

DATE: December 23, 2025

TO: Hearing Attendees and Commenters –
Oregon Administrative Rules chapter 333, division 24 –
“Newborn Screening updates to practice guidelines and alignment
with statute (HB 2741, 2025)”

FROM: Brittany Hall, Hearing Officer and Administrative Rules Coordinator

cc: Akiko Saito, Laboratory Business Director
Oregon State Public Health Laboratory

SUBJECT: Presiding Hearing Officer’s Report on Rulemaking Hearing and Public
Comment Report

Date of Hearing: December 16, 2025, via Microsoft Teams

Purpose of Hearing: The purpose of this hearing was to receive public testimony regarding the Oregon Health Authority (Authority), Public Health Division, Oregon State Public Health Laboratory's (OSPHL) Northwest Regional Newborn Bloodspot Screening Program’s (NWRNBS Program’s) proposed amendments to existing rules for newborn bloodspot screening to align with recent changes in statute (2025 Oregon Laws, Chapter 203 ([HB 2741](#))) and adjust rules to align with practice guidelines. In this proposed rulemaking, the NWRNBS Program proposes:

- Amendments to OAR 333-024-1000 and OAR 333-024-1050 to add in the ability of parents or legal guardians to opt out of screening because of their religious **or philosophical** beliefs. This aligns the rule with new statutory changes. 2025 Oregon Laws, Chapter 203 (HB 2741).

- Amendments to OAR 333-024-1000 and OAR 333-024-1050 to incorporate more inclusive language with the addition of **legal guardians** or parents. This aligns the rule with new statutory changes. 2025 Oregon Laws, Chapter 203 (HB 2741).
- Updates to OAR 333-024-1040 requiring a blood card be submitted for all babies born in Oregon. If no blood is collected on the card, because parents or legal guardians opt out of screening (refusal), the baby is transferred to another care facility prior to 24 hours of life, or the baby is deceased, the persons responsible for collecting specimens (OAR 333-024-1020 to 333-024-1025) must still complete the demographic information on the card and send it to the Oregon State Public Health Laboratory. An opt out for religious or philosophical beliefs requires the parent or legal guardian to also complete the Objection to Newborn Screening Blood Test form.
- Methods of testing for each listed disorder is being removed to allow the laboratory to update methods as needed to ensure accuracy of results and alignment with best practices (OAR 333-024-1070).
- Updates to OAR 333-024-1080 adding consistency by including **legal** before guardian.

Hearing Officer: Brittany Hall

Testimony Received: No individuals provided testimony at the hearing.

Other Comments: One organization submitted written comments during the rule advisory committee (RAC) process. Three individuals or organizations submitted written comments to OHA within the period allotted for public comment, which closed at 5:00 PM on December 22, 2025. Written comments are attached to this report as **EXHIBIT 1**.

Summary of Comments and Agency Responses:

In written comments submitted to the agency during the RAC process, OHA heard concern regarding the proposed text reviewed by the RAC on September 3, 2025, stating that “some of the new rules are unnecessary and if they are not removed, will create burdens on the health care workforce and will disrupt processes that work well for collecting newborn bloodspot screening specimens.” Proposed

changes to OAR 333-024-1010(5) and (6) were specifically addressed, relating to the requirement to maintain chain of custody of specimens. Written comments opined that “maintaining chain of custody would be a tremendous burden for hospitals” and noted that “it’s unusual for clinical laboratories to use chain of custody practices except for specimens collected for law enforcement purposes.” Written comments further opined that the “draft rule will not fix the stated problem” of clerical errors that was communicated at the RAC meeting as the reason for these rule changes. Written comments requested that sections (5) and (6) of the proposed rule text be deleted.

Subsequent written comments received during the public comment period acknowledge that the changes requested above were made to the final version of the proposed text.

Agency response: Thank you for your comments.

In written comments submitted during the RAC process and during the public comment period, OHA heard concern about the proposed changes to OAR 333-024-1010(7) that would require demographic information to be completed on a specimen collection card, even if no blood is collected, and require submission of the card to the Oregon State Public Health Laboratory along with any completed Objection to Newborn Screening Blood Test form. OHA heard concern about this new requirement and that it would “have a significant financial impact on hospitals” and midwives that pay for the expensive specimen collection cards. Written comments opined that “adding the requirement to complete a specimen collection card when no blood is collected will create an unnecessary expense and waste resources.” Written comments requested that section (7) be deleted from the proposed text and also requested that instead of sending back blank cards, there be an electronic way to report a declined sample.

Agency response: Thank you for your comments. The intent of OAR 333-024-1040 (7) is to ensure that all babies have the opportunity to be screened.

All facilities or individuals responsible for collecting newborn screening specimens must submit a collection card with demographic information, even if no blood is collected. The card provides space for the collector to indicate the reason why the

baby's blood was not collected: baby deceased, baby transferred to another hospital, or parent refusal. This new procedural requirement of submitting a card without blood provides the program with information to perform appropriate follow-up actions. With this timely information, the program can reconcile the newborn screening record with vital records (birth/death records). In the case of a transfer, the program can reach out to the receiving hospital to ensure that a screen is collected. Lastly, in the case of a parent refusal, the program has documentation that screening was offered.

For many years the program offered an option to submit parent refusal data electronically, but the uptake was very low. It was seen as a burden to have to complete another form, separate from the newborn screening card. By incorporating the parent refusal into the existing newborn screening card, the routine hospital/clinic processes associated with collection and transport can be maintained.

To help offset the purchase of a newborn screening card, the program provides a replacement card, free of charge, for any received without blood. The intent is to remove any financial burden from this procedural requirement.

The newborn screening program utilizes a prepaid billing model. This means that hospitals and midwives routinely purchase cards in advance of reimbursement by private insurance or Medicaid. In the case of a card submitted without blood, the program recognizes that there is also an upfront cost prior to receiving the replacement card. The newborn screening program is currently reviewing its billing practices to better support hospitals and midwives and hopes to have alternative billing options available in 2026.



September 9, 2025

Newborn Screening Program
7202 NE Evergreen Parkway, Suite 100
Hillsboro, OR 97214

Submitted electronically to KASFIAN.KHAN@oha.oregon.gov

RE: September 2025 Newborn Screening Rules Advisory Committee and Draft Rules

Newborn Screening Program Staff,

The Hospital Association of Oregon (HAO) represents hospitals responsible for collecting newborn bloodspot screening specimens for patients born in their labor and delivery units. The intent of HB 2741 (2025) was to clarify the current mandate for OHA to maintain a state public health laboratory and provide newborn bloodspot screening services. During the legislative session, HAO chose not to oppose HB 2471, in part because the law could achieve its objectives without creating new burdens on the health care workforce or disrupting processes that work well for collecting newborn bloodspot screening specimens. The draft rules shared with the RAC go beyond implementing HB 2471, and we set forth our specific concerns below.

The Newborn Screening Program convened a RAC on September 3, 2025, to review draft rules to implement HB 2741. We provided comment at that RAC and were able to learn more about the intent of these rules. Through that process, it has become clear that some of the new rules are unnecessary, and if they are not removed, will create burdens on the health care workforce and will disrupt processes that work well for collecting newborn bloodspot screening specimens. We appreciate that OHA engaged a RAC to create a space for these shared learnings, and we request that OHA adjust its rules now that it has more information.

333-024-1040

Newborn Screening: Manner of Collecting and Submitting Specimens

A person responsible for submitting specimens to the Oregon State Public Health Laboratory under OAR 333-024-1020 and OAR 333-024-1025 must:

(1) Collect the specimens:

(a) Using kits available from the Oregon State Public Health Laboratory; and



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(b) According to OAR 333-024-1030.

(2) Provide the Oregon State Public Health Laboratory with complete, accurate, and legible demographic information as requested on the demographics portion of the kit, which includes information that identifies the individual(s) who are responsible for the medical care and treatment of the infant and for responding to testing results generated by newborn screening.

(3) Send specimens for newborn screening to the Oregon State Public Health Laboratory as soon as they are completely dry and no later than 24 hours after collection.

(4) Ensure that specimens for newborn screening are sent via courier, express mail, or other timely delivery mechanism and received by Oregon State Public Health Laboratory within 48 hours after collection.

(5) Maintain chain of custody documentation of specimens from the point of collection to when it is received by the Oregon State Public Health Laboratory.

(6) Keep a tracking log of all specimens sent to the Oregon State Public Health Laboratory that includes the results received after testing is complete.

(7) The facility or individual responsible for collecting specimens for newborn screening under OAR 333-024-1020 and OAR 333-024-1025 must submit a specimen collection card (kit) for all infants born in Oregon. If no blood is collected, the persons responsible for collecting specimens under OAR 333-024-1020 to 333-024-1025 must still complete the demographic information on the card and submit to the Oregon State Public Health Laboratory along with any Objection to Newborn Screening Blood Test form completed under OAR 333-024-1050.

OHA and the Newborn Screening Program have not adequately considered how this rule will affect hospitals. Maintaining chain of custody would be a tremendous burden for hospitals. Chain of custody requires secure specimen storage areas under lock and key and signatures and dates for every individual who takes possession of the sample (e.g., MAs, nurses, couriers, lab staff). It's unusual for clinical laboratories to use chain of custody practices except for specimens collected for law enforcement purposes. Chain of custody forms would be redundant and inefficient for hospitals using Electronic Health Records that track specimen collection. Creating and maintaining a database of specimens and results would also impose new operational processes and costs.

Based on conversation during the RAC meeting, OHA communicated that Sections (5) and (6) of this draft rule are a response to a few instances of clerical errors that occurred during the transportation of specimens. Clerical errors can happen even with chain of custody documentation. Accordingly, the draft rule will not fix the stated problem. Therefore, we request that Sections (5) and (6) be deleted from the proposal.

In addition to not solving the stated problems, the rules are expected to create new problems and increase the burden on the health care workforce. There is a disconnect between the rules and how this work occurs in many hospitals. For example, the Newborn Screening Program hasn't considered how these new rules will impact hospitals that contract with laboratory service companies to collect or transport specimens. Contractors could stop providing service to hospitals solely due to the burden of chain of custody if they are unable to follow the strenuous documentation and storage criteria. We are



in an environment of decreasing resources, and when OHA places additional burdens on the health care workforce, as OHA is doing through Sections (5) and (6), there is a cost. We request that OHA remove these unnecessary provisions and requirements.

Section (7) will have a significant financial impact on hospitals. Hospitals pay for the specimen collection cards, and they are expensive. Adding the requirement to complete a specimen collection card when no blood is collected will create an unnecessary expense and waste resources. During the RAC meeting, OHA communicated that Section (7) is intended to improve record keeping. We request that OHA explore solutions that improve records without requiring hospitals to increase their costs. We request that OHA remove Section (7).

➤ **Request: We request that Sections (5), (6), and (7) be deleted.**

Rather than creating a new, costly rule, we encourage the Newborn Screening Program to improve their outreach to hospitals to work collaboratively in removing barriers hospitals might face in collecting and delivering specimens within the timeframes already established in administrative rule. HAO can assist with connecting program staff with the appropriate hospital staff to discuss newborn screening specimen collection and delivery procedures. OHA's focus should be to improve gaps rather than imposing challenging and costly expectations.

We will monitor this rulemaking process as it moves forward.

Sincerely,

Sierra Canfield
Director of Public Policy
Hospital Association of Oregon

About the Hospital Association of Oregon

Founded in 1934, the Hospital Association of Oregon (HAO) is a mission-driven, nonprofit trade association representing Oregon's 61 hospitals. Together, hospitals are the sixth largest private employer statewide, employing more than 70,000 employees. Committed to fostering a stronger, safer, more equitable Oregon where all people have access to the high-quality care they need, the hospital association supports Oregon's hospitals so they can support their communities; educates government officials and the public on the state's health landscape, and works collaboratively with policymakers, community based organizations and the health care community to build consensus on and advance health care policy benefiting the state's four million residents.



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December 12, 2025

Newborn Screening Program

7202 NE Evergreen Parkway, Suite 100

Hillsboro, OR 97214

Submitted electronically to publichealth.rules@odhsoha.oregon.gov

RE: Notice of Proposed Rulemaking NPRM for OAR 333-024-1000, 333-024-1040, 333-024-1050, 333-024-1070, 333-024-1080

Patrice Held,

The Hospital Association of Oregon (HAO) represents hospitals responsible for collecting newborn bloodspot screening specimens for patients born in their labor and delivery units.

The hospital association participated in the Sept. 2025 Newborn Screening Rules Advisory Committee. During the RAC we raised concerns with OAR 333-024-1040, including draft rules that would have required hospitals to maintain a chain of custody for specimens collected and a tracking log to document receipt of results. The draft rules were unnecessary, and the draft rules would have created burdens on the health care workforce and disrupted processes that work well for collecting newborn bloodspot screening specimens. We appreciate the thoughtful discussion and the opportunity for the hospital association to share information.

We have reviewed the NPRM filed on Nov. 7, 2025, including the changes to OAR 333-024-1040. We appreciate that the proposed rules reflect the discussion that occurred during the RAC. We are supportive of the proposed changes to OAR 333-024-1040.

Sincerely,

Sierra Canfield

Director of Public Policy

Hospital Association of Oregon



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From: [Rosanne James](#)
To: [Public Health Rules](#)
Subject: New rules on bloodspot cards
Date: Tuesday, December 2, 2025 10:57:00 AM

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I just have a comment on:

“Updates to OAR 333-024-1040 requiring a specimen collection card to be submitted for all babies born in Oregon, even if blood will not be collected.”

Because the cards are so expensive, I would like to problem solve on how to report a declined sample VS sending back a blank card. There has to be an electronic way or message mailed back that would be cost saving.

Thank you for your time.

Rosanne James, NCMA
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From: [Catherine Bailey](#)
To: [Public Health Rules](#)
Subject: Public Comment for Updates to rules for the newborn screening test program
Date: Thursday, December 4, 2025 2:28:57 PM

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To whom it may concern,

My name is Catherine Bailey and I am a parent and a home birth midwife in Portland, Oregon.

While I agree with many of the proposed changes, I do not agree with the requirement to send in an empty newborn screening test form to the state lab with demographic info. These tests cards are very expensive. For example, if I had a client on OHP who refused to do the newborn screening tests for their baby I would still have to spend \$175 of my own money to order the test card and then send in a blank form with their demographic info on it, and then, I doubt I would be able to bill OHP for reimbursement for this as it's not a service that I actually provided to the baby. Can you please consider this cost burden for providers?

Thank you,
Catherine Bailey