

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

DIVISION OF PUBLIC & BEHAVIORAL HEALTH

Bureau of Child, Family and Community Wellness

Maternal, Child, and Adolescent Health Section

LCB File No. R088-20RP1

Informational Statement per NRS 233B.066

1. A clear and concise explanation of the need for the adopted regulation.

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

2. 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.

Public comment and feedback were solicited from the community and partners during a public workshop which was held on January 11, 2022. Concerns were voiced at the public workshop. Information on the public workshop can be accessed at the following website:

[http://dpbh.nv.gov/Programs/Maternal,_Child_and_Adolescent_Health_\(MCH\)/](http://dpbh.nv.gov/Programs/Maternal,_Child_and_Adolescent_Health_(MCH)/)

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.

Public comment and feedback were solicited at the public hearing of the State Board of Health, held on March 4, 2022. Public comment was given during this meeting for R088-20RP1 with two (2) written submissions relating to the need for an opt-out to newborn screening for parents and the need for protections of genetic material related to newborn screening, questioning why this regulation is needed now, and safeguarding families from the selling of infant genetic information. Verbal testimony offered during public comment included the topics covered in the written testimony, as well as one comment detailing the SPHL process on destroying samples after one year.

Anyone interested in obtaining further information can contact the Bureau of Child, Family, and Community Wellness at 4150 Technology Way Suite 200, Carson City, NV 89706.

3. A statement indicating the number of persons who attended each hearing, testified at each hearing, and submitted written statements regarding the proposed regulation. This statement should include for each person identified pursuant to this section that testified and/or provided written statements at each hearing regarding the proposed regulation, the following information, if provided to the agency conducting the hearing:

- (a) Name
- (b) Telephone Number
- (c) Business Address
- (d) Business telephone number
- (e) Electronic mail address; and
- (f) Name of entity or organization represented

A public workshop held on January 11, 2022, and seventeen (17) persons attended, including Division of Public and Behavioral Health staff. The names of the attendees are Julie Miller, Joanna Bacon, Lenny Suetinseth, Charlotte Stewart, Lori Myron, Jimmy Lau, Katie Banuelos, Kat Sienkiewicz, Stephanie Vanhooser, Ofelia Gentscheff, Jena Rosa, Linda Anderson, Monica Marquez, Casey Rodgers, Desiree Wenzel, Vickie Ives, and Karissa Loper. Verbal public comment expressing concerns about the regulation were provided by Katie Banuelos, Libertarian Party of Nevada objecting to requiring all parents to submit blood samples from their newborn and indefinite blood sample storage at the state public health laboratory;

Kat Sienkiewicz, Health Freedom Nevada, stressing the need for parents to be able to opt out and expressing concerns of the screening requirement expanding beyond hospitals; Charlotte Stewart, Health Freedom Nevada, on the need for an opt out option, especially home births, and that there needs to be something in the provisions that whoever is collecting the samples should not be able to sell those samples; Lenny Suetinseth, a Licensed Midwife, on any allowance for refusal on the screening forms; Casey Rodgers, asked why samples of every child born to include those at home are needed and concerns on informed consent use of blood samples; Monica Marquez, calling to oppose; and Jena Rosa, Obstetrics Practice Consultant, had concerns on possible repercussions for those patients refusing, and the importance of parental autonomy. In response to concerns expressed, Stephanie Vanhooser, Administrative Director at the Nevada State Public Health Lab, stated there is a refusal form offered for parents and provided information related to voiced concerns, as did Ofelia Gentscheff, Nevada Newborn Screening Program, who noted there is an opt out option for parents and addressed the validity of the newborn screening specimens and why Nevada is a two-screen state.

A public hearing was held on March 4, 2022. At that hearing were 86 attendees. That number includes the members of the Board of Health, staff of the Division of Public and Behavioral Health, staff from other state agencies, as well as members of the public. As there were other items on the agenda, it is possible that not all those that signed in were in attendance for LCB File No. R088-20RP1. One person testified in support of and three against the proposed regulation or provided written statements (two total) expressing concerns during the hearing. Please see the attached document for the list of attendees.

4. A description of how comment was solicited (i.e., notices) 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 solicited comments, as well as distributed draft copies of the regulation via email and to professional medical associations and the SPHL.

A Small Business Impact Questionnaire was sent to professional medical associations and the SPHL along with a copy of the proposed regulation changes, on September 28, 2021; no responses were received.

Anyone interested in obtaining further information can contact the Bureau of Child, Family, and Community Wellness at 4150 Technology Way Suite 200, Carson City, NV 89706.

5. If, after consideration of public comment, the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

R088-20RP1 was adopted without any changes as a result of the respective public hearings because there are current options for refusal of the newborn screening via a form in response to public comment from the Public Workshop for R088-20RP1 held on January 11, 2022, and information addressing all key concerns was outlined in Board of Health supporting materials.

The ability and process by which to opt out of newborn screening are codified in **Nevada Revised Statutes (NRS) 442.008(7)** and **NAC 442.050(2)**.

The University of Nevada, Reno, Nevada State Public Health Lab (SPHL) 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>.

There is no mention of selling of genetic materials in existing or proposed NAC language related to Newborn Screening or codified in Nevada Revised Statutes (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.

6. 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:
 - (a) Both adverse and beneficial effects; and
 - (b) Both immediate and long-term effects.

Anticipated effect on regulated businesses:

- a) Adverse effect: There is no anticipated adverse effect.
- b) Beneficial effect: Businesses will benefit from the specification of 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.
- c) Immediate effect: There is no anticipated immediate effect.
- d) Long-term effect: Entities will benefit from the specification of 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. As conditions are added to the federal recommended panel in the future, there is a possibility the costs involved in screening could

increase to cover additional reagents and equipment needed to test for additional conditions to save infants lives or ameliorate outcomes with timely treatment.

Anticipated effect on the public:

- a) Adverse effect: There is no anticipated adverse economic effect on the public.
- b) Beneficial effect: The public will benefit from the specification of 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.
- c) Immediate effect: There is no anticipated immediate economic effect on the public.
- d) Long-term effect: The public will benefit from the specification of 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.

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

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

8. 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 regulating federal agency.

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

9. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions; and

There are no provisions in the regulation which are more stringent than a federal regulation which regulate the same activity.

10. If the regulation establishes a new fee or increases an existing fee, a statement indicating the total annual amount the agency expects to collect and the manner in which the money will be used.

The regulation does not establish a new fee or increase an existing fee. As conditions are added to the federal recommended panel, there is a possibility the costs involved in screening could increase to cover additional reagents and equipment needed to test for additional conditions to save infants lives or ameliorate outcomes with timely treatment.

NOTE: The Informational statement is essential. If this statement is not included with the final regulations or is incomplete or inaccurate, LCB will return the regulation to the agency. Unless a statement is supplied, the LCB will not submit the regulation to the Legislative Commission, and the regulation never becomes effective (NRS 233B.0665).

Attached: List of Attendees at Board of Health, March 4, 2022

<i>Name (Original Name)</i>	<i>User Email</i>
Joseph Filippi	jpfilippi@health.nv.gov
Paul Shubert	
Tedd McDonald MD/Waterfall Clinic/CCHO	
Patrick Hughes	
Charlotte Stewart	
Jon Pennell	
Vickie Ives	
Ofelia Gentscheff	
B. Putnam	
17752204109	
Charles Smith	
Leticia Metherell	
Casey Rodgers	
Carol Shank	
Cody Phinney	
Rex Gifford# AAIII# DPBH	
Nicki Aaker	
Shannon Ernst	
Tyler Shaw - FRPA	
Linda Anderson	
iPhone	
John Packham	
Tyler Shaw - FRPA	
Charlotte Stewart	
Casey Rodgers	
iPhone	
Charles Smith	
Carol Shank	
Linda Anderson	
Patrick Hughes	
Marena Works	
Shannon Ernst	
Tyler Shaw - FRPA	
17754300034	
Monica's iPad	
17757272830	
Alan's iPhone	
Brad Waples	
Johnathon Fayeghi S.66107	
Mommy's I Phone	
Leguen# Southern Nevada Health District	

Stephanie Vanhooser
Seres Sosnowski-Abueg
Judith Andrews Bittner
Julia Peek# Nevada DHHS
Ken Kubes (A618618)
Pierron Tackes
Kyle Devine
A618618
17028375852
Ihsan Azzam
17024864000
Lisa Sherych
Kevin Dick
Sean Applegate
Brett
Steve Messinger--NVPCA
Brooke Maylath
Colleen Lyons# MD
Valerie Balen
Lindsey Doolittle (she/her)
Kat S.
Teresa Hayes (DPBH-EHS)
17757381553
Megan Comlossy
Edith Duarte
Lindsey's iPhone
Tammy Ritter
Rebekah iPad
Debra Songer
Keibi Mejia
Randi Ranae
Evelyn Dryer
Patti Brouhard
17028011704
17024612908
Kent Ervin
Cassie Hall
Troy Ross
Randi Ranae
Jim's iPhone
Isabelle Eckert
Katania @ Health Freedom Nevada
17757720343
17753575521
Raffi Rodrigo

