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

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

AMEND: 333-024-1000

NOTICE FILED DATE: 11/07/2025

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,~~42, ORS 433.110 - 43~~1A~~3.75~~7~~0
Statutes/Other Implemented: ORS 433.~~285, 433.290,~~110 - 433.~~295~~770

AMEND: 333-024-1040

NOTICE FILED DATE: 11/07/2025

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~~,42, ORS 433.110 - 43~~1A~~3.7~~5~~70
Statutes/Other Implemented: ORS 433.~~285, 433.290~~,110 - 433.~~295~~770

AMEND: 333-024-1050

NOTICE FILED DATE: 11/07/2025

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,~~42, ORS 433.110 - 43~~1A~~3.7~~5~~70
Statutes/Other Implemented: ORS 433.~~285, 433.290,~~110 - 433.~~295~~770

AMEND: 333-024-1070

NOTICE FILED DATE: 11/07/2025

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

NOTICE FILED DATE: 11/07/2025

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,~~42, ORS 433.110 - 433.~~285~~770
Statutes/Other Implemented: ORS 433.~~285, 433.290,~~110 - 433.~~295~~770