# STATEMENT OF NEED AND REASONABLENESS (SONAR)

# NEWBORN SCREENING RULE

## MINNESOTA DEPARTMENT OF HEALTH

## October 30, 2006

**MINNESOTA DEPARTMENT OF HEALTH**

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## I. BACKGROUND AND INTRODUCTION

The Minnesota Department of Health (MDH) is proposing amendments to the current Newborn Screening Rules ("the rules"). These rules are the backbone of MDH's ability to screen newborns for potentially debilitating and sometimes deadly congenital disorders. See Attachment A for a list of these disorders.

Newborn screening is an important, live-saving part of health maintenance for all infants. It is the practice of testing and analyzing every newborn's blood for certain harmful or potentially fatal disorders that are not otherwise apparent at birth. Since 1965, the MDH Newborn Screening Program has screened all infants born in Minnesota.[1]

Metabolic[2] and other inherited disorders[3] can hinder an infant's normal physical and mental development in a variety of ways. Most of the disorders are inherited, although affected babies rarely have a family history of the disorder. For nearly all the disorders, both parents must be carriers[4] to have an affected child. Parents can pass along abnormal genes for a certain disorder without even knowing that they are carriers. With a simple blood test, MDH can tell whether a baby is at risk for having certain conditions that could cause health problems and even death. Early diagnosis and proper treatment can make the difference between lifelong impairment and healthy development.

MDH's Public Health Laboratory (PHL) screens all newborn babies in Minnesota for a wide spectrum of congenital and inherited diseases.[5] Hospitals collect blood from the newborns and submit the dried blood spot specimens to the MDH PHL. Each year MDH screens more than 72,000 newborns in Minnesota and saves the lives or greatly improves the outcomes of approximately 90 children who have a confirmed disorder. These early medical interventions prevent severe disabilities and death. For more detailed information on the newborn screening process, see Attachment B, Newborn Screening Processes and Procedures.

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[1] In 1965, the program only screened for PKU. Today the program screens for more than 50 disorders.

[2] A metabolic disorder results when a person is unable to break down certain foods into simpler substances. The simpler substances are used as building blocks for materials needed to keep the body functioning. A missing enzyme that helps break down food usually causes metabolic disorders. Changing the diet and/or taking medications can treat metabolic disorders.

[3] An inherited disorder describes a condition that is caused by an abnormal gene(s) that is passed from parent(s) to child.

[4] A carrier is person who has one abnormal gene for a recessively inherited disorder. "Recessive" means that a person must have two abnormal genes to be affected. Because a carrier has only one abnormal gene, they do not have the disorder nor do they usually have any related health problems.

[5] Parents may opt-out of the screening.

The rules regarding newborn screening cover important areas that allow for appropriate collection and transport of newborn screening specimens and follow-up of infants identified with abnormal newborn screening results. MDH last revised these rules in 2000.

In 2003, the legislature made statutory changes to the newborn screening laws (Minnesota Statutes, sections, 144.125, 144.1255, and 144.128), and as a result, the current rules are inconsistent with some of the 2003 statutory changes. In addition, over the past five years, changes have occurred in the newborn screening process and in the roles that health care providers, hospitals, and MDH play in this activity.

This rulemaking process will update the Newborn Screening Rules to reflect the 2003 statutory changes and new technological advances, as well as to clarify the roles of MDH, hospitals, and health care providers.

MDH began work on potential revisions to the rules in October 2005. The agency published a Request for Comments in the State Register on December 12, 2005. MDH notified affected parties of the Request for Comments through multiple means. (See Attachment C for efforts MDH undertook to notify affected parties of the Request for Comments.) Moreover, MDH created a website[6] where people could go to get information on the rulemaking process and draft rules. MDH also created an e-mail address to allow people to submit comments electronically.[7] MDH received four written comments.

During this same time, MDH formed a Newborn Screening Rule Advisory Committee ("Advisory Committee") to represent the various parties affected by the proposed rule amendments. The Advisory Committee includes hospitals, genetic counselors, pediatricians, nurses, parents, nonprofit organizations, and representatives from the privacy community. (See Attachment D for a list of Advisory Committee members.) MDH convened the Advisory Committee for meetings on November 16, 2005 and March 1, 2006. These meetings provided participants with an opportunity to share their views and ask questions about the proposed amendments to the rules. After each meeting, MDH modified the proposed amendments in response to Advisory Committee comments. MDH maintained contact with advisory committee members through e-mail. The agency also asked Advisory Committee members to distribute a draft of the proposed amendments to their organizational lists during the Request for Comment period. Thus, MDH received comments on the proposed amendments to the rules through the Request for Comments, the Advisory Committee, and the distribution of the proposed rules by MDH and Advisory Committee members. The proposed amendments to the rules are the products of this process.

## II. ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make a request, contact

[6] www.health.state.mn.us/divs/phl/newborn/rulechange.html
[7] The e-mail address is NBSrule@health.state.mn.us.

Patricia Segal-Freeman, Minnesota Department of Health, P.O. Box 64975, St. Paul, Minnesota, 55164-0975. Phone: 651-201-5414, 1-877-676-5414, FAX (651) 201-5501 or NBSrule@health.state.mn.us. TTY users may call the Department of Health at 651-201-5797.

## III. STATUTORY AUTHORITY

The department's statutory authority to amend the rules is set forth in Minnesota Statutes section 144.128, which provides:

> The commissioner shall: (4) adopt rules to carry out sections 144.125 to 144.128.

Under this statute, the department has the necessary statutory authority to adopt the proposed rules. This rulemaking is an amendment of existing rules and thus, Minnesota Statutes, section 14.125, does not apply.

## IV. REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, sets out seven factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (7) below quote these factors and then give the agency's response.

### A. A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

1. Classes of Persons Affected by the Proposed Rule

   The existing rules apply to persons and entities involved in the newborn screening process. These groups include those required to collect and submit blood specimens to the MDH Public Health Laboratory (PHL), persons and entities receiving the results of the screening tests, and MDH. The proposed rule amendments do not change who is affected, but rather, the roles and responsibilities of those involved in the process. These changes affect the following persons and entities:

   - Hospitals and birth attendants responsible for collecting the blood specimen ("the responsible party" as defined in the proposed rules, Minn. Rules Part 4615.0400)
   - Health care providers responsible for the infant's care after the baby is discharged from the hospital or birthing attendant ("Primary Medical Care Providers" as defined in the revised rules Minn. Rules Part 4615.04)
   - The Minnesota Department of Health
   - Parents and Guardians of newborns in Minnesota
   - Newborns

2. Classes of Persons Who Will Bear the Costs of the Proposed Rule

   - MDH will bear the cost of developing forms required by the proposed revisions.
   - Birthing centers[8] and birthing attendants[9]. Currently, birthing centers and clinicians buy specimen cards from MDH for $61 a piece. The fee is typically reimbursed by insurance. This fee covers testing for all the disorders in the newborn screening panel and necessary follow-up, which consists of tracking positive results and unsatisfactory specimens. This fee was increased from $21 to $61 during the 2003 legislative session. There was no opposition to this increase. Since all newborns are already screened, there will be no increased cost.

3. Classes of Persons Who Will Benefit From the Proposed Rule

   - Minnesota Newborns/Children. The beneficiaries of the proposed rules include all children born in Minnesota. All Minnesota children benefit because they will be screened for disorders that cause serious morbidity and mortality. If a newborn's screen is positive, that infant will be able to receive appropriate diagnostic testing and treatment. This early diagnosis and proper treatment will make the difference between lifelong impairment and healthy development.
   - Minnesota Parents/Guardians. The parents/guardians of all Minnesota children will also benefit from these revisions. Minnesota parents/guardians will be assured that their newborns are screened for these debilitating and potential deadly disorders and receive information on treatment if the diagnostic testing following an abnormal screen provides a confirmed diagnosis.
   - Primary Medical Care Providers. Primary medical care providers will benefit because these proposed revisions clarify their duties and the roles of others involved in the process. For example, the proposed rules require that hospitals forward the newborn screening results to the primary medical care provider, thereby helping them improve patient care.
   - Responsible Parties. Responsible parties will benefit because these proposed changes clarify their role and the roles of other parties involved in the process.
   - Minnesota Medical/Health System. Newborns with disorders detected by newborn screening who are not identified early cost our health care system hundreds of thousands of dollars. If these disorders are detected and treated early, these infants will grow up healthy or healthier than if they were not screened, resulting in short- and long-term health care savings.
   - Educational and Social Service System. Finally, newborns with disorders detected by newborn screening who are not caught early cost our educational and social

[8] Birthing centers include hospitals and other facilities where babies are delivered.
[9] Birthing attendants include any person who delivers a baby.

service systems hundreds of thousands of dollars. If these disorders are detected and treated early, these infants will grow up healthy or healthier than if they were not screened, resulting in educational and social services' savings.

**B. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.**

1. Probable Costs to the Agency of Implementation and Enforcement.

   The probable costs to MDH for implementing the proposed rule amendments will be minimal. Costs for developing forms and educating parties about the change will be absorbed through existing department activities.

2. Probable Costs to Any Other Agency of Implementation and Enforcement.

   There should be minimal or no cost to any other state agency. The Minnesota Department of Human Services (DHS) already covers the cost of newborn screening for those infants on Medicaid, Minnesota Care, or other subsidized Minnesota Health program.

3. Any Anticipated Effect on State Revenues.

   The proposed rule amendments will not affect state revenues. The cost of newborn screening is covered through a fee, and this fee will continue to cover the cost.

**C. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule**

MDH has proposed the least costly and least intrusive methods necessary for achieving the purpose of the rules, namely ensuring that all Minnesota newborns are screened. (This factor is also discussed in the performance-based standard section on pages 7 and 8 and the Rule by Rule Analysis.)

1. Less Costly Methods.

   There will be no increased monetary costs to the health care system since all newborns are already routinely screened in Minnesota. A less costly method would be not to screen newborns in Minnesota. However, Minnesota Statutes, section 144.125 requires all newborns to be screened unless their parent or guardian objects to the testing.

2. Less Intrusive Methods.

Less intrusive methods would include not mandating certain responsibilities that each party must follow. However, these less intrusive methods will not guarantee that all newborns are screened and referred for evaluation and may result in a newborn being missed. Moreover, the policies and procedures outlined in the proposed rules are established standards that most of the parties should have already adopted.

**D. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule**

Collecting and testing blood samples is the standard method for screening newborns to ensure early diagnosis and proper treatment for potentially debilitating and sometimes deadly congenital disorders in every state in the United States.

For discussions on alternative methods considered, see the following areas listed below.

1. This SONAR discusses both less costly and less intrusive methods (see factor C above).
2. See Performance Standard discussion.

**E. The probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals**

1. Probable costs of complying with the proposed rule.

   Since all newborns are already screened for these tests, there should no increase in costs for parents or birthing centers. Responsible parties and primary medical care providers should already have these types of policies in place. If not, they should be able to incorporate them into existing activities.

   On the newborn screening rulemaking advisory committee, there were representatives from the Minnesota Hospital Association, Minnesota Council of Health Plans, birthing centers, and primary care. The agency did not receive comments from any of these organizations, other Advisory Committee members, or the public on any added costs or work.

   Some of the proposed changes may increase affected parties' workload, though the increase should not be substantial for any one party.

2. Portion of costs to be borne by identifiable categories of affected parties.

- Government Entities: MDH is the government entity affected by any additional costs under the proposed rules. We anticipate that costs for MDH will be minimal. This is discussed under factor B of the regulatory analysis.

- Responsible parties and primary care medical providers should have no (or very limited) new costs. As mentioned above, the agency did not receive comments from any of these organizations represented on the Advisory Committee or the public on any added costs or work.

**F. The probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals**

1. Probable costs or consequences of not adopting the proposed rules are significant.

   There are significant potential costs for not going forward with the proposed amendments to the rules. The most important is the possibility that a newborn will not be screened at the earliest possible time. If the baby is not screened shortly after birth and is later found to have a treatable disorder, the baby may develop lifelong health complications and possibly die. As stated earlier, these proposed changes put policies and procedures in place to ensure the timely screening of all newborns in Minnesota unless a parent declines testing.

   Moreover, if these proposed changes are not adopted, the rule will be in conflict with some of the 2003 statutory changes made by the legislature.

**G. An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference**

There are no federal regulations regarding newborn screening. This is a state function.

## V. ADDITIONAL STATUTORY REQUIREMENTS

### A. PERFORMANCE-BASED RULES

Minnesota law (Minnesota Statutes, sections 14.002 and 14.131) requires that the SONAR describe how MDH, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting MDH's regulatory objectives and maximum flexibility for the regulated party and MDH in meeting those goals.

MDH staff asked the Advisory Committee for input on performance-based standards. The agency provided members with the statutory language on these standards and asked members the following three questions to assist them in the discussion.

1. Are there special situations we should consider in developing the rules?
2. Are there ways to reduce the burdens of the rules?
3. Do you have any other insights on how to improve the rules?

Committee members all agreed that changes to the rules were needed to ensure that all newborns are screened in a timely manner in Minnesota. They also agreed that these were best methods to achieve this goal.

Members who represent "responsible parties" had concerns on how to fill out the newborn screening card when the primary medical care provider is unknown. This might include babies who are dropped off at safe-haven hospitals,[10] babies who will live in neighboring states but are born in Minnesota, and other cases where primary medical care providers may be unknown. MDH realizes this is a problem and suggested that in these cases the responsible party should give the name of a contact with whom MDH can follow-up if necessary. Currently, two birthing centers in the state often give the name of a contact person at their facility for follow-up purposes. MDH has worked with these facilities on this issue. In December 2005, MDH revised the newborn screening card to ask for the name of the primary care provider. MDH had not received any complaints about the card as of August 4, 2006.

Originally, part 4615.05500 (F) and 4615.0600 (H) seemed vague to members. The original draft required the parties to use reasonable efforts to obtain repeat specimens. The group suggested it would be less burdensome and would improve the rules if we used the term "best efforts." MDH revised the draft to reflect members' input.

Another member spoke about the need to "close the loop"—that is, to ensure that primary medical care providers receive the newborn screening report. Primary medical care providers sometimes find it difficult to get records from the responsible party. MDH will work on ways to facilitate communication and will ensure this information is highlighted in the implementation materials.

The group agreed that translated materials provided by MDH would reduce the burden on all parties. Members also agreed that reducing the time-frame for screening and reporting results would also be helpful.

[10] Minnesota has a law (Safe Place For Newborns Act) that allows a person to leave a newborn with a hospital - no questions asked. These hospitals are referred to as "safe-haven hospitals."

## B. ADDITIONAL NOTICE

Minnesota law (Minnesota Statutes, sections 14.131 and 14.23) requires that the SONAR contain a description of MDH's efforts to provide additional notice to persons who may be affected by the proposed amendments to the rules.

MDH submitted an additional notice plan to the Office of Administrative Hearings, which reviewed and approved it on October 24, 2006 by Administrative Law Judge Barbara L. Neilson.

The additional notice plan consists of the following steps:

1. Mailing a summary of the proposed rules and the dual notice to all persons who have registered to be on MDH's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.

2. Posting the proposed rules, the dual notice, the SONAR, and a fact sheet containing a summary of the substantive amendments on MDH's Newborn Screening Rulemaking website at http://www.health.state.mn.us/divs/phl/newborn/rulechange.html.

3. Providing a copy of the dual notice, the SONAR, the fact sheet containing a summary of the substantive amendments, and a web link to the proposed rules to members of the Advisory Committee, and also asking them to forward this information to the organizations they represent and their colleagues. The Advisory Committee was made up of a variety of health care professionals and organizations. (See Attachment D for list of members.)

4. Providing a copy of the dual notice, the SONAR, the fact sheet containing a summary of the substantive amendments, and a web link to the proposed rules via e-mail, directly or through a listserve, to various individuals, groups and organizations. MDH also requested, when possible, that these organizations post the information on their website and send it out to their listserv. This list includes, but is not limited to:

   - Health care providers who provide medical care to infants.
     - Minnesota Medical Association
     - Minnesota Academy of Family Physicians
     - Minnesota Chapter of the American Academy of Pediatrics
     - Minnesota Council of Health Plans
     - Minnesota Hospital Association
     - Minnesota Nurses Association

   - Medical laboratories
     - MDH's Minnesota Laboratory System list. This list includes approximately 160 laboratories, including public health and private clinical laboratories,

which serve Minnesota residents.

5. Notifying the Minnesota Legislature per Minnesota Statutes, section 14.116 and Minnesota Statutes, sections 121A.15, subdivision 12(2)(b) and 135A.14, subdivision 7(d). This will include sending the proposed rules, SONAR, dual notice, and summary of substantive amendments to the chairs and ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter.

6. Sending a press release about the proposed rules to news organizations in the state.

## C. CONSULT WITH FINANCE ON LOCAL GOVERNMENT IMPACT

As required by Minnesota Statutes, section 14.131, the Department has consulted with the Commissioner of Finance. We did this by sending to the Commissioner of Finance copies of the documents sent to the Governor's Office for review and approval by the Governor's Office prior to the Department publishing the Notice of Intent to Adopt. We sent the copies on September 13, 2006. The documents included: the Governor's Office Proposed Rule and SONAR Form; final draft rules; and almost final SONAR. The Department of Finance had no comments.

## D. COST OF COMPLYING FOR SMALL BUSINESS OR CITY

### 1. Agency Determination of Cost

As required by Minnesota Statutes, section 14.127, the Department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city. The Department has determined that the cost of complying with the proposed rules in the first year after the rules take effect will not exceed $25,000 for any small business or small city.

The Department has made this determination based on the probable costs of complying with the proposed rule, as described in the Regulatory Analysis section of this SONAR on pages six and seven. As stated earlier, since all newborns are already screened, there should be no increase in costs for parents or birthing centers. On the newborn screening rulemaking advisory committee, there were representatives from the Minnesota Hospital Association, Minnesota Council of Health Plans, birthing centers, and primary care. The agency did not receive comments from any of these organizations, other Advisory Committee members, or the public on any added costs or work.

**2. Effect of Cost Determination.** Since there is no cost this part does not apply.

## E. LIST OF NON-AGENCY WITNESSES

If these rules go to a public hearing, the Department anticipates having the following witnesses testify in support of the need for and reasonableness of the rules:

1. Mr. Steve Johnson will testify about the benefit of newborn screening and his own personal experience with it.
2. Dr. Susan Berry will testify about the newborn screening process.

## VI. RULE-BY-RULE ANALYSIS

The following amendments are proposed by MDH to the Newborn Screening Rules, Minnesota Rules, Chapter 4615. MDH has concluded, after careful consideration, that each amendment is reasonable and necessary to further the department's goal that every Minnesota newborn is screened.

### PART 4615.0300 PURPOSE AND SCOPE.

This proposed change replaces the list of disorders with a general reference to disorders listed in the newborn screening panel list as defined in Minnesota Statutes, section 144.125, subd. 2. This is necessary to update the Rules to reflect 2003 statutory changes that replaced the list of diseases with a general reference to the newborn screening panel.

### PART 4615.0400 DEFINITIONS

The definitions proposed in this revision are reasonable and necessary to ensure all Minnesota newborns are screened for life-threatening congenital disorders. These amendments will ensure that these words are used consistently and understood among health care professionals and MDH for purposes of these rules.

**4615.0400, Subpart 2. Attending physicians**. (see "Repealer" section in Revisor's Rule) This amendment repeals subp. 2, attending physician, in the current rules and replaces it with subp. 4a, "primary medical care provider." The current definition of "attending physician" does not cover all possible medical care providers for an infant. This proposed revision ensures that all those who care for infants are included in the rules.

**4615.0400, Subpart 2a. Business Day**. This new subpart adds the term "business day" to the rules. The term is used in part 4615.0500 (I) of the proposed rules. Defining this term ensures that MDH and the "responsible party"[11] use the term, "business day," consistently. The advisory committee requested that the department include a definition of business day to ensure there is no confusion on its meaning. The department added this definition to the rules based on the advisory committee discussion.

[11] Responsible party is defined in Part 4615.0400 subpart 5 of the proposed rules.

**4615.0400, Subpart 2b. Commissioner; Subpart 2c. Department**. These two proposed additions add "commissioner" and "department" to the rules. Under these amendments, "Commissioner" means the Commissioner of the Department of Health, and "department" means the Minnesota Department of Health. Both of these terms are currently used throughout the rules; however, they are not defined in the rules. Adding these definitions clarifies these terms in the current rules.

**4615.0400, Subpart 2d. Infant.** Under the proposed amendments, there are many references to "infant."[12] This definition clarifies that an "infant" means a child up to one year of age. MDH consulted the advisory committee for the definition to ensure that the term would be acceptable to all parties. The proposed definition is the definition commonly used and accepted in the medical field.

4**615.0400, Subpart 3. Newborn infant.** The current rules define "newborn infant" as a child from birth through the first five days of life. The proposed amendment expands the definition to include infants up to one month of age. This change is necessary because a baby may need to have a repeat specimen taken when a baby is older than five days of life and still under the care of the responsible party. For example, the screening protocol for low birth weight babies in the neonatal intensive care unit (NICU) requires that 3 samples are collected (24-48 hours after birth, 14 days after birth, and 30 days after birth). Thus, the previous definition, "child from birth through first five days of life," does not accommodate all circumstances of newborn screening.

**4615.0400, Subpart 3a. Newborn Screening Panel**. This proposed amendment defines "Newborn Screening Panel" as the genetic and/or congenital diseases tested for by the Newborn Screening Program as determined by the provision of Minnesota Statutes, section 144.125, subd 2[13]. This amendment is necessary to ensure that the rules are consistent with the 2003 statutory changes that replaced the listing of metabolic disorders with a provision that allows the commissioner to determine which tests will be included in the newborn screening.

**4615.0400, Subpart 3b. Parent.** Under the proposed amendments, there are several references to "parent"[14] in the rules. This addition defines "parent" as the presumptive biological parent or legal guardian of the newborn at the time of testing. Even though the term is used in the current rule, it is not defined. This definition clarifies who is a parent for purposes of this rule.

**4615.0400, Subpart 4. Positive screening results.** This proposed amendment adds the phrase "results" to the current definition of positive screening results. The proposed amendment defines "positive screening results" as the laboratory tests results that clearly indicate the infant is at a high risk for having one or more of the genetic or congenital diseases included in the newborn screening panel according to Minnesota Statutes, section 144.125, subd. 2. This change clarifies

[12] The following are just a few examples, Part 4615.05504.C, Part 4615.0600 B, Part 4615.0700A.
[13] Minn. Stat. §144.125, subd. 2. Determination of tests to be administered. This statute gives the commissioner authority to determine what tests will be included in the newborn screening panel for diagnostic testing of infants.
[14] It is used, for example, in parts 4615.0550 subparts B, C; 4615.0600 subparts E, F; 4615.0700 subpart 1(C), (E), subpart 3

that it is the results of the test that must be positive. The current rules also refer to specific diseases listed in parts of the rule. This reference is obsolete as a result of the 2003 legislative changes and the proposed changes update the rules to reflect those changes.

**4615.0400, Subpart 4a. Primary medical care provider**. There are two parts to this definition. The first refers to the physician or clinic identified by the parent or guardian as the entity that will be providing the infant's medical care after the baby is discharged from the hospital or from the care of the birth attendant. The second refers to the hospital-based physician or nurse practitioner in cases of long-term infant hospitalization. This part is necessary because there are times when an infant may have to stay in the hospital for an extended period. For example, some premature infants may have to remain in the hospital for one month or more. Having both of these parts ensures that an infant is covered under all possible circumstances. See, also, discussion of "attending physician," under 4615.0400, subp.2.

**4615.0400, Subpart 5. Responsible party.** This proposed amendment clarifies and broadens the definition of "responsible party" to include all potential birthing centers or birth attendants and to reflect the intent of the current statute. In addition, the proposed amendment clarifies that the responsible party is limited to the institution that cares for newborn infants one month or less of age (or the person required in pursuance of the provisions of Minnesota Statutes, section 144.215) thus further distinguishing the responsible party from the primary medical care provider. This addition also corresponds to the definition of "newborn infant" above.

**4615.0400, Subpart 6. Screen**. This proposed amendment replaces the list of metabolic disorders with a general reference to the screening panel according to Minnesota Statutes, section 144.125 subd. 2. This ensures that the rules are consistent with current statute.

**4615.0400, Subpart 7. Specimen.** The proposed amendment in this subpart is technical and clarifies the definition of specimen. The amendment replaces the word "specimen" with the word "sample" so the definition does not use the word in the title to define itself.

**4615.0400, Subpart 8. Specimen card.** There are two proposed technical amendments in this subpart that clarify the definition of "specimen card" as a filter paper card <u>purchased from</u> the Minnesota Department of Health and used to collect the <u>infant's blood</u> specimen for newborn screening. The current rules say that MDH will provide the card; however, the rules do not include any information on how it is provided or who pays for the card. The first change clarifies current practice that requires the individual or facility collecting the specimen to purchase the card from MDH. The second change clarifies that the specimen is the "infant's blood," which is specific and reduces the possibility of another specimen type being mistakenly placed on the specimen card.

**4615.0400, Subpart 9. Unsatisfactory Specimen.** Under the proposed amendments, there are several references to "unsatisfactory specimen." Unsatisfactory specimen means that the blood sample submitted is not adequate for analysis due to problems with the specimen collected, the

processing of the specimen, or the circumstances of the specimen collection. This term is not used in the current rule. This term is commonly used in the newborn screening field.

**4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN NEWBORN METABOLIC SCREENING PROGRAM**. Because of the 2003 statutory changes and obsolete provisions in this part, this part was repealed. It was replaced by 4615.0550, which incorporated, with changes, responsibilities from 4615.0500. (See "Repealer" section of Revisor's Rule.)

**4615.0550 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN NEWBORN SCREENING PROGRAM.**

There are a number of amendments to this part. The majority of the amendments codify current medical practices already used in Minnesota. Each of these amendments is reasonable and necessary to ensure that all newborns are screened in a timely manner for potentially life-threatening disorders and that they receive follow-up if the test results are positive.

The amendments are discussed in alphabetical order as they appear in the proposed rules.

**4615.0550 A.** This proposed amendment requires the responsible party to "adopt policies or practices within their institutions to ensure that all infants born in or transferred to their care have newborn screening specimens collected and submitted to the department prior to discharge or before 48 hours of life, unless the parents opt-out of the screening." Requiring adoption and enforcement of newborn screening policies and practices is necessary to ensure that newborns are screened in a timely manner so disorders are identified and promptly treated. This is standard practice in newborn screening. This amendment also requires the responsible party to ensure that all babies actually have a newborn screening specimen collected.

**4615.0550 B.** This proposed amendment requires the responsible party to adopt a policy to ensure that all parents are informed verbally, and in writing, about newborn screening prior to specimen collection. This includes:

1. providing parents of a newborn infant in their care written materials made available by the Department Newborn Screening Program or approved by the program;

2. informing the parents or legal guardian that their newborn infant will be screened for the genetic and/or congenital diseases that meet the criteria set forth in statute 144.125 included on the Minnesota newborn screening panel. This information will include an explanation for the reasons for the screening and their right to refuse the screening and the elements designated in Minn. Stat. §144.125;

This amendment is necessary and reasonable to ensure that the responsible party complies with

Minnesota Statutes, section 144.125 subd. 3[15] and that there is consistency of information delivered to parents.

The first part of this amendment ensures that all parents in Minnesota will receive the same information no matter where the child is delivered. In addition, requiring responsible parties to use materials developed by MDH ensures that the information is consistent and that the most up-to-date information is provided to the parents. Advisory committee members agreed that having the department produce the materials is the best practice. Moreover, it relieves the responsible party of any extra burden of having to create new materials. A department staff person also assured members that each time a birthing center or birth attendant orders newborn screening specimen cards, the entity will receive the same number of parent brochures.

Advisory members asked if these materials would be available in other languages. A department staff person informed the members that the department is planning on translating the parent brochure into Spanish in late 2006. Department staff is looking into the possibility of other language translations

The second part of this amendment is similar to 4615.055 (A) in the current rules. However, the proposed changes update the rules to reflect the 2003 statutory change under M.S. 144.125 subp. 3 that requires responsible parties to inform the parents 1) that the department may retain the sample, 2) of the benefit of sample retention, and 3) the option of parents to decline testing or to elect to have the results destroyed.

**4615.0550 C**. This proposed amendment requires "a parent who refuses newborn screening to sign a waiver form provided by the department. The responsible party must keep a copy of the signed form, include a copy of the signed form in the infant's medical record, and send a copy of the signed form to the commissioner of health within one week from the time the parents sign the form."

This amendment was added to make this part consistent with the 2003 statutory changes in Minnesota Statutes, section 144.125 subp.3. Specifically, the statute says, "the objection or election shall be recorded on a form that is signed by a parent or legal guardian and made part of the infant's medical record." This change codifies current practice in Minnesota. As of 2003, the department has provided forms for parents to sign if they decline screening or if they want the tests results and blood sample destroyed. Both of these forms are available to a responsible party via the department's website at http://www.health.state.mn.us/newbornscreening. (See attachments E and F).

This amendment also ensures that all Minnesota parents receive the same information. This is important because parents must be well-informed of the benefits of screening and the risks of not being screened.

[15] Minn. Stat.§144.125 subd.3 requires persons with a duty to perform testing advise parents of their right to refuse screening and/or request destruction of the infant's blood specimen.

The proposed amendment also requires the responsible party to send this form to the commissioner within one week from the time the parents sign the form. This time frame is essential because MDH tracks whether or not infants have newborn screening specimens submitted to ensure no babies are missed. Thus, MDH should be informed if parents elect not to screen their infant.

**4615.0550 D**.
This proposed amendment requires "a parent who requests the destruction of their infant's blood sample and results sign a waiver form provided by the department." The responsible party must document this refusal in the infant's medical record. This amendment is necessary for the same reasons iterated above in 4615.0500 (C).

**4615.0550 E**. This proposed amendment requires the responsible party to collect a second blood sample from the newborn infant by seven days of life, if the specimen was taken prior to 24 hours after birth. The responsible party may delegate the responsibility for repeat blood collection to the newborn infant's primary medical care provider. This amendment codifies current screening practice in Minnesota. Currently, if a specimen is taken prior to 24 hours after birth, the department will contact the responsible party and have them collect another specimen to ensure an adequate analysis.

Due to the newborn infant's development, there are biological maturity issues with the laboratory markers used to test for disorders in the newborn screening panel. Thus, a blood sample taken prior to 24 hours after birth is considered unsatisfactory because some of the screening tests may be inaccurate and non-diagnostic.

The department did not receive any comments opposing this practice. This duty is placed on the responsible party because they have had the most recent contact with the newborn infant, and it is their responsibility to collect an adequate specimen the first time.

**4615.0550 F**. This proposed amendment requires the responsible party to collect or cause to be collected any repeat specimens requested by the department due to initial unsatisfactory specimens. This amendment is broader than proposed amendment 4615.0500 (E), which only addresses specimens taken prior to 24 hours after birth. "Unsatisfactory specimen" is defined in these rules under 4615.0400 subp. 9. This amendment codifies current practice. The department did not receive any comments opposing this practice. This duty is placed on the responsible party because they have had the most recent contact with the infant, and it is their responsibility to collect an adequate specimen the first time.

**4615.0550 G**. This proposed amendment requires the responsible party to "accurately complete all fields on the newborn screening card including demographic information and primary medical care provider information as provided by the parent."

An Advisory Committee member questioned the best way to fill out the demographic section of

the newborn screening card for infants who have been dropped off or abandoned at a hospital. The hospital has no information about the parent or where the infant will be in the coming days. The department recommended that the responsible party write down a specific person at the hospital as the contact. If an abnormal result is obtained, the department will call that specific individual.

During the Request for Comment period, one large hospital commented that obtaining the name of the primary medical care provider is not always easy, especially from their non-English speaking patients. Department staff met with representatives from this hospital and encouraged them to provide the name of the primary medical care clinic whenever possible. If that is not possible, the birthing hospital will provide a contact at their hospital. The hospital assured the department that a person would be available Monday through Saturday to assist the department if necessary.

**4615.0550 H**. This proposed amendment requires the responsible party to verify that newborn screening has been completed for every newborn infant born in their care or transferred to their care prior to discharge. This verification serves as an internal check for the responsible party to ensure that no baby is missed. Blood collection can take place at any time (night or day), and multiple staff members may be involved in the blood collection, card completion, and specimen transportation to the department. Because the process has many layers, responsible parties must verify that newborn screening has been completed for every newborn infant in their care or transferred to their care. This amendment ensures that no infant will be missed.

**4615.0550 I**. This proposed amendment requires the responsible party to record the date and time the specimen is collected on the newborn infant's medical chart. This amendment is a clarification to 4615.0500 C in the current rules. This clarification is necessary for two reasons. First, if there are any discrepancies or disputes about whether or when the specimen was collected, the information is available. Second, this information is important to ensure that the specimen was not collected too early, which can invalidate the results.

**4615.0550 J**. This proposed amendment requires the responsible party to send the completed specimen card with blood to the department so it arrives there by 4:30 p.m. the next business day from the time of collection via courier, overnight delivery, or other expedited service. Business day is defined in the definition section, 4615.0400 subp.2a. This amendment is similar to subpart 4615.0500 D in current rules that require the responsible party to "send the specimen card including all of the required information as indicated on the card to the Minnesota Department of Health laboratory within 24 hours after collection."

The first two changes are technical and clarify what materials the department needs to receive to ensure adequate screening and follow-up if necessary. The first change adds the word "completed" before specimen card and the second change adds the word "blood" after the phrase "specimen card with." See attachment G for a copy of the specimen card.

The third change replaces "within 24 hours after collection" to "by 4:30 pm the next business

day from the time of collection." The advisory committee requested that the department include a definition of business day to ensure there is no confusion on its meaning. The department added this definition to the rules based on the advisory committee discussion.[16] This short time period is necessary to ensure that the department receives and analyzes the specimen with a reasonable time period to begin any needed treatment in a timely manner.

The amendment also adds information on how the specimen should be delivered, "via courier, overnight delivery or other expedited service." Department staff informed Advisory Committee members that the department pays for UPS Next Day Air Service for all specimen submitters who choose to take advantage of this service.

**4615.0550 K**. This proposed amendment states that "if the newborn infant is transferred to a second health care facility before the specimen is collected, the responsible party shall inform the second facility of this fact and may delegate to it the responsibility for collecting and transmitting the specimen." It also requires the responsible party to document this in the newborn's infant's medical chart.

This requirement will ensure that all Minnesota newborns receive screening by putting into place a system that requires the responsible party to tell the transfer hospital that the newborn infant was not screened. This is the current practice in Minnesota. Requiring documentation in the medical record will prevent future disputes from arising.

**4615.0550 L**. This proposed amendment requires the responsible party to "alert the department's Newborn Screening Program and the infant's primary medical care provider as designated by the parent about any newborn infant who did not have a newborn screening specimen collected and sent to the department prior to discharge." This amendment ensures that the department is aware that the responsible party did not screen the newborn infant and delegated this responsible to another facility. It ensures that the department will follow-up if they do not receive a specimen on that infant. Advisory committee members requested that the phrase "as designated by the parent" be included after primary medical care provider to ensure that it is clear that parents are responsible for providing this information.

**4615.0550 M.** This amendment requires the responsible party to "forward a copy of the newborn screening results to the infant's primary medical care provider, as designated by the parent, within two weeks of receiving the results from the department." Even though this is standard medical practice for newborn screening, it does not always happen, and the primary care medical provider must spend time tracking down this information. This change will help ensure that the primary care provider receives the screening results and can verify that all infants in their practice have documented results. Advisory Committee members felt that this was a very important part of the rule changes. Several members told the department that when the rules are implemented, it will be important to educate all responsible parties about this duty.

[16] Business day is defined in Minn. Rules, Part 4615.0400, subp.

The amendment also specifies the time period ("within two weeks") within which they must send the results. To allow primary medical care providers to verify that newborn screening was completed for each infant in their practices in a timely manner, it is critical that the primary medical care provider receive the screening results as soon as possible. Advisory Committee members agreed upon a two weeks timeframe by balancing the primary care medical provider's need for the information with the burden on the responsible party.

There was a discussion among advisory committee members on the difficulties faced by birthing centers in identifying the infant's primary care provider in certain situations (e.g., if the parent has not yet identified the baby's primary care provider at the time of specimen collection). As a result, one advisory committee member suggested adding the phrase "as provided by the parent" after the word "designated" to emphasize that it is the parent's responsibility to provide the name of the primary medical care provider and that the responsible party can only get the information if the parent provides it. The department suggested that if the parent does not identify a primary care provider, the birthing center should write down the name of a person at the center who can be contacted if there is a positive screening result. The department will include this information in their implementation materials.

**4615.0550 N.** This proposed amendment requires the responsible party to facilitate the collection and transport of newborn screening specimens for infants whom the department identifies as having no submitted specimens on record. This amendment is necessary to follow-up on any infants whose specimens were not collected or were not submitted; the responsible party is required to make sure that each infant has a satisfactory specimen submitted for newborn screening. This change codifies current practice in Minnesota.

**4615.0600 DUTIES OF DEPARTMENT OF HEALTH.**

**4615.0600 A.** This proposed amendment is technical and clarifies the current process of developing and selling the specimen cards.

**4615.0600 B.** This proposed amendment is technical and replaces 4615.0600 B in the current rules. The change ensures that the rules will be consistent with changes made during the 2003 legislative session by replacing the list of disorders with a general reference to disorders listed in the newborn screening panel list as defined in Minn. Stat. §144.125, subd. 2. This is necessary to update the Rules to reflect 2003 statutory changes that replaced the list of diseases with a general reference to the newborn screening panel.

In addition, the term "cases" was replaced with the term "infant" to eliminate any confusion of which records must be kept.

**4615.0600 C**. This proposed change clarifies part 4615.0600 C in the current rules. The amendment requires the Department of Health to "notify the infant's primary medical care provider of positive screening results within a time period that will allow early diagnostic testing

and treatment, based on the disorder. MDH must notify by telephone and facsimile transmission, or by any other method that the commissioner determines is necessary to get the information to the provider within the time period."

The first change deletes the term "physician" and replaces it with the term "infant's primary medical care provider" to ensure that this part of the rules is consistent with the proposed change made in the Definition section, 4615.0400, Subpart 2, Attending physicians. See earlier discussion under Definitions.

The 24-hour time requirement was replaced with the phrase "within a time period that will allow early diagnostic testing and treatment based on the disorder." This change was made to give the department flexibility in providing results based on the clinical characteristics of the disorder and treatment needed. There are standard medical protocols for treatment of each disorder.

The means of notification were also changed based upon an advisory committee discussion. Both MDH staff and advisory committee members felt that telephone and facsimile transmission were more appropriate and practical than in writing by deposition of first class mail. The committee and MDH staff also felt that there may be times (especially in the future) when other means of notification may be more reasonable. MDH and advisory committee members felt it was appropriate to give the commissioner authority to use other methods if she determines it is necessary to get the information to the provider within the time period.

**4615.0600 D.** This proposed amendment requires the department to provide contact information on available diagnostic and treatment sources to primary medical care providers of infants with positive results. This will ensure that all primary medical care providers receive the most current and up-to-date information on the disorder and ensure consistent diagnostic and treatment sources across the state.

**4615.0600 E.** This proposed amendment requires the department to develop and make available forms for parents to decline newborn screening. This amendment was added as a result of the 2003 statutory changes in Minnesota Statutes, section 144.125 subp.3 (3)(i). Specifically, the statute says, "the objection or election shall be recorded on a form that is signed by a parent or legal guardian and made part of the infant's medical record." This change codifies current practice in Minnesota. As of 2003, the department has provided this form for parents to sign if they want to decline screening. This form is available to a responsible party via the department's website at http://www.health.state.mn.us/newbornscreening (See attachments E).

**4615.0600 F**. This proposed amendment requires the department to develop and make available forms a parent can use to indicate that that they want their infant's blood sample and test results destroyed after two years from the time of screening. This amendment was added as a result of the 2003 statutory changes in Minnesota Statutes, section 144.125 subp.3 (3)(ii). Specifically, the statute says, "the objection or election shall be recorded on a form that is signed by a parent or legal guardian and made part of the infant's medical record." This change codifies current practice in Minnesota. As of 2003, the department has provided this form for parents to sign if

they want to decline screening. This form is available to a responsible party via the department's website at http://www.health.state.mn.us/newbornscreening (See attachments F).

**4615.0600 G**. This proposed amendment requires the department to notify the responsible party when the department identifies infants as not having been screened by MDH. This codifies current practice. The responsible party is currently the party that collects the repeat specimen when necessary. This corresponds to proposed amendments 4615.0550 E and F.

**4615.0600 H**. This proposed amendment requires the department to track and use best efforts to obtain needed repeat testing for up to 60 days on all infants who require repeat testing. There are a number of reasons that MDH may require repeat testing. For example, the results may have been inconclusive because 1) the specimen was not drawn or handled correctly or 2) the specimen had mildly abnormal results that need to be checked again before the baby is referred to a specialist. The original draft required MDH to use reasonable efforts to obtain repeat specimens. The group suggested it would improve the rules if we used the term "best efforts." MDH revised the draft to reflect members' input.

## 4615.0700 DUTIES OF ~~ATTENDING PHYSICIAN~~ PRIMARY MEDICAL CARE PROVIDER.

Throughout this part, the term "attending physician" is replaced with the term "primary medical care provider" to ensure consistency throughout the rules. The reason for this change is discussed 4615.0400, subpart 2. Attending physicians and 4615.0400, Subpart 4a. Primary medical care provider.

**4615.0700, Subpart 1A**. This subpart has three proposed technical amendments. The first change replaces the phrase "instances of" with "infants with" to clarify what the primary medical care provider must report to the department.

The second change replaces the list of disorders with a general reference to disorders listed in the newborn screening panel list as defined in Minn. Stat. §144.125, subd. 2 to ensure that this part is consistent with changes made during the 2003 legislative session.

The third change deletes the department's address, which is no longer correct, with a general reference to the Newborn Screening Program at the Minnesota Department of Health. The department's newborn screening literature and website all contain the department's new address and phone number. The department and Advisory Committee members felt a specific address was unnecessary.

**4615.0700, Subpart 1B**. This proposed change requires the primary medical care provider to obtain and submit repeat specimens from infants in their care at the request of the department. Even though the responsible party is usually required to get a repeat specimen, there are times when it is more practical for the primary medical care provider to get the specimen. This is done

under current practice. The department does not request this often but needs the ability to be able to do it to ensure all Minnesota newborns are screened.

**4615.0700, Subpart 1C**. This proposed amendment requires the primary medical care provider to provide the parents of an infant with a positive newborn screen the results of the screening test and educational materials about the disorder for which the infant is positive as provided by the department. This change will ensure that parents of an infant with a positive screen receive the information they need to make decisions about their child's health. This amendment codifies current practice. This corresponds to proposed rule change part 4615.0600 (D) discussed earlier.

**4615.0700, Subpart 1D**. This proposed amendment requires the primary medical care provider to document in the medical record the complete results of newborn screening or the decision to waive screening on every infant admitted to their practice. Documenting this information in the infant's chart provides added protection to ensure that all infants in Minnesota are screened unless their parents opt-out of testing. Requiring documentation in the medical record will also prevent future disputes from arising.

During an advisory committee meeting, a member expressed the need for the department to facilitate obtaining newborn screening results for "border babies" if primary medical care providers are required to implement this part. A border baby is a child who may have been born in a state bordering Minnesota, such as Wisconsin, but sees a primary medical care provider in Minnesota. Department staff assured advisory committee members that the department would facilitate this on a case-by-case basis if the primary medical care provider is unable to obtain the screening results from a neighboring state.

Another advisory member expressed concern about current mechanisms for primary medical care providers to obtain newborn screening results for infants in their practices. For different reasons, the primary medical care provider does not always receive the screening results for an infant in their practice. There was discussion on the possibility of primary medical care providers having access to this data electronically. Department staff said that this technology is not available at this time. In the meantime, department staff encouraged primary medical care providers to call the department's newborn screening program directly for copies of the infant's results when the birthing facility fails to forward them. Proposed amendment 4615.0550 M will also help ensure that primary medical care providers receive screening results from responsible parties.

**4615.0700, Subpart 1E**. This proposed change requires the primary medical care provider to assist a parent with completion of the forms provided by the department in the event that a parent wants their infant's specimen and results destroyed. This change helps ensure that the 2003 legislative change to Minnesota Statutes, section 144.125 subd. 3, which allows a parent to request that their infant's blood sample and test results be destroyed, is put into practice. There is only a very small number of parents who want their child's specimen and results destroyed so this should not be too burdensome to any one primary medical care provider.

**4615.0700, Subpart 2**. This proposed amendment is technical and ensures this subpart is consistent with the rest of chapter 4615. It replaces the term "attending physician" with "primary medical care provider" throughout this subpart. The amendment also deletes the term "however" because it is unnecessary.

**4615.0700, Subpart 3**. This proposed amendment requires the primary medical care provider who sees an infant whose birth was not attended by one of the parties listed in parts 4615.0550, 4615.06000, or 4615.0700, to give parents of an infant written materials on newborn screening made available by the department's Newborn Screening Program or approved by the program. This new subpart will ensure that parents who gave birth to a child in a nontraditional setting are made aware of newborn screening so that they can have their child screened.

**PARTS 4615.0750 to 4615.0760.** Changes in parts 4615.0750 through 4615.0760 are all technical and ensure that these parts of the rules are consistent with the rest of the rules. The following is a brief description of each change.

**4615.0750. PURPOSE AND SCOPE.** There are three proposed technical amendments in this part. The first ensures that the rules are consistent with the 2003 statutory changes[17] that replaced the listing of metabolic disorders with a provision that allows the commissioner to determine which tests will be included in the newborn screening.

The second amendment deletes the phrase "have access to approved laboratory treatment control tests when available" because laboratory treatment control tests are no longer part of standard newborn screening practices.

The third amendment deletes unnecessary language.

**4615.0755 DEFINITIONS.** There are eight proposed amendments in this part.

**4615.0755, subpart 5. Patient**. This proposed amendment ensures that the rules are consistent with the 2003 statutory changes that replaced the listing of metabolic disorders with a provision that allows the commissioner to determine which tests will be included in the newborn screening.

**4615.0755, subpart 6. Physician**. (see "Repealer" section in Revisor's Rule.) This amendment repeals subp. 6, attending physician, in the current rules and replaces it with subp. 6a, term "primary medical care provider." This change is consistent with the change in 4615.0400 Subpart 2 and 2a.

[17] Minn. Stat. §144.125, subd. 2. Determination of tests to be administered. This statute gives the commissioner authority to determine what tests will included in the newborn screening panel for diagnostic testing of infants.

**4615.0755, subpart 6a. Primary medical care provider**. Primary medical care provider means the physician or clinic identified by the parent or guardian as the entity that will be providing the infant's medical care after the baby is discharged from the hospital or from the care of the birth attendant. See explanation above under discussion of "attending physician."

**4615.0755, subpart 8. Registry**. The fourth and fifth amendments are in subpart 8. The fourth amendment deletes unnecessary language. The fifth amendment deletes the specific listing of metabolic disorders for which an infant must be screened because they are inconsistent with the 2003 statutory changes in Minnesota Statutes, section 144.125.

**4615.0755, subparts 9, 10 and 11**. (See "Repealer" section of Revisor Rule.) The last three amendments in this part are technical and delete obsolete provisions. These provisions are obsolete because laboratory treatment control tests are no longer part of standard newborn screening practices.

**4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.**

**4615.0760, subpart 1. Treatment control test specimen kits**. (See "Repealer section of Revisor Rule.) This provision is deleted because these do not exist anymore.

**4615.0760, subpart 2. Reporting of test results**. (See "Repealer section of Revisor Rule.) This provision is deleted because the department is required to notify an infant's primary medical care provider pursuant to proposed Part 4615.0600 subpart B. In addition, parents do not submit specimens.

**4615.0760, subpart 3. Assistance in obtaining treatment**. The proposed amendments in this subpart ensure that this part is consistent with current practice and the 2003 statutory changes made to the newborn screening law. It also deletes unnecessary and obsolete language.

**4615.0760, subpart 4. Registry of cases**. The first proposed amendment replaces the term "cases" with the term "patients" to eliminate any confusion of which records must be kept. The second amendment deletes the specific listing of metabolic disorders for which an infant must be screened because they are inconsistent with the 2003 statutory changes in Minnesota Statutes, section 144.125. The third amendment deleted the word "metabolic" because it does not cover all the disorders.

The fourth amendment in subpart 4 (H) replaces the term "physician" with "primary medical care provider" to ensure this part is consistent with the rest of the rules.

**CONCLUSION**

Based on the foregoing, the proposed rules are both needed and reasonable.

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[Date] Dianne M. Mandernach, Commissioner
Minnesota Department of Health

## LIST OF ATTACHMENTS

| | |
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| Attachment A | List of Disorders |
| Attachment B | Newborn Screening Process and Procedures |
| Attachment C | Methods of Notifying and Persons Notified of Request for Comments |
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# ATTACHMENT A

## List of Newborn Screening Disorders

**Amino Acid Disorders**
Arginemia (ARG, Arginase deficiency)
Argininosuccinate acidemia (ASA)
Defects of biopterin cofactor biosynthesis (BIOPT-BS)
Defects of biopterin cofactor regeneration (BIOPT-REG)
Citrullinemia type I (CIT-I, argininosuccinate synthetase)
Citrullinemia type II (CIT-II, citrin deficiency)
Homocystinuria (HCY, cystathionine beta synthase)
Hyperphenylalaninemia (H-PHE)
Hypermethioninemia (MET, I/III deficiency)
Maple Syrup Urine Disease (MSUD, branched-chain ketoacid dehydrogenase)
Phenylketonuria
Tyrosinemia type I (TYR-1)
Tyrosinemia type II (TYR-II)
Tyrosinemia type III (TYR-III)

**Fatty Acid Oxidation Disorders**
Carnitine acylcarnitine translocase deficiency (CACT)
Carnitine uptake defect (CUD, carnitine transport defect)
Carnitine palmitoyltransferase deficiency I (CPT-1a)
Carnitine palmitoyltransferase deficiency II (CPT-II)
Dienoyl-CoA reductase deficiency (DE-RED)
Glutaric acidemia type II (GA-II)
Long-chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD)
Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)
Medium-chain ketoacyl-CoA thiolase deficiency (MCKAT)
Medium/Short chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (M/SCHAD)
Short-chain acyl-CoA dehydrogenase deficiency (SCAD)
Trifunctional protein deficiency (TFP)
Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)

**Organic Acid Disorders**
2-Methyl-3-hydroxybutyric aciduria (2M3HBA)
2-Methylbutyryl-CoA dehydrogenase deficiency (2MBG, SBCAD)
3-Hydroxy 3-methylglutaric aciduria (HMG, 3-Hydrox 3-methylglutaryl-CoA lyase)
3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)
3-Methylglutaconic aciduria (3MGA, Type I hydratase deficiency)
Beta ketothiolase (BKT, mitochondrial acetoacetyl-CoA thiolase, short-chain ketoacyl thiolase)
Glutaric acidemia type I (GA-1)
Isobutyryl-CoA dehydrogenase deficiency (IBG)

Isovaleric acidemia (IVA, Isovaleryl-CoA dehydrogenase deficiency)
Malonic acidemia (MAL, Malonyl-CoA decarboxylase)

Methylmalonic acidemia (CBL A,B; Vitamin B12 Disorders)
Methylmalonic acidemia (CBL C,D)
Methylmalonic acidemia (MUT, methylmalonyl-CoA mutase)
Multiple carboxylase deficiency (MCD, holocarboxylase synthetase)
Propionic acidemia (PROP, propionyl-CoA carboxylase)

**Endocrine Disorders**
Congenital adrenal hyperplasia (CAH)
Congenital hypothyroidism (CH)

**Hemoglobinopathies**
Sickle cell disease (HB S/S)
Sickle-C disease (HB S/C)
S-βeta thalassemia

**Others**
Biotinidase deficiency (BIO)
Classic galactosemia (GALT)
Galactose epimerase deficiency (GALE)
Galactokinase deficiency (GALK)
Cystic fibrosis
Hearing - Voluntary

# ATTACHMENT B

## Newborn Screening Processes and Procedures

### Overview

Newborn screening is an important, live-saving part of health maintenance for all infants. The Minnesota Department of Health (MDH) now screens for more than 53 disorders. In Minnesota, newborn screening is mandated by Minnesota Statutes 114.125-144.128. All infants must have newborn screening unless a parent objects in writing. Each state is different with respect to the disorder panel, whether parents have a choice to opt-out of screening, and the mechanics of the newborn screening program. The rules regarding newborn screening cover important areas that allow for appropriate collection and transport of newborn screening specimens, as well as follow-up of infants identified with abnormal newborn screening results.

### Opt-out

In 2003, Minnesota Statutes 144.125-144.128, "Tests of Infants for Heritable and Congenital Disorders," were updated. The revisions included a subdivision on the "Objection of parents to test" that provides parents with two options: 1) to decline to have newborn screening and 2) to elect to have newborn screening, but to require that all blood samples and records of test results be destroyed within 24 months of the testing. The statute reads that parents must object in writing. If parents do not object to newborn screening, the tests will be performed. MDH has developed two separate opt-out forms that are available on the internet: http://www.health.state.mn.us/divs/fh/mcshn/nbsopt.htm

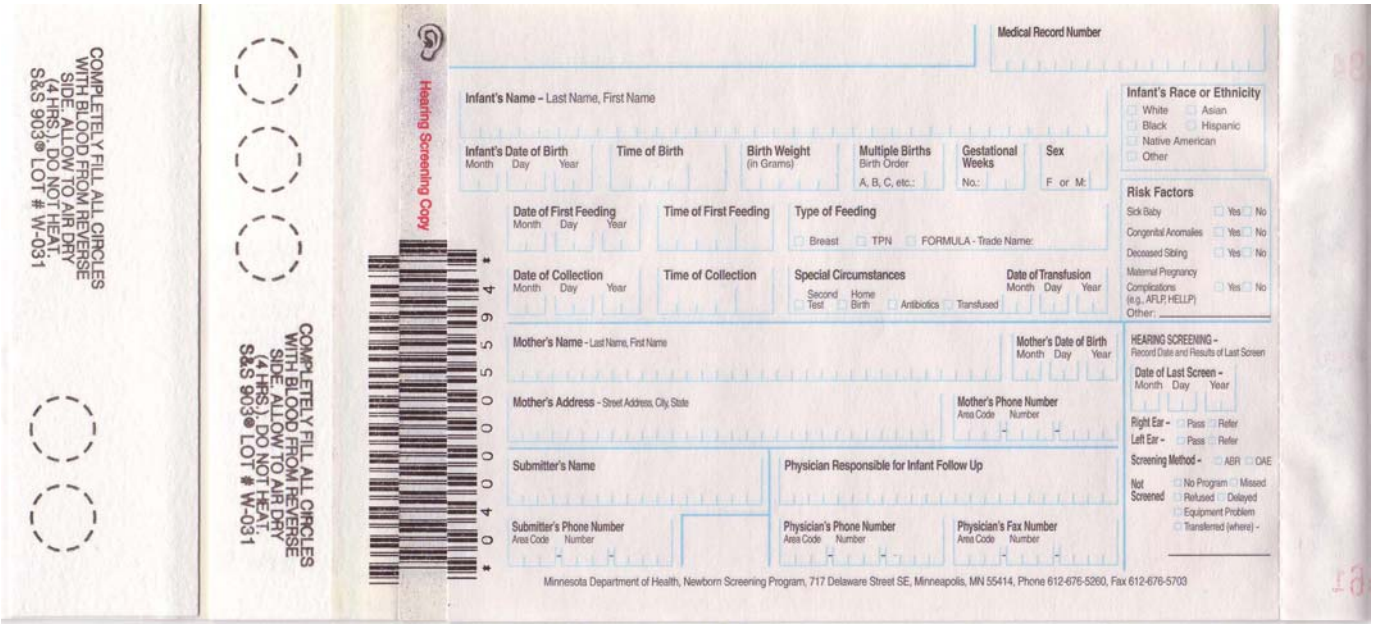
### Cost

Birthing Centers and providers that work with newborns, buy specimen cards from MDH for $61. This fee covers diagnostic testing for all 53 disorders in the newborn screening panel and necessary follow-up on positive screens and unsatisfactory specimens. This fee was increased from $21 to $61 during the 2003 legislative session to cover the cost of the increased number of tests conducted and the cost of transporting the specimens to MDH.

### At the hospital

Before a newborn infant is discharged from a birthing center, drops of blood are collected on a newborn screening specimen card that is available from MDH. If an infant is not born at a hospital, the birthing attendant is responsible for collecting the blood. In the rules, the birthing hospital—or birthing attendant in the case of a home-birth—is designated as the "responsible party." Responsible parties must have internal mechanisms to ensure that all infants in their care have a newborn screening specimen collected and sent to MDH. The blood collection should

take place 24-48 hours after birth. The newborn screening specimen card also has a demographic section that should be filled out completely (see below).




*Before* the blood is collected, the responsible party should inform parents about newborn screening and their parental options. One of the easiest ways for the responsible party to talk to parents about newborn screening is to use the parent brochure developed by the newborn screening program. The brochure is available on the internet: http://www.health.state.mn.us/divs/fh/mcshn/nbsbroc.htm

The newborn screening program is developing a new parent brochure that will be mailed one-for-one each time the responsible party orders newborn screening specimen cards.

If parents refuse newborn screening or choose to proceed with screening but to have the specimen and results destroyed, the parents must sign a waiver form.

**Sending the specimens to MDH**

In the 2003 legislative changes, MDH secured funding to pay for courier service to transport newborn screening specimens from birthing centers to MDH. Any submitter of newborn screening specimens can sign up for UPS Next Day Air Service to be paid for by the newborn screening program. This transport option helps ensure that specimens arrive at MDH as quickly as possible. The sooner results are available, the sooner affected babies can be treated.

**In the laboratory**

A portion of the specimen is couriered to the Mayo Clinic where tandem mass spectrometry (MS/MS) is performed to detect a number of metabolic disorders including amino acidemias,

organic acidemias, and fatty acid oxidation disorders. The remaining portion of the specimen is retained by MDH to conduct other tests for endocrine abnormalities, hemoglobinopathies, galactosemia, and biotinidase deficiency. MDH has established a unique public-private partnership with the Mayo Clinic. By acting as an agent of public health, the Mayo Biochemical Genetics Laboratory offers its MS/MS expertise to complement the existing newborn screening laboratory operations.

Screening is typically completed within two days from specimen receipt. Once screening is complete, the remaining blood spot specimen, the documentation of test results, and the baby's demographic information are securely stored indefinitely at MDH. MDH maintains a record of all newborn screening cases with confirmed diagnoses.

**Newborn screening results**

All newborn screening results are released together in an MDH report that is mailed to the responsible party who originally submitted the specimen. The responsible party should forward the results to the infant's primary medical care provider. By documenting that every infant in his/her practice has newborn screening results, the primary medical care provider helps ensure that infants are not missed.

Positive results

If a baby has a positive newborn screening result, MDH contacts the infant's primary medical care provider* by phone (in addition to mailing the baby's report back to the responsible party). This action makes more sense than contacting the birthing hospital since babies have usually been discharged by the time newborn screening results are available, and for many of the screened disorders, time is of the essence for locating the baby and beginning evaluation. MDH also contacts an appropriate medical specialist and connects the primary medical care provider with the specialist. MDH asks the primary medical care provider to contact the infant's family to initiate or coordinate follow-up evaluations in conjunction with the medical specialist. In addition to the infant's newborn screening results, MDH faxes the following to the primary medical care provider: disorder-specific fact sheets aimed at the provider and contact information for the relevant specialist. The primary medical care provider should provide MDH with the results of diagnostic evaluations of all infants in his/her care who have positive newborn screening results. The primary medical care provider can also ask the medical specialist to complete this task.

* Note in the demographic section of the newborn screening card, the responsible party is asked to write the name and phone number of the "physician responsible for infant

follow-up." For clarification purposes, this field is in the process of being changed to "physician responsible for infant follow-up *after discharge*."

Borderline results

If a baby has a borderline (mildly abnormal) newborn screening result, MDH contacts the infant's primary medical care provider (in addition to sending the baby's report back to the responsible party). MDH asks the primary medical care provider to collect and send a repeat newborn screening specimen from the baby.

Unsatisfactory specimens

If a baby's specimen is unsatisfactory for any reason, MDH contacts the responsible party who submitted the specimen. This practice helps instill accountability for collecting high quality specimens and also adheres to standard laboratory practice (specimen-submitting laboratories are responsible for the quality of their specimens).

**Adding tests to the newborn screening panel**

Based on nationally accepted criteria, the Minnesota Department of Health Newborn Screening Advisory Committee makes recommendations on disorder inclusion to the Commissioner of Health. The Newborn Screening Advisory Committee meets two times each year to talk about newborn screening issues. Members include parents of affected children, health care providers, hospital representatives, and other medical experts. The Commissioner has final approval for the addition of new disorders to the panel.

## ATTACHMENT C

## Request For Comments: Notification to Affected Parties

1. Mailed the Request for Comments to all persons who had registered to be on MDH's rule making mailing list under Minnesota Statutes, section 14.14, subdivision 1a.

2. Posted the proposed rules, the dual notice, the SONAR, and a fact sheet containing a summary of the substantive amendments on MDH's Newborn Screening Rulemaking website at www.health.state.mn.us/divs/phl/newborn/rulechange.html.

3. Provided a copy of the dual notice, the SONAR, the fact sheet containing a summary of the substantive amendments, and a web link to the proposed rules to members of the Advisory Committee, and also asked them to forward this information to the organizations they represent and their colleagues. The Advisory Committee was made up of a variety of health care professionals and organizations. (See Attachment D for list of members)

4. Provided a copy of the dual notice, the SONAR, the fact sheet containing a summary of the substantive amendments, and a web link to the proposed rules via e-mail, directly or through a listserve, to various individuals, groups and organizations. MDH also requested, when possible, that these organizations post the information on their website and send it out to their listserv. This list included, but was not limited to:

   - Health care providers who provide medical care to infants
     - Minnesota Medical Association
     - Minnesota Academy of Family Physicians
     - Minnesota Chapter of the American Academy of Pediatrics
     - Minnesota Council of Health Plans
     - Minnesota Hospital Association
     - Minnesota Nurses Association

   - Medical laboratories
     - MDH's Minnesota Laboratory System list. This list includes approximately 160 laboratories, including public health and private clinical laboratories, which serve Minnesota residents.

5. Published information on the Request for Comments in the Minnesota Department of Health's Weekly Briefing.

# Attachment D

## Newborn Screening Rules

### Advisory Committee Representation

1. Center for Bioethics, Dr. Dianne Bartels
2. Children's Hospital and Clinics, Mpls, Dr. Nina Perdue
3. Children's Hospital and Clinics, St. Paul, Dr. James McCord
4. Fairview University Medical Center, Ridges, Susan Shaft
5. Hennepin County Medical Center, Dana Brown
6. Hennepin County Medical Center, Dr. Richard Lussky
7. March of Dimes, Marianne Keuhn
8. Mayo Clinic, April Studinski
9. Minnesota Academy of Family Physicians, Dr. Louise Mattson
10. Minnesota Civil Liberties Union, Chuck Samuelson
11. Minnesota Council of Health Plans, Melinda Meher
12. Minnesota Hospital Association, Tania Daniels
13. Parent, Steven Johnson
14. Regions Hospital, Julie Thompson-Larson
15. Rice Memorial Hospital, Willmar, Wendy Ulferts
16. St. Mary's Medical Center, Kim Pearson
17. University of Minnesota & Minnesota Medical Association, Dr. Susan Berry

**Attachment E**

# Parental Refusal of Newborn Screening

Refusal of Newborn Screening
Minnesota Department of Health
Newborn Screening Program
Public Health Laboratory
Phone: (800)-664-7772
Revised 12/05

| | |
|---|---|
| Name of Infant | Hospital of Birth |
| Birth Date | Street Address |
| Parent's Full Name (Print) | City/State/Zip |

By signing below, you acknowledge:

I have received and read the Minnesota Department of Health's brochure concerning the newborn screening tests for metabolic, endocrine, and hemoglobin disorders.

I have been informed and I understand that these tests are required by Minnesota Statutes, section 144.125, for all infants born in Minnesota with the exception of infants whose parents choose not to participate in the Minnesota Department of Health Newborn Screening Program.

I have been informed and I understand that these tests are given to detect disorders that may not cause symptoms for several weeks or months.

I have had explained to me and I understand the risks involved if I decline to have my child screened.

I have been informed and I understand that if my child happens to have one of the conditions and the condition is not detected, delayed treatment of the disease may cause permanent damage to my child, including serious mental retardation, growth failure and, in some cases, death.

I have been informed and I understand that if my child were screened, I could request to have the blood sample and test results destroyed within 24 months after the testing.

I have been informed that more information on newborn screening is available at: www.health.state.mn.us/divs/fh/mcshn/nbs.htm

I have discussed the testing requirements with_____.
Hospital staff or witness

I do not want _____tested for these conditions by the Minnesota Newborn Screening Program.
Name of child

_____ ____/____/____ _____
Signature Date Witness

_____ _____
Relationship Witness (print name)

Original: Infant's Medical Record
Copies: Parent, Practitioner, and the Minnesota Department of Health

Minnesota Department of Health
Newborn Screening Program
P.O. Box 64899
St. Paul, MN 55164-0899
Phone: (800) 664-7772
Fax: (651) 201-5471
E-mail: newbornscreening@health.state.mn.us

**Attachment F**

# Request to Dispose of Newborn Screening Test Results and/or Blood Sample

Minnesota Department of Health
Newborn Screening Program
Public Health Laboratory
Phone: (800)-664-7772
Revised 12/05

Name of Child: _____ Date of birth: _____

_____

Hospital of Birth: _____

PARENTS: Please read the newborn screening policies below before signing this form.

Data privacy protections:
The Minnesota Department of Health classifies newborn screening information as private. This means that only those involved in the newborn screening program, the patient/parents/legal guardian(s) and the medical provider(s) caring for that child have access to the newborn screening information on an individual. Sharing individually identifiable information with anyone else requires the patient, parent or guardian to sign a consent allowing the release of such information.

The results of newborn screening are kept and stored securely by the Minnesota Department of Health Newborn Screening Program. This is necessary to provide a permanent record that the screening was completed, of the results of that screening, and of any outcomes that are relevant to the screening results.

Individuals who are screened and have abnormal results are followed up on by newborn screening staff. This is done to make sure that newborns with abnormal results receive appropriate diagnosis and treatment. This information is kept to help provide seamless, comprehensive care to children and their families.

Blood sample storage policy:

Blood samples and newborn screening information are securely stored by the Minnesota Department of Health Newborn Screening Program for an indefinite period of time.

Authorized uses of samples:
Portions of the blood sample may be used (without identifiers on them) within the Minnesota Department of Health Newborn Screening Program to assist in test development or quality control.

A portion of the blood sample may be used for research purposes outside of the Minnesota Department of Health. This only happens when the project is approved by the Minnesota Department of Health Institutional Review Board and all information identifying the individual has been removed from the sample.

The blood sample with identification cannot otherwise be released or tested outside the Minnesota Department of Health Newborn Screening Program without the written consent of the patient or legal designee.

The reasons for blood sample storage include:
1. Quality Assurance: If the Minnesota Department of Health Newborn Screening Program is notified about a child with one of the disorders detected by the panel, the initial blood sample is re-tested to make sure that the results originally reported were accurate.
2. To develop new tests: The Minnesota Department of Health Newborn Screening Program is continuously developing new tests for treatable conditions. Anonymous newborn blood spots are used to be sure that new tests are accurate and determine the ranges of “normal” values.
3. Use by parents/legal guardians: Some families have used stored blood samples to make a diagnosis after a child died. This helps families understand what happened, the chances of it happening again and options for dealing with those chances.

By signing below, you agree that:

Blood sample storage:
I have received and read the information about data practices and blood sample storage policies (described above) of the Newborn Screening Program of the Minnesota Department of Health.

I have been informed that saving the blood samples from the Minnesota Department of Health Newborn Screening Program serves many functions, including possible access to the blood sample for identification purposes; use in future diagnostic testing when no other blood sample is available, development of new tests and verification of the original results of newborn screening.

I have been informed that saving of the newborn screening blood sample and results is for the purpose of providing a permanent record of this testing.

I acknowledge that destroying this blood sample will make the blood sample unavailable for any future potential use for medical or identification purposes.

Screening results:
I acknowledge that destruction of the Minnesota Department of Health's copy of the newborn blood screening test results will make them unavailable from Minnesota Department of Health and that the only copies of these results will reside with me and my child's primary care provider.

I understand that the risks involved in destroying my child's newborn blood screening test results may include duplicative testing in the future and limited access to these results by clinicians.

I understand that the risks involved in destroying my child's newborn screening blood sample will result in loss of the blood sample for medical or identification purposes.

I request my child's newborn screening blood sample be destroyed immediately or within twenty-four months of testing, whichever is later.

I request my child's newborn blood screening test results stored at the Minnesota Department of Health's Newborn Screening Program be destroyed immediately or within twenty four months of testing, whichever is later.

Requestor's Signature: _____ Print Name: _____
_____

Relationship to Child: _____ Date: _____
_____

Address: _____ City: _____ Zip:__
_____

Phone: _____

Verification code:_____
(Enter a code that you will be asked to verify the request)

Request Verification:
1. Parent/guardian must have signature notarized, indicating that they have the legal authority to make the request
OR
2. Parent/guardian must present appropriate documentation of authority to enact request (i.e., copy of birth certificate) and photo ID to Public Health or medical personnel. This person must then sign as a witness:

I witness the signature of the above named person who possesses the legal authority to make this request and have verified the identity of the person through photo identification

Witness Name: _____

Witness Position: _____

Witness Phone: _____

Minnesota Department of Health
Newborn Screening Program
P.O. Box 64899
St. Paul, MN 55164-0899
Phone: (800) 664-7772
Fax: (651) 201-5471, E-mail: newbornscreening@health.state.mn.us

# Attachment G

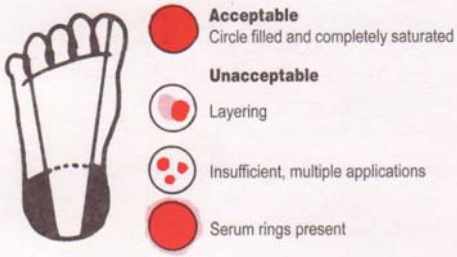
(140-0053)

MDH Newborn Screening Program
All information must be printed firmly with ballpoint pen

## BLOOD COLLECTION FOR HEELSTICK

1. Sterilize heel skin with rubbing alcohol, dry, and puncture with sterile lancet not longer than 2.0 mm.
2. Wipe away first drop of blood with gauze. Allow large drops to form and apply directly to filter paper. If bleeding is slow, hold limb in dependent position.
3. Completely fill all circles with blood to allow saturation through the paper. Filled circles should appear the same on both sides of the paper (see below).
4. Allow blood to dry at room temperature in a horizontal position for three or more hours.
5. Ship dry specimens immediately via courier or overnight delivery to:
   Minnesota Department of Health
   601 North Robert Street
   St. Paul, MN 55155-2531

DO NOT squeeze tissue to obtain blood.
DO NOT use devices that contain EDTA or capillary tubes.
DO NOT apply specimen to both sides of filter paper.
DO NOT expose card to heat, moisture, or direct sunlight.
DO NOT hold specimens to form batches. Send to the screening laboratory immediately!
DO NOT stack wet specimens.



**Acceptable**
Circle filled and completely saturated

**Unacceptable**

Layering

Insufficient, multiple applications

Serum rings present

## Newborn Hearing Screening

1. Follow the hearing screening directions and protocols at your facility.
2. Screen every newborn before discharge.
3. If the blood spot is obtained before hearing screening is complete, detach "Hearing Screening Copy" from the card. Do not delay submitting blood sample or "wait" for hearing results.
4. Before discharge, submit the hearing screening form with results to the Minnesota Department of Health Newborn Screening Program.
5. If a newborn is not screened or is transferred, check the appropriate box on the form, including where the baby was transferred (e.g. NICU or name of hospital).
6. Additional information on newborn hearing screening is available by calling (800) 664-7772 or go to www.health.state.mn.us/divs/fh/mch/unhs.

Medical Record Number
Infant's Name - Last Name, First Name
Infant's Date of Birth
Month Day Year
Time of Birth
Birth Weight
(in Grams)
Multiple Births
Birth Order
A, B, C, etc.:
Gestational Weeks
No.:
Sex
M or F:
Infant's Race or Ethnicity
White
Black
Native American
Other
Asian
Hispanic
Risk Factors
Sick Baby
Congenital Anomalies
Deceased Sibling
Maternal Pregnancy Complications (e.g., APLP, HELLP)
Other:
Yes No
Date of First Feeding
Month Day Year
Time of First Feeding
Type of Feeding
Breast
TPN
FORMULA - Trade Name:
Date of Collection
Month Day Year
Time of Collection
Special Circumstances
Second Test
Home Birth
Antibiotics
Transfused
Date of Transfusion
Month Day Year
HEARING SCREENING -
Record Date and Results of Last Screen
Date of Last Screen -
Month Day Year
Right Ear -
Left Ear -
Pass
Refer
Screening Method -
AABR
OAE
Not Screened
Missed
Refused
Delayed
Equipment Problem
Transferred (where) -
Mother's Name - Last Name, First Name
Mother's Date of Birth
Month Day Year
Mother's Address - Street Address, City, State
Mother's Phone Number
Area Code Number
Submitter's Name
Physician Responsible for Infant Follow-up after Discharge
Submitter's Phone Number
Area Code Number
Physician's Phone Number
Area Code Number
Physician's Fax Number
Area Code Number
Minnesota Department of Health, Newborn Screening Program, 601 Robert St. N., St. Paul, MN 55155-2531, Phone 800-664-7772
ALLOW A SUFFICIENT QUANTITY OF BLOOD TO SOAK THROUGH AND COMPLETELY FILL EACH CIRCLE. BLOOD SHOULD BE APPLIED ONLY TO ONE SIDE OF THE FILTER PAPER.
WHATMAN 903® LOT # W-041
ALLOW A SUFFICIENT QUANTITY OF BLOOD TO SOAK THROUGH AND COMPLETELY FILL EACH CIRCLE. BLOOD SHOULD BE APPLIED ONLY TO ONE SIDE OF THE FILTER PAPER.
WHATMAN 903® LOT # W-041