Steve Sisolak
Governor

Richard Whitley, MS
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

Helping people. It's who we are and what we do.

Lisa Sherych
Administrator

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN the Division of Public and Behavioral Health will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 442 (LCB File Number R088-20RP1).

The workshop will be conducted via videoconference beginning at 8:00 AM on January 11, 2022, at the following locations:

Via Teams: Click here to join the meeting

Join by phone
+1 775-321-6111 US Toll
Access code: 60244279#
One touch call: +1 775-321-6111,,60244279#

The workshop will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

1. Introduction of workshop process
2. Public comment on proposed amendments to Nevada Administrative Code 442 (LCB File Number R088-20RP1)
3. Public Comment

The proposed changes will revise Chapter 442 of the Nevada Administrative Code (LCB File Number R088-20RP1) and are being proposed in accordance with NRS 439.200 and 441A.420.

The proposed regulations provide provisions for the following:

- Details processes by which the State Public Health Laboratory (SPHL) can request information and payment related to laboratory and non-laboratory tests and examinations
- Specifies how the SPHL and primary care physicians will share relevant information and examination and testing results and ensure proper referral and care for infants suspected of or diagnosed with specific preventable or inherited conditions
- Details specific blood sample processes and standardized criteria by amending Nevada Administrative Code 442.044
- Creates a means by which the SPHL can detail a public process by which fees can be changed, includes examinations and non-laboratory tests related to newborn screening needed as part of diagnostic screening for all required conditions, and

- Establishes clear processes for parental or guardian information sharing and referral and care transition from SPHL and health care providers and for information sharing to the Department of Health and Human Services Chief Medical Officer and local health officers

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Vickie Ives, Deputy Bureau Chief, Child, Family and Community Wellness, at the following address:

4150 Technology Way, Suite 210
Carson City, NV 89706
vives@health.nv.gov

Members of the public who require special accommodations or assistance at the workshop are required to notify Vickie Ives in writing by sending the correspondence to the Division of Public and Behavioral Health, 4150 Technology Way, Suite 210, Carson City, NV 89706, or by calling (775) 220-4109 at least five (5) working days prior to the date of the public workshop.

You may also contact Vickie Ives by calling (775) 220-4109 for further information on the proposed regulations or how to obtain copies of the supporting documents. A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

List of offices where the proposed regulation will be on file for inspection:

Division of Public and Behavioral Health
4150 Technology Way, Suite 210
Carson City, NV 89706

A copy of the regulations and small business impact statement can be found on the Division of Public and Behavioral Health website: https://dpbh.nv.gov/Programs/Maternal,_Child_and_Adolescent_Health_(MCH)/

A copy of the public workshop notice can also be found at Nevada Legislature's website: https://www.leg.state.nv.us/App/Notice/A/

A copy of the public workshop notice can also be found at https://notice.nv.gov

A copy of this notice has been posted at the following location: Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City

Copies may be obtained by mail, or by calling the Division of Public and Behavioral Health at (775) 684-1030 in Carson City or (702) 486-6515 in Las Vegas.

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

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Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

MEMORANDUM

DATE: January 23, 2022

TO: Jon Pennell, DVM, Chairperson, State Board of Health

FROM: Lisa Sherych, Administrator, Division of Public and Behavioral Health

RE: Public Hearing on Legislative Counsel Bureau (LCB) File No. R088-20RP1 Newborn Screening and LCB File No. R086-20P Diapering Proposed Draft Regulation

In accordance with Nevada Administrative Rulemaking law, it is the responsibility of the State Board of Health (BOH) to review proposed draft regulations.

This memorandum is a request to the State Board of Health for Public Hearing on two (2) Proposed draft regulations, LCB File Numbers R088-20RP1 and R086-20P. Attached please find draft regulations, small business impact statements, small business impact summaries for each. In addition, supporting materials for R088-20RP1 are included to demonstrate current options for refusal of the newborn screening blood spot test via a form in response to public comment from the Public Workshop for R088-20RP1 held on January 11, 2022.

LCB File Number R086-20P proposed changes would revise Chapter 422A of the Nevada Administrative Code (NAC) and detail the processes by which the Division of Public and Behavioral Health (DPBH) Administrator or their designee will approve and administer grants made pursuant to Nevada Revised Statutes (NRS) 422A.660 from the Diapering Resources Account of the DPBH.

LCB File Number R088-20RP1 proposed changes would revise NAC Chapter 442 and detail processes by which the State Public Health Laboratory (SPHL) can request information and payment related to laboratory and non-laboratory tests and examinations and specific blood sample processes and standardized criteria, specify how the SPHL and primary care physicians will share relevant information and examination and testing results and ensure proper referral and care for infants suspected of or diagnosed with specific conditions, create a means by which the SPHL can detail a public process which includes examinations and non-laboratory tests related to newborn screening needed as part of diagnostic screening for all required conditions, and establish clear processes for parental or guardian information sharing and referral and care transition from SPHL and health care providers and for information sharing to the Department of Health and Human Services Chief Medical Officer and local health officers.

Concerns were voiced during the workshop from home birthing persons, a midwife based out of state but practicing in Nevada, and groups concerned with a perceived mandatory aspect to participating in newborn screening. Specific areas of concern mentioned focused on the process of newborn screening as opposed to the specific changes in the

regulations. Some callers believed that home births were not covered under existing law; however, Nevada midwives are required to report currently as are hospitals and obstetric centers.

Concerns voiced included the following topics: indefinite retention of blood spot cards; possible genetic use and selling of infant blood spot data; the need for codified opt out language; having to perform and pay for the blood spot screening fee with a home birth; the need for the informed consent information and the opt out form to be paired with the collection kit but also available so parents do not have to pay for the kit to get the refusal form; opting out making a person feel judged in a hospital setting; the need for free blood spot screening and only one screen as opposed to the two required in Nevada; questioning the utility of amino acid screening; concerns about relying on federally determined Recommended Universal Screening Panel conditions and local ability to add conditions; and, a request for more public and provider education about the refusal form and the Newborn Screening Program's booklet.

The ability and process by which to opt out of newborn screening are codified in NRS and NAC, respectively, and are highlighted in yellow, below.

NRS 442.008 Examination of infants: Regulations; performance of tests by State Public Health Laboratory; duties of physician, midwife, nurse, obstetric center or hospital; exemption. [Effective January 1, 2020.]

1. The State Board of Health shall adopt regulations governing examinations and tests required for the discovery in infants of preventable or inheritable disorders, including tests for the presence of sickle cell disease and its variants and sickle cell trait.

2. Except as otherwise provided in this subsection, the examinations and tests required pursuant to subsection 1 must include tests and examinations for each disorder recommended to be screened 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. The State Board may exclude any such disorder upon request of the Chief Medical Officer or the person in charge of the State Public Health Laboratory based on:

(a) Insufficient funding to conduct testing for the disorder; or

(b) Insufficient resources to address the results of the examination and test.

3. Any examination or test required by the regulations adopted pursuant to subsection 1 which must be performed by a laboratory must be sent to the State Public Health Laboratory. If the State Public Health Laboratory increases the amount charged for performing such an examination or test pursuant to NRS 439.240, the Division shall hold a public hearing during which the State Public Health Laboratory shall provide to the Division a written and verbal fiscal analysis of the reasons for the increased charges.

4. Except as otherwise provided in subsection 7, the regulations adopted pursuant to subsection 1 concerning tests for the presence of sickle cell disease and its variants and sickle cell trait must require the screening for sickle cell disease and its variants and sickle cell trait of:

(a) Each newborn child who is susceptible to sickle cell disease and its variants and sickle cell trait as determined by regulations of the State Board of Health; and

(b) Each biological parent of a child who wishes to undergo such screening.

5. 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:

(a) Make or cause to be made an examination of the infant, including standard tests that do not require laboratory services, to the extent required by regulations of the State Board of Health as is necessary for the discovery of conditions indicating such preventable or inheritable disorders.

(b) Collect and send to the State Public Health Laboratory or cause to be collected and sent to the State Public Health Laboratory any specimens needed for the examinations and tests that must be performed by a laboratory and are required by the regulations adopted pursuant to subsection 1.

6. If the examination and tests reveal the existence of such conditions in an infant, the physician, midwife, nurse, obstetric center or hospital attending or assisting at the birth of the infant shall immediately:

(a) Report the condition to the Chief Medical Officer or the representative of the Chief Medical Officer, the local health officer of the county or city within which the infant or the mother of the infant resides, and the local health officer of the county or city in which the child is born; and

(b) Discuss the condition with the parent, parents or other persons responsible for the care of the infant and inform them of the treatment necessary for the amelioration of the condition.

7. An infant is exempt from examination and testing if either parent files a written objection with the person or institution responsible for making the examination or tests.

8. As used in this section, "sickle cell disease and its variants" has the meaning ascribed to it in NRS 439.4927.

(Added to NRS by 1967, 208; A 1977, 114, 960; 1989, 1893; 1999, 1062, 3511; 2011, 461; 2019, 812, 2161, effective January 1, 2020)

NAC 442.050 Duties of nurse in charge or person legally responsible for registering birth of child; completion of newborn screening collection form required when blood sample not taken. (NRS 442.008)

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, 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 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.

[Bd. of Health, Metabolic Error Screening of Newborns Reg. §§ 4.1 & 4.2, eff. 12-27-77] — (NAC A 10-23-87; 10-10-90; R033-16, 11-2-2016)

The University of Nevada, Reno, Nevada State Public Health Lab (NSPHL) has parent resources on informed consent posted online at https://med.unr.edu/nsphl/newborn-screening/parents/informed-consent.

They also have posted parent facing materials online at https://med.unr.edu/nsphl/newborn-screening/parents/dos-donts-parents, https://med.unr.edu/nsphl/newborn-screening/parents/premature-and-sick-infants, and https://med.unr.edu/nsphl/newborn-screening/faq.

A copy of the parent refusal form in English and Spanish is included as part of the packet of materials associated with R088-20RP1. There is no mention of selling of genetic materials in existing or proposed NAC language related to Newborn Screening or codified in NRS.

The Health Resources and Services Administration's Recommended Uniform Screening Panel being adopted by proposed regulation provides guidance, but it recognizes the authority of the state to determine the needs of Nevada's children and there is a pathway by which individuals can suggest additions to the panel to be considered (https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/nominate.html).

The Board of Health (BOH) retains the authority to make changes to the regulations or to grant variances for any hardship or change per NRS 439.200. Therefore, the regulations do not need a specific "opt out" provision as there is already a path by which to seek a variance from the requirements and/or simply opt out using the parent refusal form.

The proposed regulations and the associated Public Workshop highlighted the importance of sharing information to families to empower them to make the best decisions for their child by providing information and education. Continued discussion on the need for education and about form elements going forward were highlighted as opportunities which

could take place outside of codification in regulation. The onus of ensuring testing occurs is on 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 ensure that a blood sample is taken from the infant (Section 5 of revised proposed draft regulation R088-20RP1), unless subsection 7 of NRS 442.008 is exercised.

Dissemination of the blood spot refusal form and informed consent and parent information posted on the NSPHL website to those who were part of Small Business Impact Statement and Summary outreach was completed along with the posting and dissemination of the Notice of Public Hearing document.

Thank you for your consideration.

PRESENTER

Vickie Ives, MA, Deputy Bureau Chief, Bureau of Child, Family and Community Wellness

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.

NOTICE OF PUBLIC HEARING

Intent to Adopt Regulations
(LCB File No. R088-20RP1)

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider amendments to Chapter 442 of Nevada Administrative Code (NAC). This public hearing is to be held in conjunction with the State Board of Health meeting on March 4, 2022.

The State Board of Health will be conducted virtually beginning at 9:00 AM on March 4, 2022, at the following locations:

Join Zoom Meeting

https://zoom.us/j/92537552135?pwd=aEQzR3BCMGJXL1Z6UnJkU21EcWVpdz09

Meeting ID: 925 3755 2135

Passcode: 818303

Dial by your location

+1 669 900 9128 US (San Jose)

833 548 0276 US Toll-free

Meeting ID: 925 3755 2135

Passcode: 818303

Find your local number: https://zoom.us/u/aciOVuG6ex

The proposed changes to NAC Chapter 442 include the following:

- Details processes by which the State Public Health Laboratory (SPHL) can request information and payment related to laboratory and non-laboratory tests and examinations
- Specifies how the SPHL and primary care physicians will share relevant information and examination and testing results and ensure proper referral and care for infants suspected of or diagnosed with specific preventable or inherited conditions
- Details specific blood sample processes and standardized criteria by amending NAC 442.044

- Creates a means by which the SPHL can detail a public process by which fees can be changed, includes examinations and non-laboratory tests related to newborn screening needed as part of diagnostic screening for all required conditions, and
- Establishes clear processes for parental or guardian information sharing and referral and care transition from SPHL and health care providers and for information sharing to the Department of Health and Human Services Chief Medical Officer and local health officers.

1. Anticipated effects on the business which NAC 442 regulates:
   A. *Adverse effects:* Adverse effects to businesses in the State of Nevada include the pathway the regulation develops to create a public hearing process for fee increases which could result in a higher fee and introduces a means to require payment either at the time of newborn screening kit purchase or at the time of testing.

   B. *Beneficial:* Beneficial effect to businesses in the State of Nevada include the creation of a transparent process with public hearing for increases to the SPHL fee for newborn screening and for discussion of any additions to the newborn screening conditions.
   C. *Immediate:* As soon as the proposed regulation becomes effective it would allow for a public hearing process for fee increases and newborn screening condition additions available to businesses in the State of Nevada.
   D. *Long-term:* Long-term beneficial effects to businesses in the State of Nevada include a public hearing process for fee increases and newborn screening condition additions to newborn screening.

2. Anticipated effects on the public:
   A. *Adverse:* Adverse effects to the public in the State of Nevada include information provided to require parent or guardian follow up in relation to positive test results or diagnosis for health care providers which might increase the length and possible cost of a visit. Sharing of primary care physician recommendations for parental genetic testing might lead to a charge which may or may not be covered by parental insurance.
   B. *Beneficial:* Beneficial effects to the public in the State of Nevada include allowing for a public process by which additions to the newborn screening panel could be made which is of benefit for families and advocates in the public of the State of Nevada for specific diseases on the Recommended Universal Screening Panel. Information required to be shared in the regulation with parents and guardians and required follow up referrals and examinations benefit the public in the State of Nevada by improving medical outcome of diagnosed infants and linking them to appropriate treatment in a timely manner.
   C. *Immediate*: As soon as the proposed regulations become effective it would allow for a public process by which additions to the newborn screening panel could be made which is of benefit for families and advocates in the public of the State of Nevada for specific diseases on the Recommended Universal Screening Panel. Information required to be shared in the regulation with parents and guardians and required follow up referrals and examinations benefit the public in the State of Nevada by improving medical outcome of diagnosed infants and linking them to appropriate treatment in a timely manner.
   D. *Long-term:* Long-term beneficial effects to the public in the State of Nevada include a public process

by which additions to the newborn screening panel could be made which is of benefit for families and advocates in the public of the State of Nevada for specific diseases on the Recommended Universal Screening Panel. Information required to be shared in the regulation with parents and guardians and required follow up referrals and examinations benefit the public in the State of Nevada by improving medical outcome of diagnosed infants and linking them to appropriate treatment in a timely manner.

3. There is no estimated cost to the Division of Public and Behavioral Health for enforcement of the proposed regulations. There are no fees to the Division related to enforcement currently set in regulations to cover costs to enforce the proposed regulations.

The proposed regulations do not overlap or duplicate any other Nevada state regulations.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary, Lisa Sherych, to be received no later than February 23, 2022, at the following address:

Secretary, State Board of Health
Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

A copy of the notice and proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Division of Public and Behavioral Health
4150 Technology Way, Suite 210
Carson City, NV 89706

A copy of the regulations and small business impact statement can be found on-line by going to:
https://dpbh.nv.gov/Programs/Maternal,_Child_and_Adolescent_Health_(MCH)/.

A copy of the public hearing notice can also be found at Nevada Legislature's web page:
https://www.leg.state.nv.us/App/Notice/A/

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at (775) 684-1030 in Carson City or (702) 486-6515 in Las Vegas.
Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

White Pine County Library
950 Campton Street
Ely, NV 89301-1965

Clark County District Library
1401 East Flamingo Road
Las Vegas, NV 89119

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
80 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Green Valley Parkway
Henderson, NV 89012

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

Per NRS 233B.064(2), upon adoption of any regulation, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

SMALL BUSINESS IMPACT STATEMENT

PROPOSED AMENDMENTS TO NEVADA ADMINISTRATIVE CODE (NAC) CHAPTER 442: Newborn Screening, LCB File No. R088-20RP1

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendment LCB File No. R088-20RP1 should not have an impact upon a small business or a negative impact on the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes (NRS) Chapter 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement is made pursuant to NRS 233B.0608(3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608(3), this statement identifies the methods used by the agency in determining the impact of the proposed regulation on a small business in sections 1, 2, 3, and 4 below and provides the reasons for the conclusions of the agency in section 8 below followed by the certification by the person responsible for the agency.

Background

The value of the regulation is in detailing processes by which the State Public Health Laboratory (SPHL) can request information and payment related to laboratory and non-laboratory tests and examinations and specifies how the SPHL and primary care physicians will share relevant information and examination and testing results and ensure proper referral and care for infants suspected of or diagnosed with specific preventable or inherited conditions. The regulations also detail specific blood sample processes and standardized criteria by amending Nevada Administrative Code (NAC) 442.044. The benefit of the regulation is in creating a means by which the SPHL can detail a public process by which fees can be changed, includes examinations and non-laboratory tests related to newborn screening needed as part of diagnostic screening for all required conditions, establishes processes for parental or guardian information sharing, referral and care transition from SPHL and health care providers, and information sharing to the Department of Health and Human Services Chief Medical Officer and local health officers.

1) **A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.**

Pursuant to NRS 233B.0608(2)(a), the Division of Public and Behavioral Health has requested input via posting on the Division website and mailed copies of the proposed regulation and the small business impact statement.

A Small Business Impact Questionnaire was sent to professional medical and hospital boards and associations and the Nevada Newborn Screening program along with a copy of the proposed regulation changes, on September 28, 2021. The questions on the questionnaire were:

1) How many employees are currently employed by your business?
2) Will a specific regulation have an adverse economic effect upon your business?
3) Will the regulation(s) have any beneficial effect upon your business?
4) Do you anticipate any indirect adverse effects upon your business?
5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Response

Summary Of Comments Received (0 responses were received out of 11 small business impact questionnaires distributed by mail or by email in response to the information posted on the Division website here: https://dpbh.nv.gov/Programs/Maternal,_Child_and_Adolescent_Health_(MCH)/)			
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?**
No response	No response	No response	No response

Number of Respondents out of 11 mailings and posting to the Division website	**Adverse economic effect?**	**Beneficial effect?**	**Indirect adverse effects?**	**Indirect beneficial effects?**
0	0	0	0	0

2) Describe the manner in which the analysis was conducted.

No survey results were received for analysis.

3) The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation both adverse and beneficial effects and both direct and indirect effects.

The possible adverse impact anticipated to small businesses is the pathway the regulation develops to create a public hearing process for fee increases and introduces a means to require payment either at the time of newborn screening kit purchase or at the time of testing. The regulation requires parent or guardian follow up in relation to positive test results or diagnosis for health care providers which might increase the length and possible cost of a visit. The benefit would be a public process for discussion of proposed newborn screening fee increases.

4) Provide a description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

The Division of Public and Behavioral Health has held several opportunities for small businesses to provide input and comments regarding the proposed regulations, including the economic impact the proposed regulations may have on small businesses. The Small Business Impact Questionnaire was posted ion the Division website and mailed to professional medical and hospital associations for distribution and to the Nevada Newborn Screening program. Workshops will be held on January 11, 2022, allowing for further input by interested parties regarding the proposed regulations and how they will impact small businesses. These comments will be taken into consideration for possible revisions to the regulations to reduce the economic impact on facilities.

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

There is no estimated cost to the agency for enforcement of the proposed regulation.

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

DPBH is not expected to collect any fees as the fee increase relates to the SPHL.

7) An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

There are no duplicative or more stringent provisions than federal, state or local standards regulating the same activity.

8) Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.

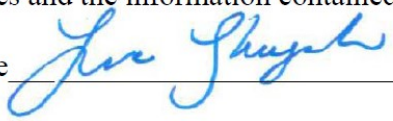
Pending any feedback from the public workshop on January 11, 2022, currently there are no responses to the small business impact questionnaire mailed and posted on the Division website on September 28, 2021.
Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Vickie Ives at the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89701

Vickie Ives
Phone: (775) 684-2201
Email: vives@health.nv.gov

Certification by Person Responsible for the Agency

I, Lisa Sherych, Administrator of the Division of Public and Behavioral Health certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Signature  Date: 12/27/2021