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TOBIAS READ
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MICHAEL KAPLAN
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
11/07/2025 12:24 PM
ARCHIVES DIVISION
SECRETARY OF STATE

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Newborn Screening updates to practice guidelines and alignment with statute (HB 2741, 2025)

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/22/2025 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Patrice Held
503-693-4172
publichealth.rules@odhsoha.oregon.gov

7202 NE Evergreen Pkwy Ste 100
Hillsboro,OR 97124

Filed By:
Public Health Division
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 12/16/2025
TIME: 1:30 PM
OFFICER: Staff

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 971-277-2343
CONFERENCE ID: 198292183
SPECIAL INSTRUCTIONS:
This hearing is being held remotely via Microsoft Teams. To provide oral (spoken) testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register and receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971- 277-2343, Phone Conference ID 198 292 183# for audio (listen) only.

This hearing will close no later than 2:30PM but may close as early as 2:00PM if everyone who signs up to provide testimony has been heard from.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

NEED FOR THE RULE(S)

The Oregon Health Authority (Authority), Public Health Division, Oregon State Public Health Laboratory's (OSPHL) Northwest Regional Newborn Bloodspot Screening Program (NWRNBS Program) is proposing to amend existing rules for newborn bloodspot screening to align with recent changes in statute (2025 Oregon Laws, Chapter 203) 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.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Northwest Regional Newborn Bloodspot Screening Practitioner's Manual
https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le8189.pdf

2025 Oregon Laws, Chapter 203 (HB 2741):
https://olis.oregonlegislature.gov/liz/2025R1/Downloads/MeasureDocument/HB2741

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The proposed changes to the rules expand inclusivity by broadening the definition from only parents to include legal guardians caring for an infant. With this rule change, parents and legal guardians can exercise their right to refuse screening for their baby for not just religious objections, but also philosophical objections. The program recognizes that broadening the definition of why parents or legal guardians may refuse screening for their newborn could inadvertently increase vulnerability to preventable conditions. Considering that BIPOC communities face many systemic barriers in accessing equitable healthcare, the absence of early screening could lead to delayed diagnosis and increase the potential burden of these long-term health disparities for these communities should they opt out. Knowing this risk, the NBS program also implemented a policy that all babies must have an NBS card completed, even if blood was not collected.

The proposed rule requires a blood card be submitted for all babies born in Oregon, even if the parent or legal guardian refuses. If no blood is collected on the card, the persons responsible for collecting specimens must still complete the demographic information and send it to the Oregon State Public Health Laboratory, along with an Objection form signed by the parent or legal guardian. This process change will help the program link the screening card to the vital statistics record of birth. The goal is to ensure that every baby born in Oregon has the opportunity to be screened. For babies that are not screened, the program will be able to use the vital records data to understand which populations are more likely to be impacted, so that outreach and education can be provided to vulnerable populations.

FISCAL AND ECONOMIC IMPACT:

There is no fiscal or economic impact to key partners (hospitals, clinics, community birth providers) as the fees for testing will not be increased.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) No significant impact is anticipated to the Oregon Health Authority or other state agencies, local government, or the public based upon this rule change.

(2)(a) Newborn bloodspot screening impacts any health system or medical provider delivering infants or caring for infants in their practices. The estimated number of small businesses is approximately 960, comprised of midwives, naturopaths, osteopaths, medical doctors, and clinics.

(b) Minimal administrative burden is anticipated for submitters (hospitals, clinics, midwives). While it is now required that a card be completed for every baby, this should have been standard of practice prior to the rule change.

(c) No significant equipment, supplies, labor, or administration is required for compliance by small businesses. There is an upfront cost for the kit (screening card) that small businesses and hospitals incur, even when the family refuses screening. However, the NWRNBS program will be reimbursing businesses for this expense.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Individuals representing large and small businesses serve on the NBS Program Advisory Board and served on the Rules Advisory Committee. Examples include representatives of midwifery practices, Hospital Association of Oregon, and pediatric or family practice offices.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
333-024-1000, 333-024-1040, 333-024-1050, 333-024-1070, 333-024-1080

AMEND: 333-024-1000

RULE SUMMARY: Amend OAR 333-024-1000

- Adds in the ability of parents or legal guardians to opt out of screening because of their religious or philosophical beliefs. This aligns rules with new Oregon laws found in 2025 Oregon Laws, Chapter 203 (HB 2741).
- Amendments to incorporate more inclusive language with the addition of legal guardians or parents as directed by new Oregon law.

CHANGES TO RULE:

333-024-1000
Newborn Screening: Purpose
(1) Newborn screening identifies conditions and diseases that may not be clinically evident in the first few days or weeks of an infant's life but can affect an infant's long-term health or survival. If these conditions are detected early, they can be diagnosed, and appropriate intervention can prevent death or lessen or prevent disability. In Oregon, all infants are required to be screened, except for those whose parents or legal guardian opt out because

of their religious or philosophical beliefs. The Oregon State Public Health Laboratory performs this newborn screening testing and provides the results to those designated on the testing form as responsible for the health and medical care of the infant so that they can undertake the necessary confirmatory diagnostic testing and medical follow-up. To obtain more information about Newborn Bloodspot Screening go to www.healthoregon.org/nbs.¶

(2) These rules do not apply to newborn hearing screening, congenital heart defect screening, or other "point of care" newborn screening tests.

Statutory/Other Authority: ORS 413.0~~14, 433.285, 431A.750~~42, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)

Statutes/Other Implemented: ORS 433.~~285, 433.290, 433.295~~110 - 433.770 (as amended by 2025 OL, Chapter 203)

AMEND: 333-024-1040

RULE SUMMARY: Amend OAR 333-024-1040

- Amends title of rule to include both collecting and submitting specimens.
- Adopts additional procedures for facilities or individuals responsible for collecting specimens. A specimen collection card must be submitted for all babies born in Oregon. If no blood is collected on the card, 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 (OSPHL). In the case of a parent or legal guardian opting out of screening (OAR 333-024-1050), the Objection to Newborn Screening Blood Test form must also accompany the card.

CHANGES TO RULE:

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¶
(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) 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 and submit the card to the Oregon State Public Health Laboratory. In the case of a parent or legal guardian opting out of screening, the Objection to Newborn Screening Blood Test form completed under OAR 333-024-1050 must accompany the card.
Statutory/Other Authority: ORS 413.0~~14, 433.285, 431A.750~~42, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)
Statutes/Other Implemented: ORS 433.~~285, 433.290, 433.295~~110 - 433.770 (as amended by 2025 OL, Chapter 203)

AMEND: 333-024-1050

RULE SUMMARY: Amend OAR 333-024-1050

- Adds in the ability of parents or legal guardians to opt out of screening because of their philosophical beliefs. This aligns rules with new Oregon laws found in 2025 Oregon Laws, Chapter 203 (HB 2741). Parents or legal guardians are already able to opt out due to religious beliefs.
- Repeals the requirement for a form to be completed and submitted to the Oregon State Public Health Laboratory (OSPHL) within 30 days because the opt out is now part of the specimen collection card that must be submitted to OSPHL.

CHANGES TO RULE:

333-024-1050
Newborn Screening: Religious or Philosophical Exemption from Newborn Testing
(1) A parent or legal guardian may opt not to have their infant ~~test~~screened in accordance with these rules because of religious or philosophical beliefs opposed to such testing. ~~In order t~~To claim such an exemption, the parent ~~must complete a Statement of Religious Exemption~~or legal guardian must complete an Objection to Newborn Screening Blood Test on behalf of the infant on a form prescribed by the Oregon State Public Health Laboratory. ¶
(2) The ~~form must be completed and submitted to the Oregon State Public Health Laboratory within 30 calendar days from the day the infant was born~~parent or legal guardian must sign the Objection to Newborn Screening Blood Test.
Statutory/Other Authority: ORS 413.0~~14, 433.285, 431A.750~~42, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)
Statutes/Other Implemented: ORS 433.~~285, 433.290, 433.295~~110 - 433.770 (as amended by 2025 OL, Chapter 203)

AMEND: 333-024-1070

RULE SUMMARY: Amend OAR 333-024-1070

- Removes the testing methods listed for each condition. This aligns rules with new Oregon laws found in 2025 Oregon Laws, Chapter 203 (HB 2741).
- Minor grammatical corrections

CHANGES TO RULE:

333-024-1070
Newborn Screening: The Newborn Bloodspot Screening Panel ~~and Methods~~ of Test~~ings~~
(1) Every properly collected specimen submitted for newborn screening will be tested by the Oregon State Public Health Laboratory or, at the discretion of the Oregon State Public Health Laboratory, another CLIA certified laboratory.¶
(2) Newborn screening specimens will be tested for the medical conditions listed in ~~sections (3) through (11), using the methods listed below~~this rule. At its discretion, and consistent with CLIA standards, the Oregon State Public Health Laboratory ~~may~~will use a~~n equivalent or better alternative method.~~ ¶
~~(3) Metabolic Disorders:¶~~
~~(a) Organic Acid Disorders. Method: Quantitative measurement of amino acids by tandem mass spectrometry.~~ppropriate screening methods and high-tier testing to detect the following disorders. ¶
(3) Metabolic Disorders:¶
(a) Organic Acid Disorders. ¶
(A) Propionic acidemia (PA);¶
(B) Methylmalonic acidemia (MMA);¶
(C) Isovaleric acidemia (IVA);¶
(D) 3-methylcrotonyl CoA carboxylase deficiency (3MCC);¶
(E) 3-Hydroxy-3-Methyglutaric Aciduria (HMG);¶
(F) Holocarboxylase Synthase Deficiency;¶
(G) Beta-ketothiolase deficiency (BKT);¶
(H) Glutaric acidemia, Type I (GA-I);¶
(I) Malonic acidemia (MAL);¶
(J) Isobutyrylglycinuria;¶
(K) 2-Methylbutyrylglycinuria;¶
(L) 3-Methylglutaconic aciduria; and¶
(M) 2-methyl-3-hydroxybutyric aciduria.¶
(b) Fatty acid oxidation disorders. ~~Method: Quantitative measurement of acylcarnitines by tandem mass spectrometry.~~¶
(A) Carnitine uptake defect (CUD);¶
(B) Medium chain acyl-CoA dehydrogenase deficiency (MCAD);¶
(C) Very long chain acyl-CoA dehydrogenase deficiency (VLCAD);¶
(D) Long chain 3 hydroxyacyl-CoA dehydrogenase deficiency (LCHAD);¶
(E) Trifunctional protein deficiency (TFP);¶
(F) Short chain acyl-CoA dehydrogenase deficiency (SCAD);¶
(G) Glutaric acidemia Type II (GA2);¶
(H) Carnitine palmitoyl transferase deficiency, Types I and II (CPT I and CPT II); and¶
(I) Carnitine acylcarnitine translocase deficiency; and¶
(J) X-linked adrenoleukodystrophy (XALD).¶
(c) Amino acid disorders. ~~Method: Quantitative measurement of amino acids by tandem mass spectrometry.~~¶
(A) Argininosuccinate lyase deficiency ;¶
(B) Citrullinemia, Type I (CIT);¶
(C) Maple syrup urine disease (MSUD);¶
(D) Homocystinuria (HCY);¶
(E) Phenylketonuria (PKU);¶
(F) Tyrosinemia, Types I, II, and III; and¶
(G) Arginemia (ARG).¶
(4) Endocrine disorders:¶
(a) Primary congenital hypothyroidism (CH). ~~Method: Fluorescent immunoassay of thyroxine (T4) or thyroid stimulating hormone (thyrotropin or TSH).~~¶
~~(b) Congenital adrenal hyperplasia (CAH). Method: Fluorescent immunoassay of 17-alpha hydroxyprogesterone~~

~~(17-OHP).¶~~
~~(5) Cystic fibrosis. Method: Fluorescent immunoassay of immunoreactive trypsinogen with higher tier molecular analysis for common cystic fibrosis mutations.¶~~
~~(6) Biotinidase deficiency. Method: Colorimetric or fluorometric assay for biotinidase activity.¶~~
~~(7) Classic Galactosemia. Method: Fluorescent immunoassay for galactose uridyltransferase activity and galactose levels.¶~~
~~(8) Sickle cell anemia and other hemoglobin disorders. Method: Electrophoresis and liquid chromatography to detect hemoglobin variants.¶~~
~~(9) Severe combined immunodeficiency disease (SCID). Method: PCR to detect T-cell receptor excision circles.~~¶
(b) Congenital adrenal hyperplasia (CAH).¶
(5) Cystic fibrosis. ¶
(6) Biotinidase deficiency. ¶
(7) Classic Galactosemia. ¶
(8) Sickle cell anemia and other hemoglobin disorders. ¶
(9) Severe combined immunodeficiency disease (SCID). ¶
(10) Lysosomal ~~storage~~ diseases. ~~Method: Measurement of enzyme activity by tandem mass spectrometry with higher tier testing for specific biochemical marker or molecular analysis of the gene.~~¶
(a) Pompe (glycogen storage disease Type II);¶
(b) Mucopolysaccharidosis Type I (MPS I);¶
(c) Fabry (alphagalactosidase A deficiency); ~~and,~~¶
(d) Gaucher (glucocerebrosidase deficiency)~~.~~; ¶
(11) Spinal Muscular Atrophy (SMA)~~. Method: PCR to detect deletion of exon 7 in SMN1 gene.~~; and ¶
(12) Infantile Krabbe Disease (IKD). ¶
(13) Newborn screening results may identify other medical conditions that are not listed above. Other medical conditions that are identified during routine newborn screening will be included in a result report as described in OAR 333-024-1080. It is within the discretion of an infant's health care provider and parents or legal guardians to determine what, if any, medical follow-up is needed in these circumstances.
Statutory/Other Authority: ORS 413.042, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)
Statutes/Other Implemented: ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)

AMEND: 333-024-1080

RULE SUMMARY: Amend OAR 333-024-1080

- Amendments to incorporate more inclusive language with the addition of legal guardians or parents. This aligns rules with new Oregon laws found in 2025 Oregon Laws, Chapter 203 (HB 2741).

CHANGES TO RULE:

333-024-1080
Newborn Screening: Result Reporting and Follow-up
(1) Newborn screening results will be reported by the Oregon State Public Health Laboratory to the following persons responsible for the medical care and treatment of the infant, in order of priority:¶
(a) The individual or individuals identified as responsible on the kit as required in OAR 333-024-1040(2); or¶
(b) The facility or practitioner that collected and submitted the specimen if no individual is identified on the kit as required in OAR 333-024-1040(2);¶
(2) Abnormal results will be reported by the Oregon State Public Health Laboratory as described in section (1) and to a medical specialist on contract with the Oregon State Public Health Laboratory to provide medical advice to the practitioner for the newborn screening condition with an abnormal test result.¶
(3) A parent or legal guardian may be contacted by the Oregon State Public Health Laboratory or by a medical specialist on contract with the Oregon State Public Health Laboratory in the event that a practitioner responsible for the medical care of the infant cannot be identified by other means.¶
(4) The practitioner must communicate abnormal results to the parent or legal guardian of the infant and recommend appropriate medical care.¶
(5) When diagnostic testing is ordered following the recommendations of a medical specialist on contract with the Oregon State Public Health Laboratory, the practitioner must report these test results to the Oregon State Public Health Laboratory within two weeks of the final diagnosis determination.¶
(6) Practitioner(s) must report to the Oregon State Public Health Laboratory newborn screening conditions that were not detected during newborn bloodspot screening but were detected through other testing.
Statutory/Other Authority: ORS 413.0~~14, 431A.750, 433.285~~42, ORS 433.110 - 433.770 (as amended by 2025 OL, Chapter 203)
Statutes/Other Implemented: ORS 433.~~285, 433.290, 433.295~~110 - 433.770 (as amended by 2025 OL, Chapter 203)