

**ADOPTED REGULATION OF THE
STATE BOARD OF HEALTH**

LCB File No. R033-16

Effective November 2, 2016

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

AUTHORITY: §1, NRS 440.120; §§2-5, NRS 442.008; §6, NRS 439.150 and 440.120.

A REGULATION relating to infants; revising provisions relating to the taking and testing of certain blood samples from infants; repealing provisions relating to certain fees for registering the birth of a child; 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 in infants of preventable or inheritable disorders. If the examination and tests reveal the existence of a preventable or inheritable disorder, a report must be sent to certain state and local health officers, and the parents of the infant must be notified and informed of the treatment necessary for the amelioration of the condition. An infant is exempt from such examinations and tests if either parent files a written objection with the appropriate person or institution. (NRS 442.008) Existing regulations require the taking of two blood samples from each infant born in this State within the first few weeks of life. Each blood sample must be sent for screening in a kit supplied by the Division of Public and Behavioral Health of the Department of Health and Human Services. (NAC 442.030-442.040) A form must be submitted to the Division if a required blood sample is not taken from an infant. (NAC 442.050) Upon notification by the Division that a test is abnormal or questionable, an additional blood sample must be taken, and the parent or guardian of the infant must, upon notification, take the child to a physician for a quantitative evaluation of the problem indicated by the test result. (NAC 442.046)

Sections 3-5 of this regulation transfer the obligations for providing screening kits, receiving forms indicating a blood sample was not taken and making appropriate notifications of an abnormal or questionable test from the Division to the State Public Health Laboratory, which is maintained by the University of Nevada School of Medicine. **Section 3** also specifies that the required blood sample must be obtained by means of a heel stick if the blood sample is obtained by a hospital or obstetric center.

Existing regulations require each person who is legally responsible for registering the birth of a child to submit a fee to the Division. (NAC 440.210) **Section 6** of this regulation repeals this provision.

Section 1. NAC 440.020 is hereby amended to read as follows:

440.020 If any provision of NAC 440.010 to ~~440.210,~~ **440.190**, inclusive, is declared unconstitutional or invalid for any reason, the remainder of those provisions are not affected thereby.

Sec. 2. NAC 442.020 is hereby amended to read as follows:

442.020 As used in NAC 442.020 to 442.050, inclusive:

1. ~~“Division” means the Division of Public and Behavioral Health of the Department of Health and Human Services.~~

~~—2.~~ “Hospital” means a medical facility as defined in NRS 449.0151.

~~3.~~ 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. 3. 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 ~~an appropriate~~ ***a heel stick*** blood sample 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 before he or she is 48 hours of age, the hospital or obstetric center must take ~~an appropriate~~ ***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 ~~supplied by~~ ***obtained from*** the ~~Division~~ ***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.

Sec. 4. NAC 442.046 is hereby amended to read as follows:

442.046 1. Upon notification by the ~~{Division}~~ *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 ~~{Division}~~ *State Public Health Laboratory*.

2. The parent or guardian of an infant with an abnormal or questionable test result shall upon notification promptly take the child to a physician 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 ~~{Division}~~ *State Public Health Laboratory* may require.

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

Sec. 5. NAC 442.050 is hereby amended to read as follows:

442.050 1. 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 *and placed in a newborn screening test kit obtained pursuant to NAC 442.030* before an infant is discharged from the hospital.

(b) Ensure that the blood sample is mailed 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 ~~{form for the test}~~ *report* required by NRS 442.040 is completed and signed by the parent or guardian.

2. A hospital or obstetric center shall ~~{report to the Division}~~ *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 report must be submitted on the form provided by the Division entitled "Report of Newborn Blood Sample Not Obtained."}~~ The hospital or obstetric center shall send ~~{a copy of}~~ the *newborn screening collection* form *indicating that a blood sample was not taken from an infant* to the ~~{Division}~~ *State Public Health Laboratory* within 2 working days after ~~{its completion.}~~ *the infant is discharged from the hospital or obstetric center.*

Sec. 6. NAC 440.210 is hereby repealed.

TEXT OF REPEALED SECTION

440.210 Registration of birth: Submission of fee to Division of Public and Behavioral Health. (NRS 439.150, 440.120) Each person who is legally responsible for registering the birth of a child shall submit a fee to the Division of Public and Behavioral Health of the Department of Health and Human Services for each birth as follows:

1. If paid on or before the 30th day after the date of the birth of the child, the fee is \$81.
2. If paid more than 30 days after the date of the birth of the child, the fee is \$83.

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
September 14, 2016
LCB File No. R033-16
Information Statement per NRS 233B.066

(a) A clear and concise explanation of the need for the adopted regulation.

The purpose of the proposed amendments to NAC 442.020 through 442.050, inclusive, and the repeal of NAC 440.210, is to revise authority in the Nevada Administrative Code for the testing and processing of Newborn Screening for preventable and inheritable disorders to be administered by the State Public Health Laboratory maintained by the University of Nevada, School of Medicine. These services were provided by an out of state entity through a contract with the Nevada Division of Public and Behavioral Health and have since been awarded to the Nevada State Public Health Laboratory.

(b) A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary.

On March 31, 2016, a Small Business Impact Questionnaire, along with a copy of the proposed regulation changes, was sent to birthing hospitals and midwives, statewide.

On May 16, 2016, a Public Workshop on LCB File No. R033-16 was held in Carson City and Las Vegas via videoconference. At this public workshop a total of five people attended and no public comment was provided.

No opposition was received through the small business impact questionnaire, separate email correspondence, or with location and teleconference of the public workshop.

The agency has concluded there is little or no impact of the repeal of regulation NAC 440.210 and the amendment of NAC 442.020 through 442.050, inclusive, on small businesses as the response from the Small Business Impact Questionnaire did not offer any specific evidence to the perceived impact on the business model. The fees charged by the Public Health Laboratory to the hospitals and birthing centers can be applied as maternity fees in the billing structure.

A summary of the hearing for amendment of Nevada Administrative Code (NAC) 442, LCB File #R033-16 can be obtained by contacting the State Board of Health, through the Division of Public and Behavioral Health, 4150 Technology Way, Suite 300, Carson City, Nevada 89706, phone: (775) 684-4200, fax: (775) 684-4211.

(c) The number of persons who:

(1) Attended the hearing: 5

(2) Testified at the hearing: no testimony was provided to supplement the staff presentation at the public workshop.

(3) Submitted to the agency written statements. No additional written statements were submitted at the public workshop.

(d) For each person identified in subparagraphs (2) and (3) of item (c), the following information if provided to the agency conducting the hearing: Not applicable as no additional written statements or testimony were presented at the public workshop.

(e) A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

Pursuant to NRS 233B.0608 (2) (a), the Division of Public and Behavioral Health requested input from newborn screening birthing partners in Nevada. Input was requested from small businesses (midwives who assist in the delivery of babies) and Nevada birthing hospitals in order to provide them with courtesy notification of a fee adjustment.

On March 31, 2016, a Small Business Impact Questionnaire, along with a copy of the proposed regulation changes, was sent to birthing hospitals and midwives statewide. The Small Business Impact Questionnaire was sent out to newborn screening partners throughout Nevada. These stakeholders included birthing hospitals and facilities, the Nevada Hospital Association and midwives who assist in the delivery of babies. Out of the ten responses received, seven respondents had no comment to any adverse or beneficial impact. One comment received indicated *not applicable* to any adverse or beneficial impact *due to over 1500 employees*. Another respondent specified *servicing low income populations, some patients may not have it done*. Another respondent pointed out the services *are not for profit* without any response to adverse or beneficial impact. No opposition was received through the small business impact questionnaire, separate email correspondence, or at either location, Carson City or Las Vegas, when the public workshop was held.

Summary of Response: Small Business Impact Questionnaires Responses

10 responses (3 from midwives, 7 from hospitals) were received out of 101 SBI questionnaires distributed

How many employees are currently employed by your business?	Will a specific regulation have an adverse economic effect upon your business?	Will the regulation (s) have any beneficial effect upon your business?	Do you anticipate any indirect adverse effects upon your business?	Do you anticipate any indirect beneficial effects upon your business?	Comments
>1200	No Response	No Response	No Response	No Response	None
180	No Response	No Response	No Response	No Response	None
1,516	No Response	No Response	No Response	No Response	<i>Adverse Economic Effect - "Not applicable, over 1500"</i>

					employees." <i>Beneficial Effect</i> - "Not Applicable, over 1500 employees" <i>Indirect Adverse Effect</i> -“Not applicable, over 1500 employees” <i>Indirect Beneficial Effect</i> - ”Not applicable, under 1500 employees”
200	No Response	No Response	No Response	No Response	None
1	Yes	No	No	No	<i>Adverse Economic Effect</i> - "I serve a low income population and would have to pass this cost on to the patient. I worry some patients would opt not to have testing if they had to pay for test."
Unknown	No	No	No	No	"We are not for profit."
6,000+	No Response	No Response	No Response	No Response	None
Unknown	No	No	No	No	None
0	No Response	No Response	No Response	No Response	None
885	No Response	No Response	No Response	No Response	None

(f) If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change.

No modifications to the proposed regulations have been made as a result of (1) no input and (2) no economic impact.

(g) The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:

- *Beneficial effects*: These regulations have been designed with minimal standards to ensure facilities are not over-regulated, the regulations focus mainly on health and safety

concerns of the residents, and, while a dollar amount cannot be assigned, economic benefit is anticipated

- *Adverse effects*: The fees established by these regulations were determined based on the anticipated cost of implementation; however, the fees may require adjustment when actual costs are calculated
- *Immediate effects*: In-state services will be provided, rather than out of state services.
- *Long term effects*: There is an anticipated beneficial economic effect based on the cost of providing in-state, rather than out-of-state services.

(h) The estimated cost to the agency for enforcement of the proposed regulation.

There is no additional estimated cost to the agency for enforcement of the proposed regulation as the State Public Health Laboratory has established fees for Newborn Screening Kits that are currently being applied to all hospitals and obstetric birthing centers in Nevada.

(i) A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulatory federal agency.

The proposed regulation does not overlap or duplicate any regulation of other state or local governmental entities

(j) If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

The Division is not aware of any provisions that are more stringent than a federal regulation which regulates the same activity.

(k) If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

The proposed regulation does not include a new fee nor an increase in the existing fee.