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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
09/12/2025 11:03 AM
ARCHIVES DIVISION
SECRETARY OF STATE

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Newborn Screening: incorporating a new condition, adding clarity to rules, making updates to practice guidelines

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 10/21/2025 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.

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Filed By:
Public Health Division
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HEARING(S)

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

DATE: 10/20/2025
TIME: 10:00 AM
OFFICER: Staff

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 971-277-2343
CONFERENCE ID: 924356765
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 924 356 765# for audio (listen) only.

This hearing will close no later than 11:00AM but may close as early as 10:30AM 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 Oregon Administrative Rules to add a new condition for testing, provide clarity to the current rules, and update practice guidelines. In this proposed rulemaking, the NWRNBS Program proposes:

- Minor changes made to OAR 333-024-1010 to better clarify the definition of higher-tier testing, a kit, and a specimen.
- Minor change made to OAR 333-024-1030 to better clarify the timing of third collection in premature babies.
- Updates to the screening panel (OAR 333-024-1070) to include one new condition: Infantile Krabbe Disease.
- Updates to OAR 333-024-1090 to remove educational activities as a reason for the use of residual specimens. There is no specific educational activity performed in which residual specimens are needed.

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

Newborn Bloodspot Screening (NBS) is required for all infants born in Oregon to prevent severe disability or death. The proposed rule changes will allow the program to include one additional disease, Infantile Krabbe Disease, in the screening panel, providing the opportunity for children with this congenital condition to be identified and treated. Though this disease does not disproportionally affect any one community, including it in the list increases health outcomes for newborns, which is a positive equity impact. Like the other diseases on the list, it allows for early detection and intervention that can alleviate some of the inequitable burdens that lead to health disparities, especially for BIPOC communities. Knowing this medical information gives people more access to medical information they might not have if they did not screen.

FISCAL AND ECONOMIC IMPACT:

Yes. There is a fiscal impact to the NWRNBS Program to add a new condition to the panel. The program will be using grant funding to cover the cost of testing for the new condition.

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

However, in the future, the program will need to consider a fee increase once the funding period has ended.

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). The reports will now include a new condition, and electronic medical records will need to be updated. This is standard practice for medical providers.

(c) No significant equipment, supplies, labor, or administration is required for compliance by small businesses.

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:
333-024-1010, 333-024-1030, 333-024-1070, 333-024-1090

AMEND: 333-024-1010

RULE SUMMARY: Amend OAR 333-024-1010

- Adds clarity to the definitions of “high-tier testing” and “kit” and “specimen”

CHANGES TO RULE:

333-024-1010
Newborn Screening: Definitions
As used in OAR 333-024-1000 to 333-024-1110:¶
(1) "Abnormal result" means a laboratory examination result that meets the screening criteria for a newborn screening panel condition requiring additional screening or diagnostic testing and medical follow-up.¶
(2) "Clinical Laboratory Improvement Amendments (CLIA)" means the rules that apply to clinical laboratories in OAR 333-024-0005 to 333-024-0055.¶
(3) "Facility" means:¶
(a) Hospitals and freestanding birthing centers; and¶
(b) Health care clinics and offices where practitioners and other health care professionals provide direct medical care to newborns or infants six months or younger.¶
(4) "Freestanding birthing center" has the meaning given that term in ORS 442.015.¶
(5) "Higher-~~-~~tier testing" means additional testing performed after screening on the same specimen for the purpose of reducing the number of false-positive results reported for a given disorder.¶
(6) "Hospital" has the meaning given that term in ORS 442.015¶
(7) "Kit" means the specimen collection card (also known as the filter paper collection device~~,~~) and the attached demographic form~~, and other items provided by the Oregon State Public Health Laboratory~~ for the purposes of collection ~~or~~and submission of specimens for newborn screening ~~testing~~. ¶
(8) "Newborn screening panel" means the specific medical conditions screened for under OAR 333-024-1070 by the Oregon State Public Health Laboratory or a laboratory under contract with the Oregon Health Authority.¶
(9) "Oregon State Public Health Laboratory" means the laboratory of the Oregon Health Authority that is CLIA certified, that performs testing pursuant to ORS 431A.750 and 433.285.¶
(10) "PCR" means polymerase chain reaction.¶
(11) "Practitioner" means:¶
(a) A physician licensed under ORS chapter 677;¶
(b) A naturopathic physician licensed under ORS chapter 685;¶

(c) A nurse practitioner or advanced practice registered nurse licensed under ORS chapter 678;¶
(d) A direct entry midwife licensed under ORS chapter 687;¶
(e) A chiropractic physician licensed under ORS chapter 684; and¶
(f) For purposes of OAR 333-024-1020(1) and OAR 333-024-1025(1) only, a licensed or unlicensed individual who takes responsibility for delivery or the health care of an infant born in Oregon; or being none, the individual in Oregon responsible for the health care of a pregnant person prior to the infant being born in Oregon.¶
(12) "Residual specimen" means the part of the specimen that is left after newborn screening testing activities are complete.¶
(13) "Specimen" means a blood specimen obtained from an infant by means of skin-puncture (heel stick) and placed on ~~a~~the speci~~al filter paper kit~~men collection card and allowed to air dry.¶
(14) "These rules" means OAR 333-024-1000 through 333-024-1110.
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: 333-024-1030

RULE SUMMARY: Amend OAR 333-024-1030

- Amend one month of age to 28 days related to the timing of third collection in premature babies. This change is in alignment with current practices.

CHANGES TO RULE:

333-024-1030
Newborn Screening: Timing for Collecting Specimens
(1) The facility or individual responsible for collecting specimens for newborn screening under OAR 333-024-1020 and OAR 333-024-1025 must collect newborn screening specimens from every infant born in Oregon, and surviving more than two days, unless exempt according to OAR 333-024-1050, as follows:¶
(a) The first specimen shall be collected as soon as possible after 24 hours of age but before 48 hours of age.¶
(b) The second specimen shall be collected between 10 and 14 days of age.¶
(c) Premature (babies born at <34 weeks gestation age) or low birth weight babies (babies born weighing <2000 grams) require an additional specimen collection at approximately ~~one month~~28 days of age. ¶
(d) Additional, repeat specimens shall be collected if requested by the Oregon State Public Health Laboratory and submitted according to the timeline identified by the Oregon State Public Health Laboratory.¶
(2) If an infant under six months of age enters the care of a practitioner and the practitioner is unable to determine whether the infant has been tested in accordance with these rules, a specimen shall be collected and sent to the Oregon State Public Health Laboratory within two weeks of the first visit to the practitioner.
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

- Adds one new condition to the screening panel. Beginning on, November 1, 2025, the newborn bloodspot screening specimens will be tested for Infantile Krabbe Disease.

CHANGES TO RULE:

333-024-1070
Newborn Screening: The Newborn Screening Panel and Methods of Testing
(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. At its discretion, and consistent with CLIA standards, the Oregon State Public Health Laboratory may use an equivalent or better alternative method. ¶
(3) Metabolic Disorders:¶
(a) Organic Acid Disorders. Method: Quantitative measurement of amino acids by tandem mass spectrometry.¶
(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.¶
(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.¶
(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 413.0~~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: 333-024-1090

RULE SUMMARY: Amend OAR 333-024-1090

- Repeals the use of residual specimens for educational activities because there is no specific educational activity performed in which residual specimens are needed.
- Minor grammatical corrections

CHANGES TO RULE:

333-024-1090
Newborn Screening: Use, Release and Retention of Residual Specimens
(1) Residual specimens may be used by the Oregon State Public Health Laboratory for: ¶
(a) Quality assurance and method development activities as required to maintain CLIA compliance.¶
(b) Program evaluation and quality improvement. ¶
~~(c) Educational activities as required in ORS 433.290. ¶~~
(2) The Oregon State Public Health Laboratory shall only release specimens as follows: ¶
(a) To a third-party laboratory to perform some or all testing described in OAR 333-024-1070. ¶
(b) If required by a court order.¶
(c) To the parent or legal guardian of the infant, or a third party identified by a parent or legal guardian, with a parent or legal guardian's written authorization, according to the Oregon State Public Health Laboratory procedure for requesting specimens. ¶
(3) Specimens may not be released under subsection (2)(c) of this rule within 30 days of the report of the screening results.¶
(4) Specimens submitted to the Oregon State Public Health Laboratory are retained for 12 months after which the specimen is destroyed using a secure method, except as necessary to comply with section (~~1~~2) of this rule. The destruction may occur at any time in the month following the specimen's 12-month retention limit.¶
(5) Specimens retained for longer than 12 months as necessary to comply with section (1) of this rule shall be de-identified by the Oregon State Public Health Laboratory.
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)