perform certain follow-up duties 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.”

Finally, these rare occurrences (100 out of approximately 73,000 babies born per year in Minnesota) are unlikely to burden any one provider in light of the enormous positive outcome of ensuring that children are tested and treated so they grow up healthy.

For these reasons we disagree that the proposed rule imposes unauthorized duties.

Comment 3: Nurse midwives and midwives in attendance at birth, who are among the persons with duties under this statute, are omitted from the proposed rule’s list of responsible parties. The rule should include these persons in defining responsible parties.

Response 3: After reviewing your comment with newborn screening program staff, we agree that including “the nurse midwife or midwife in attendance at the birth” in Minn. Rules, Part 4615.0400 subp. 5, Responsible party, would make the rule clearer and more consistent with the statute. This is not a substantial change because nurse midwives and midwives are already included under § 144.215, Birth Registration, but not listed specifically in the rule. We will submit this change at the administrative rules hearing on January 23, 2007.

Comment 4: The proposed rule defines “business day” as Monday through Saturday, excluding holidays. A more common definition of “business day,” i.e., Monday through Friday and excluding holiday, is preferred. Indeed some parties with responsibilities under the proposed rule may not conduct business on Saturday. The more common definition would be more consistent with other procedures.

Response 4: We understand your concern in this area; however, we believe the proposed definition of Monday through Saturday is necessary because the Minnesota Public Health Laboratories conduct regular business Monday through Saturday. The current rule, Minn. Rules, Part 4615.0500 D, actually allows less time to send the completed specimen card than proposed Part 4615.0550 J¹ because it requires the responsible party to send the specimen card in to MDH within 24 hours after collection. As stated in the Statement of Need and Reasonableness (SONAR) on page 18, this short time period is necessary to ensure the department receives and analyzes the specimen so that needed treatment can begin in a timely manner. Some disorders must be treated right away to ensure the baby remains healthy.

¹ The term “business day” is only used in Part 4615.0550 in the proposed rule revisions. There are no other references to it.

Comment 5: The rule provides only that the responsible party must include on the specimen card the designation and contact information for the PMCP “identified by the parent.” The rule should explicitly provide an alternative where parents refuse to or is not available to identify a PMCP, or does not know a PMCP to identify. If the alternative is to provide a contact person the facility submitting the specimen (as suggested in the SONAR at page 8), then this alternative should be expressly stated in the rule.

Response: We understand your concern. We do not believe, however, that a change is necessary. MDH has an excellent relationship with providers who work with newborns and infants, and we are in communication with them if problems are identified. To ensure that newborns who test positive for a disorder are followed-up as soon as possible, MDH must have the most accurate information available on the specimen collection card, which is why MDH requests the name of the PCMP. As stated in the SONAR, we understand that this is not always possible, so hospitals can put the name of a contact. However, MDH does not want to encourage this practice.

In addition, as mentioned in the SONAR, in December 2005, MDH revised the newborn screening card to ask for the name of the primary care provider responsible for follow up, and as of December 2006, MDH has not received any complaints about the new information.

Comment 6: The proposed rule should, but does not, provide any guidance for physicians who are erroneously designated on a specimen card. For example, physicians may erroneously receive results on patients of PMCPs having the same name. Are these physicians responsible for redirecting the results to the appropriate PMCP? If so, how do they determine who that PMCP is?

Response 6: The potential liability envisioned has not been a practical problem for MDH or physicians to date. Within 24 hours of receipt of a specimen card, MDH knows if the specimen yielded a positive screening result for a disorder or is an unsatisfactory specimen. In these rare cases, MDH immediately attempts to notify the physician. If our initial contact reveals that the hospital provided inaccurate information and identified the wrong provider, MDH staff members record that the physician was misidentified, and we turn our efforts to identifying the correct PMCP. The appropriate provider is almost always identified within one or two days, which allows ample time for the PMCP to fulfill the responsibilities in the proposed rule. Providers can lessen the chance of being misidentified by working closely with hospital staff to establish protocols for accurately identifying which of the infants they see in the hospital will also be followed by them in the clinic.

Comment 7: The proposed rule requires that the PMCP obtain and submit repeat specimens from infants in their care at the request of the MDH. This requirement does not acknowledge the parents’ right to refuse a repeat test, and also does not accommodate situations where the PMCP is not able to obtain the result because, for example, the PMCP is not caring for the infant, was incorrectly designated, or is not expected to be providing care to the infant in the future. The rule should, at most, require the PMCP to notify the parent of the need to obtain a repeat specimen and to facilitate of the collection and submission if the parent brings the infant to the PMCP for the repeat specimen.

Response 7: Proposed rule changes Part 4615.0600 H also requires MDH to “track and use best efforts to obtain needed repeat testing for up to 60 days on all infants who require repeat testing.” Thus, the onus is not only on the PCMP but also, and more importantly on MDH. MDH takes this responsibility very seriously and has staff that performs routine follow up and case management for newborn screens that come back positive or unsatisfactory.

This practice is necessary to ensure newborns do not get missed by the screening system. The proposed rule merely restates current medical practice that has been in place since 1965 so it does not add a new responsibility for PCMPs. As stated in Response 6, if the screen is positive or the specimen is unsatisfactory, MDH immediately follows up to identify the PMCP, usually before the infant has even seen him or her. Thus, if a PMCP has been erroneously designated on the specimen card and the infant tests positive for a disorder or has an unsatisfactory test result, MDH will learn that the physician was misidentified and will almost always identify the correct PMCP within one or two days. This gives the correct PMCP ample time to fulfill the responsibilities in the proposed rule. MDH has found that most parents are more than willing to get the repeat specimen to ensure that their child does not have one of the disorders for which the test screens. It is rare for someone to refuse a repeat specimen.

For those rare cases when parents opt out, the system works best if dealt with on a case-by-case basis. The opting-out parents should already have been informed of their right to refuse testing through the MDH newborn screening parent brochure (available as of April 2006) and hospital staff.

Comment 8: The proposed rule requires the responsible party to alert the MDH and the PMCP of all newborns for whom a sample is not collected. First, where the specimen is not collected or sent, it also may often be the case that the card is not yet completed. Since the PMCP information is on the specimen card, this again would require an alternative procedure, because the PMCP cannot be alerted if not known. Second, as written, this requirement appears to include infants for whom the parent has received information about the testing and has refused in writing. The proposed rule already provides that the MDH is to be notified of infants for whom parents refuse the testing, and the statute provides that a written objection exempts an infant from the requirements of the statute. In addition, the proposed rule does not indicate a purpose or expected response by the PMCP who receives this “alert.”

Response 8: Your first comment implies that the specimen and the card are two separate items and may be sent in separately. This is not the case. The card and specimen are actually the same thing because the responsible party collects the specimen on the card and then sends it in.

Regarding your second concern, proposed Minn. Rules, Part 4615.0550 C, requires the responsible party to send in a copy of the signed opt-out form within one week from when the parent signs the form. Therefore, if the responsible party has done that, then they have already fulfilled their responsibility in Minn. Rules, Part 4615.0550 L, alerting MDH that the sample was not collected. Regarding the notification of the PMCP, it is important that

the PMCP is aware of the parent's choice to opt out so he or she can discuss this at the well-child visit if they feel it is necessary.

Your final concern is that the proposed rule does not indicate a purpose or expected response by the PMCP. It is standard medical care in Minnesota that PMCPs ensure the infants they are seeing have been screened. If a PMCP saw an infant who was not screened, it is the current standard of care to test the infant, provided of course, that the parents do not opt out of the screening.

Comment 9: Responsible parties also are required to forward the results within two weeks. A time period based on "business days" would be preferred because "two weeks" does not account for holidays.

Response 9: We understand your concern on this issue; however, due to the importance of early detection and treatment, it is critical that primary care providers receive results as soon as possible. Two weeks is reasonable and ample time to forward the results. This time period was discussed among members of the rulemaking advisory committee and everyone agreed that is already standard medical practice. Page 19 of the SONAR addresses this. Advisory Committee members agreed upon a two week timeframe by balancing the primary medical provider's need for the information with the burden on the responsible party."

Comment 10: The proposed rule requires that PMCPs report results of diagnostic evaluation of all infants with positive test results to MDH in writing within 30 days of receipt of results from MDH. The statute does not require or provide for diagnostic evaluation by a PMCP. Further, this requirement does not acknowledge or provide any exception or process for PMCPs who are not able to reach the parents, where the infant is not presented to the PMCP for evaluation or where the PMCP has received results in error. In addition, the 30-day time limitation for this action should be changed to state "30 business days."

Response 10: The proposed rules state current standard medical practice, which already works well. Minnesota Statutes § 144.128 requires the commissioner to notify the newborns' physicians of the test results and make referrals for the necessary treatment of diagnosed disorders. Even though the statute does not explicitly state that primary medical care providers report results of diagnostic testing, it is a rational extension of the necessary communication between MDH and providers for the infant's continuum of care. This proposed change is reasonable and necessary to ensure that all newborns who test positive for a disorder are promptly evaluated and treated to ensure they remain healthy. As stated earlier, MDH has staff who follow up positive results or unsatisfactory specimen. MDH works with providers to ensure the diagnostic evaluation is done. If the PMCP were wrongly identified, MDH staff would locate the correct PMCP or the parents themselves.

Comment 11: The proposed rule does not place any duties on parents, even though a parent may be a person with a duty under the statute to arrange testing.

Response 11: In the proposed rule changes, we chose not to put any responsibilities on the parent because it would be impractical (if not impossible) to enforce. MDH cross-references

birth certificate records with newborn screening cards to make sure there is no discrepancy and all infants were screened, unless the parent opts out. This system allows MDH to contact the parent if MDH received no screening card or an opt-out form. Acknowledging that newborn screening is a medical procedure is important and most parents are not familiar with the procedure. This is also another reason why it is important to have the primary care provider involved in this process.

Comment 12: The proposed rule states in subp. 3 that if the birth was not attended by “one of the parties listed in this part or part 4615.0050 or 4615.0600, then the infant’s PMCP must provide information to the parents. One of the parties listed in part 4615.0300, however, is a parent. This subpart does not make sense as written.

Response 12: MDH agrees with your statement that this subpart is not clear as written. We intended that if the parent(s) were the only one(s) present at the birth, the PMCP must give the parents written material on newborn screening made available by the department. This is necessary to ensure that parents receive the information so they can either have their babies screened or opt out. Under Minn. Stat. § 144.215, parents have the duty to register the birth, thus having a duty to perform testing. However, we cannot assume that parents will have this knowledge and know what to do. Fortunately, these types of situations are rare.

Specifically, MDH recommends the following changes for Minn. Rules 4615.0700 subp. 3:

Delete the references to “not attended by one of the parties listed in this part, or part 4615.0500 or 4615.0600” and replace it with the phrase “was only attended by the parent(s) of the child”

This change is not a substantial change because it only clarifies MDH’s intent.

Comment 13: The proposed rule does not address the likelihood that PMCP notification may occur before the infant is under the care of the PMCP, and potentially may occur while the infant is under the care of some other provider or facility that may have a greater need for the information.

Response 13: If a screening test comes back positive or the specimen is unsatisfactory, MDH will follow up immediately with the PMCP. As stated earlier, MDH is actively involved in following-up and managing cases of positive results and unsatisfactory specimen. If the infant is not under the care of the PMCP designated on the card, MDH will go back to the responsible party to locate the infant.

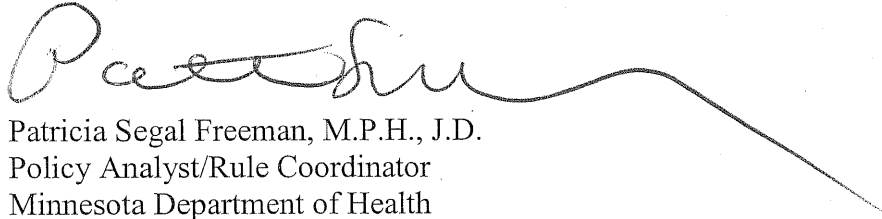
Finally, proposed rule change part 4615.0400 subp. 4a(B) specifically takes into account the possibility that the infant may be hospitalized for a long time and not see their PMCP.

Finally, it is also important to note that the proposed changes are the product of a strenuous collaborative effort that included many different providers and organizations. Our newborn screening rulemaking advisory committee reviewed the proposed changes many times and members shared the information with their colleagues and organizations to which they belong. MDH worked long and hard to prevent these proposed changes from being an undue burden on any one group or

person. However, at the same time, we believe that these changes are necessary and reasonable to carry out the legislative directive to ensure all newborns are tested for these potentially debilitating disorders, diagnosed, and treated if necessary, unless parents opt out.

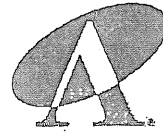
Thank you for your thoughtful consideration and constructive comments. If you have additional questions or comments, please contact me at 651-651-2001 or Mark McCann, Supervisor, Newborn Screening Program at 651-201-5545.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia", with a long, sweeping horizontal line extending to the right.

Patricia Segal Freeman, M.P.H., J.D.
Policy Analyst/Rule Coordinator
Minnesota Department of Health

Enc. Letter to MDH from Allina



ALLINA.
Hospitals & Clinics

Law Department

FACSIMILE TRANSMITTAL

TO: Patricia Segal Freeman
FAX #: 651-201-5501
RE: Comments on Proposed Amendments
DATE: December 29, 2006
NUMBER OF PAGES (INCLUDING COVER SHEET): 4
COMMENTS:

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Law Department
2925 Chicago Avenue S.
MR 10905
Minneapolis, MN 55407-1321

Mailing Address:
P.O. Box 1469
MR 10905
Minneapolis, MN 55440-1469

VIA FACSIMILE
(651) 201-5501



ALLINA
Hospitals & Clinics

December 29, 2006

Ms. Patricia Segal Freeman
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0899

Re: Comments on Proposed Amendments to Rules Governing Newborn Screening
Minnesota Rules Chapter 4615

Dear Ms. Freeman:

Please accept the following comments regarding the Department's proposed amendments to the Rules Governing Newborn Screening, Minnesota Rules Chapter 4615:

1. The statute imposes duties with respect to infants who are age 28 days or less. The proposed rule, however, defines "newborns" as infants "from birth through the first month of life" and imposes duties with respect to such newborns. This definition sets up potential ambiguity when infants are 29 to 31 days old. Defining "newborns" as infants up to 28 days of age would be consistent with the statute and less confusing.
2. The proposed rule, both in defining the responsible parties and throughout, assigns responsibilities to primary medical care providers ("PMCPs"), defined by the rule as physicians or clinics whom parents identify. This class of persons, however, is not among the persons having a statutory duty to arrange testing, except perhaps where such PMCPs are already required to register the birth of the child under § 144.215 because they were present at the time of a birth occurring outside an institution. Therefore, the rule imposes a duty on persons who do not have a duty under the authorizing statute.
3. Nurse midwives and midwives in attendance at birth, who are among the persons with duties under the statute, are omitted from the proposed rule's list of responsible parties. The rule should include these persons in defining responsible parties.
4. The proposed rule defines "business day" as Monday through Saturday, excluding holidays. A more common definition of "business day," i.e., Monday through Friday and excluding holidays, is preferred. Indeed some parties with responsibilities under the proposed

Phone: 612-262-5426 • Fax: 612-262-4264

Ms. Patricia Segal Freeman
December 29, 2006
Page 2

rule may not conduct business on Saturday. The more common definition would be more consistent with other procedures.

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Ms. Patricia Segal Freeman
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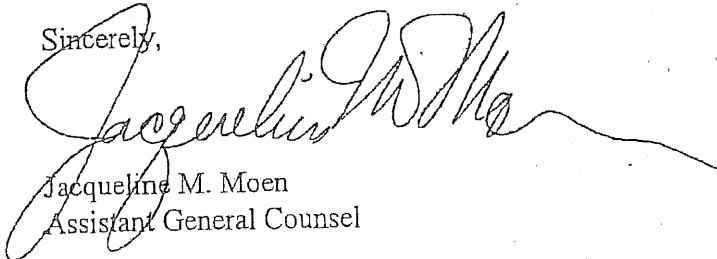
11. The proposed rule does not place any duties on parents, even though a parent may be a person with a duty under the statute to arrange testing.

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Thank you for your consideration of these comments. Please feel free to contact me if you have any questions.

Sincerely,



Jacqueline M. Moen
Assistant General Counsel

cc: Rebecca Hasse, Assistant General Counsel
Bruce McCarthy, M.D., Medical Director, Allina Medical Clinics



Protecting, maintaining and improving the health of all Minnesotans

Jacqueline M. Moen
Assistant General Counsel
Allina Law Department
2925 Chicago Ave. S
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From: "Dale Dobrin" <ddobrin@slpeds.com>
To: <NBSrule@health.state.mn.us>
Date: 12/28/2006 11:43 AM
Subject: re Newborn Screening

Hello. I suggest bolding the fifth paragraph in the "Refusal to Test" form. This paragraph says that parents refusing understand that they may be putting their infant at risk for serious disability and even death. I think it is very important that parents understand this risk. The Academy of Pediatrics has published a similar document for pediatricians to use when parents refuse vaccinations. In our experience, most parents who say they would like to refuse, do not do so after reading this document, especially its section on "...risks including death".

Also, it should be required that both parents sign off on the refusal.

Dale Dobrin, MD
Medical Director
South Lake Pediatric Clinic

p.s. - in the future, committees like the one whose membership is listed in the SONAR, in which child health issues are recommended, should include a practicing pediatrician as well

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From: Patricia.Segal Freeman
To: Dale Dobrin
Date: 12/29/2006 9:55 AM
Subject: Re: re Newborn Screening

Thank you for your helpful comments, which I pasted in below. We appreciate them.

Regarding the requirement to have both parents signature, the law/statute only requires one parent to sign so we cannot change this in rule. This would require a legislative change. However, I will bring this issue to the attention of the newborn staff for discussion.

You wrote:

"Hello. I suggest bolding the fifth paragraph in the "Refusal to Test" form. This paragraph says that parents refusing understand that they may be putting their infant at risk for serious disability and even death. I think it is very important that parents understand this risk. The Academy of Pediatrics has published a similar document for pediatricians to use when parents refuse vaccinations. In our experience, most parents who say they would like to refuse, do not do so after reading this document, especially its section on "...risks including death".

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Dale Dobrin, MD
Medical Director
South Lake Pediatric Clinic

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Patricia Segal-Freeman, J.D., M.P.H.
MN Dept. of Health, ITIH Section
Freeman Office Bldg.
625 N. Robert St (street address)
P.O. Box 64975 (mailing address)
St. Paul, MN 55164-0975
Office: 651-201-5520

From: "Dale Dobrin" <ddobrin@slpeds.com>
To: <NBSrule@health.state.mn.us>
Date: 12/28/2006 11:48 AM
Subject: p.s.

Also, will MDH be making available handouts pertaining to the conditions for which the Newborn Screen may test + (for use by Primary Care Providers)? Also the follow up reporting forms for those with + test results?

Dale Dobrin, MD
Medical Director
South Lake Pediatric Clinic

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From: BethAnn Bloom
To: Dobrin, Dale
Date: 1/2/2007 9:52 AM
Subject: Re: Newborn Screening

Dr Dobrin,
Thank you for your responses to the newborn screening SONAR.

Minnesota's newborn screening program already has handouts geared to providers for each of the disorders we screen for. The handouts are faxed to the provider with every positive result. They are also available on-line at <http://www.health.state.mn.us/newbornscreening> under provider information. There are also handouts for providers to share with parents. All of the handouts are bound within the Providers' Manual. The manual is available on-line. If you would like a hard copy please contact me.

Again, thanks for your support and please let me know if I can answer any questions about newborn screening for you,

Best regards,
Beth-Ann

Beth-Ann Bloom, MS
Genetic Counselor
Minnesota Department of Health
Newborn Screening Program
E-mail: BethAnn.Bloom@health.state.mn.us
Phone: 651-201-5453
Fax:651-201-5471
Address: 601 N Robert St
St Paul, MN 55155