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OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Update and clarify Newborn Screening rule language and rule organization

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RULES:
333-024-0205, 333-024-0210, 333-024-0215, 333-024-0220, 333-024-0225, 333-024-0230, 333-024-0231, 333-024-0232, 333-024-0235, 333-024-0240, 333-024-1000, 333-024-1010, 333-024-1020, 333-024-1025, 333-024-1030, 333-024-1040, 333-024-1050, 333-024-1060, 333-024-1070, 333-024-1080, 333-024-1090, 333-024-1100, 333-024-1110

REPEAL: 333-024-0205

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal OAR 333-024-0205 through 333-024-0235: Due to reorganization and significant amount of revision to the current rule text, the Authority is repealing current administrative rules 333-024-0205 through 333-024-0235 and replacing them with administrative rules 333-024-1000 through 333-024-1110.

CHANGES TO RULE:

~~333-024-0205~~
~~Laboratory Testing: Definitions~~
~~As used in these rules:¶~~
~~(1) "Colorimetric assay" means a qualitative laboratory procedure to detect the presence of the enzyme biotinidase which, when present, produces a color change.¶~~
~~(2) "Congenital disorder" means a condition that is present at birth. This includes but is not limited to cystic fibrosis, endocrine, hemoglobinopathy, metabolic, and immunodeficiency disorders.¶~~
~~(3) "County health department" means those county and district health departments formed under ORS 431.416.¶~~
~~(4) "Cystic fibrosis" means a disorder, usually due to a single enzyme deficiency of genetic origin, in which the individual is completely or partially unable to produce a functioning transmembrane conductance regulator protein that results in progressive multi-organ dysfunction and the accumulation of trypsinogen in the blood during the newborn period.¶~~
~~(5) "Diagnostic laboratory" means a laboratory approved to perform testing for the congenital disorders listed herein to rule out a specific disorder suspected by newborn screening or for screening infants older than six~~

months of age.¶
(6) "Division" means the Public Health Division of the Oregon Health Authority.¶
(7) "Dried blood specimen" means a blood specimen obtained from an infant by means of capillary-puncture or skin-puncture (heel stick), not by means of venipuncture or any other method, which is placed on special filter paper kits and allowed to air dry.¶
(8) "Endocrine disorders" means disorders related to hormone production or utilization resulting in abnormal growth and development, fluid and electrolyte imbalance or other disturbance, including hypothyroidism and congenital adrenal hyperplasia.¶
(9) "Fluorescent immunoassay" means a competitive binding or direct assay creating specific antibody-antigen reactions to detect thyroxin, thyroid stimulating hormone, 17-alpha-hydroxyprogesterone and immunoreactive trypsinogen.¶
(10) "Fluorescent spot test" means a biochemical laboratory test procedure utilizing certain naturally occurring enzymes in erythrocytes and added chemicals used to detect galactose in blood specimens as a screening test for galactosemia. It is described occasionally in the scientific literature as a "Hill test."¶
(11) "Hemoglobinopathy" means one of a group of disorders which results in abnormal structure and function of hemoglobin that leads to variable degrees of anemia, hemolysis and other complications. These include sickle cell disease and other clinically significant hemoglobinopathies.¶
(12) "High performance liquid chromatography" means the utilization of a separation column to detect various hemoglobin proteins based on their retention time.¶
(13) "Immunodeficiency disorders" means a group of disorders in which the immune system is not functioning properly. This includes severe combined immunodeficiency (SCID), a primary immune disorder characterized by a defect in T-cell production and function. SCID is also described as the "bubble boy disease".¶
(14) "Isoelectric focusing" means a laboratory procedure in which protein, hemoglobin in blood, is subjected to an electric field in a gel medium with a gradient pH causing it to migrate to its pH and isoelectric point, revealing specific patterns for each type of hemoglobin.¶
(15) "Kit" means any or all parts of the combined materials, laboratory slips, tubes, mailing containers, or other components provided by the state public health laboratory for the purposes of collection or submission of specimens for laboratory tests.¶
(16) "Metabolic disorders" means those disorders of intermediary metabolism and hormone production, regulation, or utilization in which the individual is completely or partially incapable of normal metabolism of biotin, single amino acids, galactose, or fatty acids resulting in the abnormal accumulation of those and other metabolites in the blood. These include phenylketonuria and medium-chain acyl-CoA dehydrogenase deficiency.¶
(17) "Newborn screening panel" means those disorders identified by the Oregon Health Authority in these rules for which all infants shall be tested, except if the infant is being reared as an adherent to a religion the teachings of which are opposed to such testing.¶
(18) "Practitioner" means a person duly and regularly licensed by the proper authority to practice medicine, naturopathy or chiropractic or to be a nurse practitioner. For purposes of OAR 333-024-0215(1) only, this definition is extended to include the licensed or unlicensed person who takes responsibility for delivery or the health care of the baby; or being none, the person responsible for the health care of the mother prior to birth of the baby.¶
(19) "Precision" of an assay means a quantitative measure of reproducibility of a laboratory procedure in assaying a particular chemical under defined conditions. Examples include, but are not limited to, statistically determined values of standard deviations from the mean and coefficients of variation.¶
(20) "Sensitivity" of an assay means the lowest concentration or quantity of a particular chemical that can be reliably detected or measured by a laboratory assay procedure under defined conditions.¶
(21) "Specificity" of an assay means the accuracy with which a laboratory assay procedure can reliably identify or measure the quantity of a particular chemical to distinguish it from other related or unrelated chemicals under defined conditions.¶
(22) "Specimen for newborn screening" means a dried blood specimen from an infant submitted to the state public

~~health laboratory to detect congenital disorders included on the newborn screening test panel.¶~~
~~(23) "State public health laboratory" means the Oregon State Public Health Laboratory of the Public Health Division, 3150 NW 229th Avenue, Hillsboro, Oregon 97124.¶~~
~~(24) "Tandem mass spectrometry" means a laboratory procedure in which amino acids and acylcarnitines are detected and quantified in a sample taken from a dried blood spot.¶~~
~~(25) "These rules" means OAR 333-024-0205 through 333-024-0240.¶~~
~~(26) "TREC assay" means a DNA polymerase chain reaction method to detect T-cell receptor excision circles. An absence or reduction in TRECs can be used as an indicator for severe combined immunodeficiency or other primary immune deficiencies.~~
~~Statutory/Other Authority: ORS 431.310~~
~~Statutes/Other Implemented: ORS 433.285, 433.290, 433.295~~

REPEAL: 333-024-0210

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal OAR 333-024-0205 through 333-024-0235: Due to reorganization and significant amount of revision to the current rule text, the Authority is repealing current administrative rules 333-024-0205 through 333-024-0235 and replacing them with administrative rules 333-024-1000 through 333-024-1110.

CHANGES TO RULE:

~~333-024-0210~~
~~Testing for Metabolic Diseases: Infants Tested for Metabolic Diseases ¶~~

~~(1) Every infant born in Oregon on or after May 1, 2014, shall be tested for at least the following congenital disorders by the state public health laboratory:¶~~
~~(a) Cystic fibrosis (CF).¶~~
~~(b) Endocrine disorders:¶~~
~~(A) Congenital hypothyroidism (CH); and¶~~
~~(B) Congenital adrenal hyperplasia (CAH).¶~~
~~(c) Galactosemia (GALT).¶~~
~~(d) Hemoglobin disorders:¶~~
~~(A) Sickle cell disease (Hb S/S);¶~~
~~(B) Sickle cell/beta thalassemia (Hb S/A); and¶~~
~~(C) Sickle cell/hemoglobin C disease (Hb S/C).¶~~
~~(e) Metabolic disorders:¶~~
~~(A) Amino acid disorders:¶~~
~~(i) Homocystinuria (HCY);¶~~
~~(ii) Phenylketonuria (PKU); and¶~~
~~(iii) Tyrosinemia (TYR).¶~~
~~(B) Biotinidase deficiency;¶~~
~~(C) Fatty acid oxidation disorders:¶~~
~~(i) Carnitine uptake defect (CUD);¶~~
~~(ii) Carnitine/acylcarnitine translocase deficiency (CT);¶~~
~~(iii) Carnitine palmitoyl transferase deficiency (CPT), Types I and II;¶~~
~~(iv) Glutaric acidemia, Type II (GA-II);¶~~
~~(v) Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency (LCHAD);¶~~
~~(vi) Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);¶~~
~~(vii) Short-chain acyl-CoA dehydrogenase deficiency (SCAD);¶~~
~~(viii) Trifunctional protein deficiency (TFP); and¶~~
~~(ix) Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD).¶~~
~~(D) Organic acid disorders:¶~~
~~(i) Beta-ketothiolase deficiency (BKT);¶~~
~~(ii) Glutaric acidemia, Type I (GA-I);¶~~
~~(iii) Isobutryl-CoA dehydrogenase deficiency (IBG);¶~~
~~(iv) Isovaleric acidemia (IVA);¶~~
~~(v) Malonic aciduria (MAL);¶~~
~~(vi) Maple syrup urine disease (MSUD);¶~~
~~(vii) Methylmalonic acidemia (MMA);¶~~
~~(viii) Propionic acidemia (PA);¶~~
~~(ix) 2-Methyl-3-hydroxybutyryl CoA dehydrogenase deficiency (2M3HBA);¶~~
~~(x) 2-Methylbutyryl CoA dehydrogenase deficiency (2MBG);¶~~

~~(xi) 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG);¶~~
~~(xii) 3-methylcrotonyl-CoA carboxylase deficiency (3-MCC);¶~~
~~(xiii) 3-methylglutaconyl-CoA hydratase deficiency (3MGA); and¶~~
~~(xiv) Multiple carboxylase deficiency (MCD).¶~~
~~(E) Urea Cycle Disorders:¶~~
~~(i) Arginase deficiency (ARG);¶~~
~~(ii) Argininosuccinate lyase deficiency (ASA); and¶~~
~~(iii) Citrullinemia, Type I (CIT I).¶~~
~~(f) Severe combined immunodeficiencies (SCID).¶~~
~~(2) In addition, every infant born in Oregon on or after October 1, 2018, shall be tested for the following lysosomal storage disorders by the state public health laboratory:¶~~
~~(a) Fabry (alpha-galactosidase A deficiency);¶~~
~~(b) Gaucher (glucocerebrosidase deficiency);¶~~
~~(c) Mucopolysaccharidosis Type I (MPS I); and¶~~
~~(d) Pompe (glycogen storage disease Type II).~~
~~Statutory/Other Authority: ORS 433.285~~
~~Statutes/Other Implemented: ORS 433.285~~

REPEAL: 333-024-0215

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal OAR 333-024-0205 through 333-024-0235: Due to reorganization and significant amount of revision to the current rule text, the Authority is repealing current administrative rules 333-024-0205 through 333-024-0235 and replacing them with administrative rules 333-024-1000 through 333-024-1110.

CHANGES TO RULE:

~~333-024-0215~~
~~Testing for Metabolic Diseases: Person Responsible for Submitting Specimens for Newborn Screening Testing~~
~~(1)(a) The person responsible for assuring that specimens are submitted for testing the infant for congenital disorders shall be in order of responsibility:¶~~
~~(A) The hospital, freestanding birthing center, or other health care facility licensed under ORS Chapter 441, or if the infant is not in such a facility;¶~~
~~(B) The practitioner, or if no practitioner is in attendance;¶~~
~~(C) The parent or legal guardian.¶~~
~~(b) For purposes of this section and OAR 333-024-0225, in the case of infants entering a health care facility before 48 hours of age as a result of transfer from another health care facility or from out-of-hospital birth, the receiving health care facility shall be responsible for the timely collection of specimens.¶~~
~~(2) The state public health laboratory may perform tests for certain congenital disorders for patients from outside Oregon.~~
~~Statutory/Other Authority: ORS 433.285~~
~~Statutes/Other Implemented: ORS 433.285~~

REPEAL: 333-024-0220

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal OAR 333-024-0205 through 333-024-0235: Due to reorganization and significant amount of revision to the current rule text, the Authority is repealing current administrative rules 333-024-0205 through 333-024-0235 and replacing them with administrative rules 333-024-1000 through 333-024-1110.

CHANGES TO RULE:

~~333-024-0220~~
~~Testing for Metabolic Diseases: Manner of Submitting Specimens ¶~~

~~(1) All specimens submitted to the state public health laboratory for testing for congenital disorders shall be collected using kits available from the state public health laboratory according to procedures, protocols, and shipping instructions specified in the Practitioner's Manual located on the website maintained by the state public health laboratory, www.healthoregon.org/nbs.¶~~
~~(2) Specimens collected for newborn screening testing shall be sent to the state public health laboratory within 24 hours of collection.¶~~
~~(3) Specimens shall be transmitted to the state public health laboratory in such a manner that they are received by the laboratory as soon as possible after collection, preferably within 24 to 48 hours.~~
~~Statutory/Other Authority: ORS 433.285~~
~~Statutes/Other Implemented: ORS 433.285~~

REPEAL: 333-024-0225

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal OAR 333-024-0205 through 333-024-0235: Due to reorganization and significant amount of revision to the current rule text, the Authority is repealing current administrative rules 333-024-0205 through 333-024-0235 and replacing them with administrative rules 333-024-1000 through 333-024-1110.

CHANGES TO RULE:

~~333-024-0225~~
~~Testing for Metabolic Diseases: Time of Collecting Specimens for Testing Infants ¶~~

~~A specimen for newborn screening testing shall be collected between 24 and 48 hours after birth from every infant surviving more than two days, as follows:¶~~
~~(1) In the case of infants born outside a hospital or other health care facility and of infants who will remain in the hospital or health care facility for 24 hours or more, a specimen shall be collected as soon after 24 hours as possible but before 48 hours of age. A second specimen shall be collected between 10 and 14 days but before one month of age.¶~~
~~(2) In the case of infants discharged from a hospital or other health care facility before 24 hours of age, a specimen shall be collected just prior to discharge from the facility, and a second specimen shall be collected from such infants 10 to 14 days after birth.¶~~
~~(3) In the case of infants who are preterm, low birth weight or ill and are admitted to a special care baby unit or neonatal intensive care unit, a specimen shall be collected at 24 hours of age or prior to transfusion if transfusion occurs before 24 hours of age, a second specimen collected between 10 and 14 days of age and a third specimen collected at 28 days of life.¶~~
~~(4) In the case of infants up to six months of age entering the care of a practitioner and for whom the screening status is unknown or cannot be determined, a specimen shall be collected within two weeks of the first visit to the practitioner and sent to the state public health laboratory for screening.¶~~
~~(5) In the case of an infant over six months of age entering the care of a practitioner and for whom the screening status is unknown or cannot be determined, the infant shall be evaluated by the practitioner.~~
~~Statutory/Other Authority: ORS 433.285~~
~~Statutes/Other Implemented: ORS 433.285~~

REPEAL: 333-024-0230

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal OAR 333-024-0205 through 333-024-0235: Due to reorganization and significant amount of revision to the current rule text, the Authority is repealing current administrative rules 333-024-0205 through 333-024-0235 and replacing them with administrative rules 333-024-1000 through 333-024-1110.

CHANGES TO RULE:

~~333-024-0230~~
~~Testing for Metabolic Diseases: Methods of Testing ¶~~

~~Infants shall be tested for the congenital disorders on the newborn screening test panel by the methods established in this section, performed on dried blood specimens. ¶~~
~~(1) Amino acid and urea cycle disorders: Quantitative measurement of amino acids by tandem mass spectrometry. ¶~~
~~(2) Biotinidase deficiency: Colorimetric or fluorometric assay for biotinidase activity.¶~~
~~(3) Congenital adrenal hyperplasia: Fluorescent immunoassay of 17-alpha hydroxyprogesterone (17-OHP).¶~~
~~(4) Congenital hypothyroidism: Fluorescent immunoassay of thyroxine (T4) with secondary assay of thyroid stimulating hormone (thyrotropin or TSH).¶~~
~~(5) Cystic fibrosis: Primary screening by fluorescent immunoassay for the presence or absence of immunoreactive trypsinogen (IRT) with second tier testing for cystic fibrosis genotypes.¶~~
~~(6) Fatty acid oxidation disorders: Quantitative measurement of acylcarnitines by tandem mass spectrometry.¶~~
~~(7) Galactosemia: Fluorescent immunoassay for the presence or absence of detectable galactose uridyl transferase in erythrocytes and galactose.¶~~
~~(8) Hemoglobinopathies: Primary screening by isoelectric focusing and confirmation by high performance liquid chromatography to detect hemoglobin variants.¶~~
~~(9) Severe combined immunodeficiencies: Polymerase chain reaction (PCR) to detect the absence or presence of T-cell receptor excision circles (TREC assay).¶~~
~~(10) Lysosomal storage disorders: Measurement of the activity of lysosomal storage enzymes by quantitative fluorometric enzymatic activity assay or tandem mass spectrometry.~~
~~Statutory/Other Authority: ORS 433.285~~
~~Statutes/Other Implemented: ORS 433.285~~

REPEAL: 333-024-0231

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal OAR 333-024-0205 through 333-024-0235: Due to reorganization and significant amount of revision to the current rule text, the Authority is repealing current administrative rules 333-024-0205 through 333-024-0235 and replacing them with administrative rules 333-024-1000 through 333-024-1110.

CHANGES TO RULE:

~~333-024-0231~~
~~Testing for Metabolic Diseases: Procedures for Follow-Up of Specimens Administered Too Early, Improperly Collected, and Those That Show Abnormal Results ¶~~

~~(1) Improperly collected specimens. Where specimens contain insufficient blood, are contaminated or are found to be otherwise unsuitable for testing (refer to Newborn Screening Specimen Collection in the Practitioner's Manual located on the website maintained by the state public health laboratory, www.healthoregon.org/nbs), a repeat specimen will be requested. A letter will be mailed or faxed by the state public health laboratory to the primary care provider caring for the infant within two to four working days after receiving the sample. If there is no response after 10 working days, the state public health laboratory will send a follow-up letter.¶~~
~~(2) Specimens that show anomalous results. The state public health laboratory will refer anomalous results to the screening program's medical consultants. Reports of anomalous findings will be made by the medical consultants to individual practitioners. Requests for repeat or diagnostic specimens will be made through the medical consultants by letter or telephone call, depending upon the urgency of the situation. The practitioner will inform the state public health laboratory of the final resolution or confirmation of each case to ensure timely and complete follow-up.~~
~~Statutory/Other Authority: ORS 433.285~~
~~Statutes/Other Implemented: ORS 433.285~~

REPEAL: 333-024-0232

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal of OAR 333-024-0232 “Newborn Screening: Testing for Metabolic Diseases: Demographic Data”: Removal of outdated language.

CHANGES TO RULE:

~~333-024-0232~~
~~Testing for Metabolic Diseases: Demographic Data~~
~~The state public health laboratory will maintain demographic data records on infants to be used for the purposes of monitoring statistical trends and screening practices in hospitals, birthing facilities, and individual practices. This monitoring will enable the state public health laboratory to:¶~~
~~(1) Identify facilities and health care providers that submit inadequate specimens;¶~~
~~(2) Evaluate the overall effectiveness of the screening program;¶~~
~~(3) Monitor and ensure timely and complete follow-up; and¶~~
~~(4) Ensure that the most effective newborn screening program for the State of Oregon will be maintained.~~
~~Statutory/Other Authority: ORS 433.285, 433.290~~
~~Statutes/Other Implemented: ORS 433.285, 433.290~~

REPEAL: 333-024-0235

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Repeal OAR 333-024-0205 through 333-024-0235: Due to reorganization and significant amount of revision to the current rule text, the Authority is repealing current administrative rules 333-024-0205 through 333-024-0235 and replacing them with administrative rules 333-024-1000 through 333-024-1110.

CHANGES TO RULE:

~~333-024-0235~~
~~Testing for Metabolic Diseases: Religious Exemption from Newborn Screening Testing~~
~~(1) A religious exemption from testing for congenital disorders may be claimed if the infant is being reared as an adherent to a religion the teachings of which are opposed to such testing.¶~~
~~(2)(a) In the event a religious exemption is claimed from the requirements for testing for congenital disorders, the person otherwise responsible for submitting the specimen for testing shall be responsible for submitting a completed statement to the state public health laboratory signed by the infant's parent or legal guardian using the following language:¶~~
~~STATEMENT OF RELIGIOUS EXEMPTION¶~~
~~The undersigned parent or legal guardian of_____, born on_____, states that this child is exempt from newborn screening testing for detection of congenital disorders in that the child is being reared as an adherent to a religion the teachings of which are opposed to such testing. _____¶~~
~~(Signature of parent or legal guardian)¶~~
~~_____¶~~
~~(Date)¶~~
~~(b) The completed statement in subsection (a) of this section may be made on the reverse side of the original specimen identification form which otherwise accompanies the dried blood specimen used to test the infant for congenital disorders.~~
~~Statutory/Other Authority: ORS 431.180~~
~~Statutes/Other Implemented: ORS 433.285~~

AMEND: 333-024-0240

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Amendment to OAR 333-024-0240 “Fees for Tests Performed in the State Laboratory”: Language about ordering newborn screening collection kits, newborn screening fees and newborn fee exemptions moved to OAR 333-024-1100 “Newborn Screening: Ordering Specimen Collection Kits and Fees” and language added to clarify that remaining fee information pertains to communicable disease testing. There are no fee changes.

CHANGES TO RULE:

333-024-0240
Fees for Tests Performed in the State Laboratory ¶

(1)(a) The person responsible for submitting communicable disease specimens for those tests performed on specimens received in the state public health laboratory on or after March 1, 2014, shall pay a test fee upon billing by the Authority, in accordance with the August 2013 Division of Medical Assistance Programs Fee for Service Fee Schedule.¶
(b) Public and private non-profit agencies may apply for a reduction or waiver of the test fees stated in subsection (1)(a) of this rule. Reduction or waiver requests must be sent to the director of the state public health laboratory and be accompanied by proof of non-profit status. Requests should include the estimated number and type of tests anticipated per year. The decision to reduce or waive fees is discretionary with the state public health laboratory.¶
(2) ~~For Oregon practitioners, newborn screening test kits purchased by prepayment on or after April 1, 2018:¶~~
~~(a) $59 per one-specimen kit; or¶~~
~~(b) $80 per two-specimen kit; or¶~~
~~(c) $80 per three-specimen kit (neonatal intensive care unit (NICU) and special baby care unit (SBCU) use only).¶~~
~~(3)~~ Specimens which are submitted in an inadequate quantity or any unsatisfactory condition shall be subject to the fee of $5 per repeat specimen except for newborn screening specimens, which may be subject to a charge of $59 per specimen. Additional specimens from the same infant or patient specifically required or requested by the state public health laboratory, but not because the original specimen was inadequate or unsatisfactory, shall be exempt from additional fees.¶
(~~4) Kits requested for newborn screening shall be prepaid by the requestor in the amount as specified in section (2) of this rule. Kit requests must be accompanied by payment for the full amount of the order.¶~~
~~(5) No Oregon infant shall be denied newborn screening because of inability of the infant's parent or legal guardian to pay the fee for a test or kit:¶~~
~~(a) A practitioner or parent or legal guardian requesting exemption from fees shall complete a statement indicating the following:¶~~
~~STATEMENT OF FEE EXEMPTION¶~~
~~The undersigned parent or legal guardian of_____, born on_____, attests that they are unable to pay the fee/charge for labor and delivery services and for newborn screening because of lack of sufficient funds, insurance or Medicaid coverage. _____¶~~
~~(Signature of parent or legal guardian)¶~~
~~_____¶~~
~~(Date)¶~~
~~(b) The above completed statement shall be completed by the parent or legal guardian on the original specimen identification form which accompanies the dried blood specimen used to test the infant for congenital disorders.¶~~
~~(c) Exemption statements must be received by the state public health laboratory within 90 days of the first newborn screening.¶~~
~~(d) Upon receipt of the statement in subsection (5)(a) of this rule, and confirmation of Oregon Health Authority records, the Oregon Health Authority will issue a refund check. The state public health laboratory will issue a~~

~~refund check to the payer of record. The state public health laboratory will replace kits, damaged or unused, which are returned to the laboratory.¶~~

~~(6~~3) For tests performed for or on behalf of Oregon state or local government agencies, as determined by the administrator to have a significant public health impact, a lesser fee, calculated to recover costs, may be charged.¶

(~~7~~4) All specimens submitted to the state public health laboratory shall be collected according to procedures, protocols, and shipping instructions specified on the Oregon State Public Health Laboratory's website.

Statutory/Other Authority: 433.285, ORS 431A.750

Statutes/Other Implemented: 433.285, ORS 431A.750

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

NOTE: Tables or attachments referenced are not included in this document. You may view the tables at the following link: https://secure.sos.state.or.us/oard/view.action?ruleNumber=333-024-0240

ADOPT: 333-024-1000

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Adoption of OAR 333-024-1000 “Newborn Screening: Purpose”: Language is being added to clarify the purpose of the Newborn Screening Program and distinguish what newborn screening testing the rules apply to.

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, except for those whose parents opt out because of their religious beliefs, are required to be screened. 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, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

ADOPT: 333-024-1010

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1010 “Newborn Screening: Definitions”: Previously located under OAR 333-024-0205 “Laboratory Testing: Definitions”: Language is being updated to revise and clarify definitions of terminology used throughout the administrative rules.

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 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) "Hospital" has the meaning given that term in ORS 442.015¶
(6) "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) "Low birth-weight" means an infant that weighs less than 2500 grams at birth.¶
(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 mother prior to the infant being born in Oregon.¶
(12) "Premature" means an infant born more than three weeks prior to the start of the 37th week of pregnancy.¶
(13) "Preterm" means an infant born prior to the start of the 37th week of pregnancy.¶
(14) "Residual specimen" means the part of the specimen that is left after newborn screening testing activities are complete. ¶
(15) "Second tier testing" means additional testing performed for the purpose of reducing the number of false-positive results reported for a given disorder. ¶
(16) "Specimen" means a blood specimen obtained from an infant by means of capillary-puncture or skin-puncture (heel stick) and is placed on a special filter paper kit and allowed to air dry.¶
(17) "These rules" means OAR 333-024-1000 through 333-024-1110.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285

Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

ADOPT: 333-024-1020

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1020 “Newborn Screening: Persons Responsible for Ensuring that First Specimens are Collected and Submitted”: Previously located under OAR 333-024-0215 “Testing for Metabolic Diseases: Person Responsible for Submitting Specimens for Newborn Screening Testing”: Language is being updated to clarify roles and responsibilities for persons responsible for ensuring that first specimens are collected and submitted, and distinguish these from the roles and responsibilities of persons responsible for ensuring that second, third and repeat specimens are collected and submitted (now delineated in OAR 333-024-1025).

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) Hospitals and freestanding birthing centers, if the infant is born at the hospital or freestanding birthing center.¶
(b) A facility or practitioner responsible for the infant's medical care soon after birth.¶
(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 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 Practitioner Manual, 10th Edition; 2018 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, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

NOTE: Tables or attachments referenced are not included in this document. You may view the tables at the following link: https://secure.sos.state.or.us/oard/view.action?ruleNumber=333-024-1020

ADOPT: 333-024-1025

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1025 “Newborn Screening: Persons Responsible for Ensuring that Second, Third and Repeat Specimens are Collected and Submitted”: Previously located under OAR 333-024-0215 “Testing for Metabolic Diseases: Person Responsible for Submitting Specimens for Newborn Screening Testing”: Language is being updated to clarify roles and responsibilities for persons responsible for ensuring that second, third and repeat specimens are collected and submitted, and distinguish these from the roles and responsibilities of persons responsible for ensuring that first specimens are collected and submitted (now delineated in OAR 333-024-1020).

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 Practitioner Manual, 10th Edition; 2018 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, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

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ADOPT: 333-024-1030

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1030 “Newborn Screening: Timing for Collecting Specimens”: Previously located under OAR 333-024-0225 “Testing for Metabolic Diseases: Time of Collecting Specimens for Testing Infants”: Language is being updated to clarify timing of specimen collection and the timing of third specimens for low birth-weight or ill infants.

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 but before one month of age.¶
(c) Repeat specimens shall be collected if requested by the Oregon State Public Health Laboratory.¶
(2) For 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 of age but before one month of age. ¶
(c) Repeat specimens shall be collected if requested by the Oregon State Public Health Laboratory. ¶
(3) For an infant who is preterm, low birth weight or ill requiring admission to a special care baby unit or 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 but before one month 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 the Oregon State Public Health Laboratory at their request.¶
(4) 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, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

ADOPT: 333-024-1040

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1040 “Newborn Screening: Manner of Submitting Specimens”: Previously located under OAR 333-024-0220 “Testing for Metabolic Diseases: Manner of Submitting Specimens”: Language is being updated to clarify how specimens are collected and are sent the Oregon State Public Health Laboratory (OSPHL).

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 provided by the Oregon State Public Health Laboratory, which can be viewed in the Oregon Practitioner Manual, 10th Edition; 2018 found at www.healthoregon.org/nbs.¶
(2) Provide the Oregon State Public Health Laboratory with information that identifies the individual or individuals 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 Practitioner Manual, 10th Edition; 2018 found at www.healthoregon.org/nbs.¶
(4) Ensure that specimens for newborn screening are sent via courier, express mail, or other timely delivery mechanism.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

NOTE: Tables or attachments referenced are not included in this document. You may view the tables at the following link: https://secure.sos.state.or.us/oard/view.action?ruleNumber=333-024-1040

ADOPT: 333-024-1050

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1050 “Newborn Screening: Religious Exemption from Newborn Testing”: Previously located under OAR 333-024-0235 “Testing for Metabolic Diseases: Religious Exemption from Newborn Screening Testing”: Language has been updated to clarify how to claim a religious exemption from newborn testing.

CHANGES TO RULE:

333-024-1050
Newborn Screening: Religious Exemption from Newborn Testing
(1) A parent may opt not to have their infant tested in accordance with these rules because of religious beliefs opposed to such testing. In order to claim such an exemption the parent must complete a Statement of Religious Exemption 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.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

ADOPT: 333-024-1060

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1060 “Newborn Screening: Improperly Collected Specimens”: Previously located under OAR 333-024-0231 “Testing for Metabolic Diseases: Procedures for Follow-Up of Specimens Administered Too Early, Improperly Collected, and Those That Show Abnormal Results”: Language has been updated to clarify the process around improperly collected specimen notification and the timeline for re-submission. Language regarding result reporting and follow-up moved to OAR 333-024-1080 “Newborn Screening: Result Reporting and Follow Up.”

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 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 OAR 333-024-1020 and 333-024-1025.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

ADOPT: 333-024-1070

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1070 “The Newborn Screening Panel and Methods of Testing”: Previously located under OAR 333-024-0230 “Testing for Metabolic Diseases: Methods of Testing” and OAR 333-024-0210 “Testing for Metabolic Diseases: Infants Tested for Metabolic Diseases”: Language has been updated to clarify the medical conditions tested in the Newborn Screening Panel, the testing method used and the identification of secondary conditions.

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 below, 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-methylglutaryl CoA lyase deficiency (HMG);¶
(F) Multiple carboxylase deficiency (MCD);¶
(G) Beta-ketothiolase deficiency (BKT);¶
(H) Glutaric acidemia, Type I (GA-I);¶
(I) Malonic acidemia (MAL);¶
(J) Isobutyryl-CoA dehydrogenase deficiency (IBD);¶
(K) 2-methylbutyryl CoA dehydrogenase deficiency (2MBC);¶
(L) 3-methylglutaconyl CoA hydratase deficiency (3MGH); and¶
(M) 2-methyl-3-hydroxybutyryl CoA dehydrogenase deficiency (2M3HBA).¶
(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.¶
(c) Amino acid disorders. Method: Quantitative measurement of amino acids by tandem mass spectrometry. ¶
(A) Argininosuccinate lyase deficiency (e.g. Arginosuccinic aciduria or ASA);¶
(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) Arginase deficiency (ARG).¶
(4) Endocrine disorders:¶
(a) Primary congenital hypothyroidism (CH). Method: Fluorescent immunoassay of thyroxine (T4) with secondary assay of 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 fluorescent immunoassay for the presence or absence of immunoreactive trypsinogen with second tier PCR testing for common cystic fibrosis genotypes.¶
(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 and galactose levels.¶
(8) Sickle cell anemia. Method: Primary screening for sickling hemoglobin by isoelectric focusing and confirmation by high performance 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: Measurement of the activity of lysosomal storage enzymes by quantitative fluorometric enzymatic activity assay or tandem mass spectrometry with second tier testing by tandem mass spectrometry, PCR, enzymatic assay or DNA sequencing.¶
(a) Pompe (glycogen storage disease Type II);¶
(b) Mucopolysaccharidosis Type I (MPS I);¶
(c) Fabry (alphagalactosidase A deficiency); and¶
(d) Gaucher (glucocerebrosidase deficiency).¶
(11) Newborn screening results may identify medical conditions, commonly referred to as "secondary conditions", that are not listed above. Any secondary condition that is identified during 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 for a secondary condition that is identified.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

ADOPT: 333-024-1080

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1080 “Newborn Screening: Result Reporting and Follow Up”: Previously located under OAR 333-024-0231 “Testing for Metabolic Diseases: Procedures for Follow-Up of Specimens Administered Too Early, Improperly Collected, and Those That Show Abnormal Results”: Language has been updated to address reporting of both normal and abnormal results to clarify who results are reported to and the responsibilities of those persons in regards to follow up care. Language regarding improperly collected specimens moved to OAR 333-024-1060 “Newborn Screening: Improperly Collected Specimens”.

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 form submitted with the specimens as required in OAR 333-024-1040(2); or¶
(b) The entity or individual that collected and submitted the specimen if no individual is identified on the form 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 report these test results to the Oregon State Public Health Laboratory.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

ADOPT: 333-024-1090

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Adoption of OAR 333-024-1090 “Newborn Screening: Use, Release, and Retention of Residual Specimens”: Language has been added to delineate the use, release and retention of residual newborn screening specimens.

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 one year 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 one-year retention limit.¶
(5) Specimens retained for longer than one year 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, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295

ADOPT: 333-024-1100

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Changes to sections of OAR 333-024-1100 “Newborn Screening: Ordering Specimen Collection Kits and Fees”: Previously located under OAR 333-024-0240 “Fees for Tests Performed in the State Laboratory”: Language associated with the ordering of newborn screening specimen collection kits, newborn screening fees and fee exemption were removed from OAR 333-024-0240 “Fees for Tests Performed in the State Laboratory”. In addition, language was added clarifying who qualifies for fee exemptions. There are no fee changes.

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. Refunds will not be issued for specimens that cannot be used for testing due to an error in the collection 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) $59 per one-specimen kit.¶
(b) $80 per two-specimen kit.¶
(c) $80 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, attesting that the family income would qualify them for Oregon WIC and the mother has no health insurance.¶
(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 issue a refund check or replace the kit. The Oregon Health Authority will issue a refund check or the replacement 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

ADOPT: 333-024-1110

NOTICE FILED DATE: 10/23/2018

RULE SUMMARY: Adoption of OAR 333-024-1110 “Newborn Screening: Failure to Comply”: Language added to describe what actions OSPHL may take if these rules are not complied with.

CHANGES TO RULE:

333-024-1110
Newborn Screening: Failure to Comply
The Oregon State Public Health Laboratory may refer a hospital, freestanding birthing center or a practitioner to the appropriate licensing entity for failure to comply with these rules.
Statutory/Other Authority: ORS 413.014, 431A.750, 433.285
Statutes/Other Implemented: ORS 433.285, 433.290, 433.295