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CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Newborn Bloodspot Screening: Remove practitioner's manual from rule; alignment with current practices and statute.

EFFECTIVE DATE: 11/20/2024

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RULES:
333-024-1000, 333-024-1010, 333-024-1020, 333-024-1025, 333-024-1030, 333-024-1040, 333-024-1060, 333-024-1070, 333-024-1080, 333-024-1090, 333-024-1100

AMEND: 333-024-1000

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1000

- Minor grammatical edits

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 ~~that~~ 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 opt out because of their religious 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 413.014, 433.285, 431A.750
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1010

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1010

- Minor grammatical edits
- Removed pre-term from the definitions list and included the exact criteria within the text of the rule (babies weighing less than 2000g at birth or babies born at less than 34 weeks gestational age).
- Updated second-tier testing terminology to current terminology – higher-tier testing.
- Updated specimen definition to describe the ideal specimen type – skin puncture (heel stick)

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 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¶
(~~6~~7) "Kit" means the filter paper collection device, attached demographic form, and other items provided by the Oregon State Public Health Laboratory for the purposes of collection or submission of specimens for newborn screening testing.¶
(~~7~~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.¶
(~~8~~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.¶
(~~9~~10) "PCR" means polymerase chain reaction.¶
(1~~0~~1) "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 ~~mother~~person prior to the infant being born in Oregon.¶
~~(11) "Preterm" means an infant born prior to the start of the 37th week of pregnancy.¶~~
(12) "Residual specimen" means the part of the specimen that is left after newborn screening testing activities are complete.¶
(13)~~ "Second tier testing" means additional testing performed for the purpose of reducing the number of false-positive results reported for a given disorder. ¶~~
~~(14)~~ "Specimen" means a blood specimen obtained from an infant by means of ~~capillary-puncture or~~ skin-puncture (heel stick) and placed on a special filter paper kit and allowed to air dry.¶
(1~~5~~4) "These rules" means OAR 333-024-1000 through 333-024-1110.
Statutory/Other Authority: ORS 413.014, 433.285, 431A.750
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1020

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1020

- Edited for clarity who is responsible for collection of the first screen.
- Removed reference to practitioner's manual. The practitioner's manual is a large document (more than 100 pages) that details all aspects of the program and provides information about each of the 40+ conditions on the panel. There are only a few directives within the practitioner's manual that need to be retained within the Oregon Administrative Rules. The Northwest Regional Newborn Bloodspot Screening (NWRNBS) Program would like the flexibility to update the practitioner's manual as information changes, without having to go through the rule making process. When changes are needed to the directives that will remain in rule, the program will follow the rule making/editing process.
- Removed statement on how the second- or third- part of the collection kit should be given to the responsible entity. This does not need to be detailed in rule.

CHANGES TO RULE:

333-024-1020
Newborn Screening: Persons Responsible for Ensuring that First Specimens are Collected and Submitted
(1) The following, in order of priority, are responsible for ensuring that first specimens are collected and submitted in accordance with this rule:¶
(a) ~~H~~Facilities (hospitals ~~and~~, freestanding birthing centers, or health care clinics), if the infant is born at the ~~hospital or freestanding birthing center.¶~~
~~(b) A facility or practitioner~~is location.¶
(b) A facility or practitioner who assisted with delivery or is responsible for the infant's medical care ~~soon after birth~~within the first 48 hours of life.¶
(c) Parents or legal guardians of the infant when the birth is unattended by a practitioner.¶
(2) The persons described in section (1) of this rule must ensure that specimens are collected within the time frames and in the manner described in OAR 333-024-1030 to 333-024-1040~~, and in accordance with the instructions provided by the Oregon State Public Health Laboratory available in the Oregon Newborn Bloodspot Screening Practitioner's Manual (Practitioner's Manual), 12th Edition; 2022 found at www.healthoregon.org/nbs, unless the infant is exempt pursuant to OAR 333-024-1050. ¶~~
~~(3) A person who collects and submits the first specimen from a two-part or three-part collection kit must provide the remaining specimen card(s) to the person described in OAR 333-024-1025 who has the responsibility for ensuring that the second specimen is collected and, when applicable, the third specimen.~~
Statutory/Other Authority: ORS 413.014, 433.285, 431A.750
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1025

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1025

- Removed reference to practitioner's manual. Ensure critical processes for newborn screening remain in rule to be enforceable, if needed. See summary of OAR 333-024-1020 for details.

CHANGES TO RULE:

333-024-1025
Newborn Screening: Persons Responsible for Ensuring that Second, Third and Repeat Specimens are Collected and Submitted
(1) The following, in order of priority, are responsible for ensuring that the second specimens, and when applicable, third or repeat specimens, are collected and submitted in accordance with this rule:¶
(a) A facility or practitioner responsible for the care of an infant at any time during the first six months of life. ¶
(b) A parent or legal guardian.¶
(2) The persons described in section (1) of this rule must ensure that specimens are collected within the timeframes and in the manner described in OAR 333-024-1030 to 333-024-1040~~, and in accordance with the instructions provided by the Oregon State Public Health Laboratory available in the Oregon Newborn Bloodspot Screening Practitioner's Manual (Practitioner's Manual), 12th Edition; 2022 found at www.healthoregon.org/nbs, unless the infant is exempt pursuant to OAR 333-024-1050~~. ¶
(3) A person who is responsible for collecting and submitting the second or third specimen must either obtain the remaining specimen card(s) from the person who collected and submitted the first specimen or obtain a single specimen card from the Oregon State Public Health Laboratory as described in OAR 333-024-1100.
Statutory/Other Authority: ORS 413.014, 433.285, 431A.750
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1030

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1030

- Edited to match the protocol for premature babies (additional collections at 1 month of age)
- Removed early discharge and transfusion details on specimen collection. These are subject to change and are covered under the requirement to collect additional specimens if requested by the Oregon State Public Health Laboratory (OSPHL).

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) ~~Repeat specimens shall be collected if requested by the Oregon State Public Health Laboratory.¶~~
~~(2~~Premature (babies born at <34 weeks gestation age) ~~F~~or ~~an infant discharged from a hospital or freestanding birthing center before 24 hours of age:¶~~
~~(a) The first specimen shall be collected just prior to discharge from the facility. ¶~~
~~(b) The second specimen shall be collected between 10 and 14 days~~low birth weight babies (babies born weighing <2000 grams) require an additional specimen collection at approximately one month of age. ¶
(~~c~~d) ~~R~~Additional, repeat specimens shall be collected if requested by the Oregon State Public Health Laboratory~~. ¶~~
~~(3) For an infant requiring admission to a neonatal intensive care unit: ¶~~
~~(a) A first specimen shall be collected at 24 hours of age or prior to transfusion (if transfusion occurs before 24 hours of age). ¶~~
~~(b) A second specimen shall be collected as follows:¶~~
~~(A) On infants who were transfused prior to 24 hours of age a second specimen shall be collected between 48 and 72 hours of age.¶~~
~~(B) On infants who were not transfused prior to 24 hours of age a second specimen shall be collected between 10 and 14 days of age.¶~~
~~(c) A third specimen shall be collected on these infants at approximately one month after birth, but not before 28 days, regardless of whether they still reside in the NICU or have been discharged.¶~~
~~(d) Repeat specimens shall be collected and submitted to~~ and submitted according to the timeline identified by the Oregon State Public Health Laboratory~~ at their request~~.¶
(4~~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 413.014, 433.285, 431A.750
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1040

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1040

- Removed reference to practitioner's manual. Ensure critical processes for newborn screening remain in rule to be enforceable, if needed. See summary of OAR 333-024-1020 for details.
- Edited to provide clarity on completion of the requisition form (kit)
- Edited to provide clarity on the timeline requirements for receipt of specimen at the Oregon State Public Health Laboratory (OSPHL) after collection.

CHANGES TO RULE:

333-024-1040
Newborn Screening: Manner of 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 ~~instructions p~~OAR 333-024-1030.¶
(2) Provide~~d by~~ the Oregon State Public Health Laboratory~~,~~ w~~hich can be viewed in the Oregon Newborn Bloodspot Screening Practitioner's Manual (Practitioner's Manual), 12th Edition; 2022 found at www.healthoregon.org/nbs.~~¶
~~(2) Provide the Oregon State Public Health Laboratory with~~ith complete, accurate, and legible demographic information as requested on the demographics portion of the kit, which includes information that identifies the individual~~or individuals~~(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 ~~within 24 hours of collection and drying in accordance with the shipping instructions provided by the Oregon State Public Health Laboratory, which can be viewed in the Oregon Newborn Bloodspot Screening Practitioner's Manual (Practitioner's Manual), 12th Edition; 2022 found at www.healthoregon.org/nbs~~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.
Statutory/Other Authority: ORS 413.014, 433.285, 431A.750
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1060

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1060

- Edited to provide clarity on the process for recollection of unsuitable specimens.; who is responsible and the timelines.

CHANGES TO RULE:

333-024-1060
Newborn Screening: Improperly Collected Specimens
(1) If a specimen contains insufficient blood, is contaminated or ~~is~~ found to be otherwise unsuitable for testing, the Oregon State Public Health Laboratory will notify the ~~individual or individuals~~practitioner(s) or facility identified as responsible for collecting and submitting the specimen ~~in~~ (OAR 333-024-1020 and OAR 333-024-1025) that the specimen submitted is unsuitable for testing and that a repeat specimen must be collected~~ and submitted to the Oregon State Public Health Laboratory in accordance with OAR 333-024-1030 and OAR 333-024-1040, no later than 10 calendar days from receiving notice. ¶~~
~~(2) If the Oregon State Public Health Laboratory does not receive the repeat specimen as specified in section (1) of this rule, the Oregon State Public Health Laboratory will send a second notice to the individual or individuals identified as responsible for patient care in.~~¶
(2) The practitioner(s) or facility identified as responsible for collecting and submitting the specimen shall collect and submit the repeat specimen to the Oregon State Public Health Laboratory in accordance with OAR 333-024-10~~2~~30 and OAR 333-024-10~~25~~40 no later than seven calendar days from receiving the notice.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1070

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1070

- Edited to match current testing practices (assay, algorithms, instruments, etc)

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 ~~S~~screening specimens will be tested for the medical conditions listed in ~~sub~~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) ~~with secondary assay of~~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: ~~Primary screening by f~~Fluorescent immunoassay ~~for quantification~~ of immunoreactive trypsinogen with ~~second tier PCR amplification followed by allele-specific probe hybridization~~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 ~~the presence or absence of detectable~~ galactose uridyl-transferase ~~in erythrocytes~~activity and galactose levels.¶
(8) Sickle cell anemia and other hemoglobin disorders. Method: ~~Primary screening for sickling hemoglobin by isoelectric focusing and confirmation by high performance~~Electrophoresis and liquid chromatography to detect hemoglobin variants.¶
(9) Severe combined immunodeficiency disease (SCID). Method: PCR to detect ~~the absence or presence of~~ T-cell receptor excision circles.¶
(10) Lysosomal storage diseases. Method: ~~Quantitative m~~Measurement of enzyme ~~levels~~activity by tandem mass spectrometry with ~~second tier for specific analytes using tandem mass spectrometry or DNA sequencing~~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 ~~presence or absence of the SMN1 gene. ¶~~
~~(12) Beginning on or before January 1, 2023, Newborn Screening specimens will also be tested for X-linked Adrenoleukodystrophy (X-ALD). Method: tandem mass spectrometry.~~ deletion of exon 7 in SMN1 gene.¶
(1~~3~~2) 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 413.014, 433.285, 431A.750
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1080

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1080

- Added language to include reporting of confirmatory test results to the Oregon State Public Health Laboratory (OSPHL) by the practitioner within two weeks of final diagnosis determination.
- Added language to include the reporting of newborn screening conditions that were not detected during newborn bloodspot screening but were detected through other testing.

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 ~~ent~~facility or ~~individual~~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 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 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 ~~will~~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 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1090

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1090

- Changed retention of specimens to 12 months, due to space and storage limitations within the laboratory.

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 1~~8~~2 months after which the specimen is destroyed using a secure method, except as necessary to comply with section (1) of this rule. The destruction may occur at any time in the month following the specimen's 1~~8~~2-month retention limit.¶
(5) Specimens retained for longer than 1~~8~~2 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 413.014, 433.285, 431A.750
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

AMEND: 333-024-1100

NOTICE FILED DATE: 09/30/2024

RULE SUMMARY: Amend OAR 333-024-1100

- Edited to include language that a fee exemption will be granted if the individual requesting the exemption is unable to pay the fee.

CHANGES TO RULE:

333-024-1100
Newborn Screening: Ordering Specimen Collection Kits and Fees
(1) Kits for collecting specimens for newborn screening must be ordered from the Oregon State Public Health Laboratory.¶
(2) Orders must be accompanied by payment for the full amount of the order, based on the fees in section (3) of this rule, or fee exemption request based on section (4) of this rule. Refunds will not be issued for specimens that cannot be used for testing due to an error in the collection or transport of the specimen or incomplete patient information.¶
(3) The fees for newborn screening specimen collection kits include the cost of newborn screening services provided by the Oregon State Public Health Laboratory and are as follows:¶
(a) $100 per one-specimen kit.¶
(b) $175 per two-specimen kit.¶
(c) $175 per three-specimen kit.¶
(4) No Oregon infant shall be denied newborn screening because of the inability of the infant's parent or legal guardian to pay the fee for a test or kit:¶
(a) A practitioner, parent, or legal guardian requesting an exemption from fees shall complete a form, available from the Oregon Health Authority, ~~attes~~demonstrating that the ~~family income would qualify them for Oregon WIC and the mother has no health insuranc~~individual requesting the exemption is unable to pay the fee.¶
(b) Exemption forms must be received by the Oregon State Public Health Laboratory within 30 calendar days from the day the infant was born.¶
(c) Upon receipt of a form requesting a fee exemption and confirmation through Oregon Health Authority records that exemption criteria are met, the Oregon Health Authority will grant an exemption~~, issue a refund check, or replace the kit. The Oregon Health Authority~~ and will issue a refund check or ~~the~~provide or replace~~ment~~ the kit to the payer of record.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295