

**REVISED PROPOSED REGULATION OF THE
STATE BOARD OF HEALTH**

LCB File No. R088-20

July 13, 2021

EXPLANATION – Matter in *italics* is new; matter in brackets ~~omitted material~~ is material to be omitted.

AUTHORITY: §§ 1-8, NRS 439.200 and 442.008.

A REGULATION relating to health care; revising requirements concerning the screening of infants for preventable and inheritable disorders and the management of such disorders; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law requires the State Board of Health to adopt regulations governing examinations and tests required for the discovery of preventable or inheritable disorders in infants. Existing law requires those examinations and tests to include tests and examinations for each disorder for which screening is recommended by the Health Resources and Services Administration of the United States Department of Health and Human Services by not later than 4 years after the recommendation is published. To accomplish this testing, existing law requires any physician, midwife, nurse, obstetric center or hospital of any nature attending or assisting in any way any infant, or the mother of any infant, at childbirth to: (1) examine the infant to the extent required by regulations of the State Board of Health; and (2) collect and send to the State Public Health Laboratory any specimens needed for the examinations and tests that must be performed by a laboratory. (NRS 442.008) **Section 2** of this regulation adopts by reference the *Recommended Uniform Screening Panel* published by the Health Resources and Services Administration and a publication of the Clinical and Laboratory Standards Institute concerning the collection of blood samples from infants. **Section 3** of this regulation: (1) requires all blood samples taken from infants to be taken in accordance with that publication and sent to the State Public Health Laboratory; and (2) prescribes the information that must be provided to the State Public Health Laboratory with each blood sample. **Section 4** of this regulation makes a conforming change to indicate the placement of **sections 2 and 3** in the Nevada Administrative Code.

Existing regulations require a hospital or obstetric center at which an infant is born to take a blood sample from the infant at certain times and at certain stages of the infant’s life. (NAC 442.030, 442.040, 442.044) Existing regulations require that a blood sample be taken from an infant not later than the seventh day of the infant’s life and sent to the State Public Health Laboratory for screening. (NAC 442.030) **Section 5** of this regulation expands the requirement that an obstetric center or hospital take a blood sample from an infant not later than the seventh day of an infant’s life to also apply to any physician, midwife or nurse attending an infant or the

mother of an infant at childbirth. **Section 5** also requires such a physician, midwife, nurse, obstetric center or hospital to ensure the performance of testing, other than testing that must be performed in a laboratory, for each disorder for which screening is recommended by the Health Resources and Services Administration. If the testing reveals the existence of such a disorder, **section 5** requires the physician, midwife, nurse, obstetric center or hospital to ensure that the disorder is: (1) reported to the appropriate public health authorities; and (2) discussed with the parent or guardian of the infant. **Section 6** of this regulation revises the requirement in existing regulations that one blood sample be taken from an infant who receives care in a hospital for more than 15 consecutive days to instead require three blood samples to be taken from an infant who receives extended care in a hospital. If the infant requires a blood transfusion and the transfusion must be done before the first blood sample is taken, **section 6** requires a fourth sample to be taken 120 days after the transfusion instead of between the third and seventh day after the transfusion, as required under existing regulations. (NAC 442.044)

Section 7 of this regulation requires the State Public Health Laboratory, upon receiving the blood sample of an infant, to perform the laboratory tests necessary to detect each disorder for which screening is recommended by the Health Resources and Services Administration. If the testing reveals the existence of such a disorder, **section 7** requires: (1) the State Public Health Laboratory to report the result to the Nevada Newborn Screening Program at the University of Nevada, Reno, and the primary provider of health care for the infant; and (2) the Program, the provider of health care and the parent or guardian of the infant to take certain actions to manage the disorder.

Existing regulations impose certain requirements related to the taking of a blood sample from an infant born in a hospital. (NAC 442.050) **Section 8** of this regulation extends these requirements with respect to an infant born in an obstetric center.

Section 1. Chapter 442 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this regulation.

Sec. 2. 1. ***The Recommended Uniform Screening Panel published by the Health Resources and Services Administration of the United States Department of Health and Human Services is hereby adopted by reference. The publication is available, free of charge, at the Internet address <https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/>, or, if that Internet website ceases to exist, from the Division.***

2. ***Dried Blood Spot Specimen Collection for Newborn Screening, 7th Edition, published by the Clinical and Laboratory Standards Institute, is hereby adopted by reference. The publication is available for \$180 from the Clinical Laboratory Standards Institute at the Internet address <https://clsi.org/standards/products/newborn-screening/documents/nbs01>.***

3. If the publication adopted by reference in subsection 1 or 2 is revised, the Division will review the revision to determine its suitability for this State. If the Division determines that the revision is not suitable for this State, the Division will hold a public hearing to review its determination and give notice of that hearing within 90 days after the date of the publication of the revision. If, after the hearing, the Division does not revise its determination, the Division will give notice that the revision is not suitable for this State within 90 days after the hearing. If the Division does not give such notice, the revision becomes part of the publication adopted by reference in subsection 1 or 2, as applicable.

Sec. 3. *1. Any blood sample taken pursuant to NAC 442.030 to 442.044, inclusive, must be taken in the manner prescribed by the publication adopted by reference in subsection 2 of section 2 of this regulation.*

2. A physician, midwife, nurse, obstetric center or hospital that takes a blood sample from an infant pursuant to NAC 442.030 to 442.044, inclusive, shall ensure that:

(a) The blood sample is placed in a newborn screening test kit obtained from the State Public Health Laboratory and provided to the State Public Health Laboratory along with at least the following information concerning the childbirth:

- (1) The name and gender of the infant;*
- (2) The name, address and phone number of the mother;*
- (3) The gestational age of the infant at birth;*
- (4) The age of the infant at the time the sample was taken;*
- (5) The feeding history of the infant;*
- (6) A description of any antibiotics or hyperalimentation administered to the infant; and*
- (7) Any other information requested by the State Public Health Laboratory.*

(b) Payment for the laboratory testing required by subsection 1 of NAC 442.046 is submitted directly to the State Public Health Laboratory at the time of the testing or when the newborn screening test kit is obtained from the State Public Health Laboratory.

Sec. 4. NAC 442.020 is hereby amended to read as follows:

442.020 As used in NAC 442.020 to 442.050, inclusive ~~{ }~~, *and sections 2 and 3 of this regulation:*

1. “Hospital” means a medical facility as defined in NRS 449.0151.
2. “Obstetric center” has the meaning ascribed to it in NRS 449.0155.
3. “State Public Health Laboratory” means the State Public Health Laboratory maintained by the University of Nevada School of Medicine pursuant to NRS 439.240.

Sec. 5. NAC 442.030 is hereby amended to read as follows:

442.030 1. Except as otherwise provided in NAC 442.035, ~~{every hospital or obstetric center in which an infant is born must take a heel stick}~~ *any physician, midwife, nurse, obstetric center or hospital of any nature attending or assisting in any way any infant, or the mother of any infant, at childbirth shall ensure:*

(a) That a blood sample is taken from the infant ~~{before he or she is discharged from the hospital or obstetric center. The sample must be taken}~~ not later than the seventh day of the infant’s life regardless of the feeding status of the infant. If an infant is discharged *from a hospital or obstetric center* before he or she is 48 hours of age, the hospital or obstetric center must take a ~~{heel stick}~~ blood sample as close as possible to the time of the infant’s discharge from the hospital or obstetric center.

~~{2.—The sample must be placed in a newborn screening test kit obtained from the State Public Health Laboratory and must be mailed to the address indicated on the kit within 24 hours after the sample is taken.~~

~~—3.—If an infant is not born in a hospital or obstetric center, the person who is legally responsible for registering the birth of the child must have a physician, hospital, public health nurse or the State Public Health Laboratory take the first blood sample between the 3rd and 7th day and the second blood sample between the 15th and 56th day of the infant’s life.~~

~~—4.—As used in this section, “heel stick blood sample” means a small amount of blood obtained by means of a small puncture made to the heel of an infant.}~~

(b) The performance of any examinations and tests, other than tests that must be performed in a laboratory, necessary to detect the disorders described in the publication adopted by reference in subsection 1 of section 2 of this regulation.

2. If the examination and testing performed pursuant to paragraph (b) of subsection 1 reveals the existence of a disorder described in the publication adopted by reference in subsection 1 of section 2 of this regulation, the physician, midwife, nurse, obstetric center or hospital, as applicable, shall ensure that:

(a) The disorder is reported to the Chief Medical Officer or his or her designee, the local health officer of the jurisdiction in which the infant resides and the local health officer of the jurisdiction in which the infant was born; and

(b) The disorder and options for treatment of the disorder are discussed with the parent or guardian of the infant.

Sec. 6. NAC 442.044 is hereby amended to read as follows:

442.044 1. Each hospital in which an infant receives *extended* care ~~{for more than 15 consecutive days}~~ shall take ~~{a second}~~ :

(a) A first blood sample from the infant upon admission to that hospital and before any blood products are administered to the infant;

(b) A second blood sample not earlier than 48 hours but not later than 72 hours after the infant is admitted to that hospital; and

(c) A third blood sample 28 days after the infant is admitted to that hospital or, if the infant is discharged less than 28 days after the infant is admitted to that hospital, before the infant is discharged from that hospital.

2. ~~{A blood sample must be taken from any infant, regardless of age, who requires}~~ *If* an additive blood transfusion or a partial or complete exchange blood transfusion ~~{before the transfusion is begun. A second}~~ *is performed before a blood sample is drawn pursuant to paragraph (a) of subsection 1, a fourth* blood sample must be taken from the infant ~~{between the 3rd and 7th day,}~~ *120 days* after the transfusion is completed.

Sec. 7. NAC 442.046 is hereby amended to read as follows:

442.046 1. Upon ~~{notification by}~~ *receiving a blood sample pursuant to section 3 of this regulation*, the State Public Health Laboratory ~~{that a test is abnormal or questionable, the child's physician or the person who is legally responsible for registering the birth of the child}~~ shall ~~{cause to have taken an additional blood sample and any additional tests which are required to evaluate the possible abnormality and shall report that action to the State Public Health Laboratory.}~~ *perform the laboratory testing necessary to detect the disorders described in the publication adopted by reference in subsection 1 of section 2 of this regulation.*

2. *If the testing performed pursuant to subsection 1 reveals the existence of a disorder described in the publication adopted by reference in subsection 1 of section 2 of this regulation, the State Public Health Laboratory shall:*

(a) Report the positive test to the primary provider of health care for the infant, if any, and to the Nevada Newborn Screening Program at the University of Nevada, Reno, or its successor program. The employee of the Program who receives the report shall:

(1) Recommend any additional confirmatory or diagnostic testing determined by the employee to be necessary; and

(2) Collaborate with the primary provider of health care for the infant, if any, to manage the infant until the positive test is confirmed.

(b) Coordinate with the Nevada Newborn Screening Program at the University of Nevada, Reno, or its successor program, to ensure the performance of the testing recommended pursuant to subparagraph (1) of paragraph (a) and the timely management of the infant.

(c) If the infant has a primary provider of health care, recommend that the primary provider of health care for the infant:

(1) Notify the parent or guardian of the infant of the requirements of subsection 4 and any follow-up testing or other actions required to confirm the presumptive diagnosis and provide any necessary referrals, including, without limitation, referrals for genetic testing or genetic counseling when necessary; and

(2) Discuss the disorder and options for the treatment of the disorder with the parent or guardian of the infant.

3. *If the testing performed pursuant to subsection 1 reveals the existence of a disorder described in the publication adopted by reference in subsection 1 of section 2 of this regulation*

and the infant does not have a primary provider of health care, the Nevada Newborn Screening Program at the University of Nevada, Reno, or its successor program, shall perform the duties described in subparagraphs (1) and (2) of paragraph (c) of subsection 2.

4. The parent or guardian of an infant with ~~{an abnormal or questionable}~~ *a positive* test result *for a disorder described in the publication adopted by reference in subsection 1 of section 2 of this regulation* shall, upon notification *of the positive test result*, promptly take the child to a ~~{physician}~~ *provider of health care* who shall ensure that a quantitative evaluation of the problem indicated by the test result is performed.

~~{3. The person taking the blood sample shall:~~

~~—(a) Provide all available information including:~~

~~—(1) The name and gender of the infant and the name and address of the mother;~~

~~—(2) The feeding history of the infant;~~

~~—(3) The gestational age of the infant at birth;~~

~~—(4) The age of the infant at the time of testing;~~

~~—(5) The use of antibiotics or hyperalimentation; and~~

~~—(6) Any additional information the State Public Health Laboratory may require.~~

~~—(b) Obtain a sufficient blood sample to ensure adequate diagnostic testing on the infant.]~~

5. *As used in this section, “provider of health care” means a physician or physician assistant licensed pursuant to chapter 630 or 633 of NRS or an advanced practice registered nurse.*

Sec. 8. NAC 442.050 is hereby amended to read as follows:

442.050 1. ~~{The}~~ *If an infant is born in a hospital or obstetric center, the* nurse in charge or the person legally responsible for registering the birth of the child shall:

(a) Determine that a blood sample has been properly drawn ~~†~~ *and* executed *pursuant to NAC 442.030* and placed in a newborn screening test kit obtained ~~{pursuant to NAC 442.030}~~ *from the State Public Health Laboratory* before an infant is discharged from the hospital ~~†~~ *or obstetric center.*

(b) Ensure that the blood sample is mailed *to the State Public Health Laboratory* within 24 hours after it is drawn.

(c) Record on the infant's medical chart the fact that the sample was taken and the date it was taken.

(d) Ensure that the report required by NRS 442.040 is completed and signed by the parent or guardian.

2. A hospital or obstetric center shall complete a newborn screening collection form obtained from the State Public Health Laboratory if a blood sample is not taken from an infant before his or her discharge from the hospital or obstetric center, unless the infant is transferred to a hospital that provides a higher level of neonatal care. The hospital or obstetric center shall send the newborn screening collection form indicating that a blood sample was not taken from an infant to the State Public Health Laboratory within 2 working days after the infant is discharged from the hospital or obstetric center.