NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Update of the Newborn Screening rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/23/2019 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.
A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later.
If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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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 a permanent rulemaking for administrative rules in chapter 333, division 24 pertaining to newborn screening. The proposed rulemaking updates the effective dates of rules to be in alignment with the effective dates of other rules in division 24 pertaining to newborn screening. Rules proposed in this rulemaking reference other rules in chapter 333, division 24 that were recently amended, effective November 25, 2019, and this rulemaking is necessary to ensure that any reference made to other rules is to the most recent version of the rules. In addition, the proposed rule amendments update language to reflect the definitions outlined in the rules.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:
OAR chapter 333, division 24: https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1239

FISCAL AND ECONOMIC IMPACT:
There is no anticipated fiscal impact associated with these proposed rule updates.

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) There is no anticipated cost of compliance impact to state agencies, units of local government or the public.
Newborn screening impacts hospitals, birthing centers, primary care providers, and midwives. The estimated number of small businesses is 962, comprised of midwives, naturopaths, osteopaths, medical doctors and clinics.

There is no anticipated cost of compliance.

No small businesses were involved in the development of this rule.

An Administrative Rule Advisory Committee was not consulted because this rulemaking will only update rule effective dates and rule language for clarity and has no substantive effect on clients.

RULES PROPOSED:
333-024-1060, 333-024-1080, 333-024-1110

RULE SUMMARY: Proposed change to OAR 333-024-1060 "Newborn Screening: Improperly Collected Specimens": Update of rule effective date to be in alignment with the effective date of rules referred to in the text (OAR 333-024-1020, 333-024-1025, 333-024-1030 and 333-024-1040) to ensure that the most recent version of the rules is referenced. No proposed changes to rule text.

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
RULE SUMMARY: Proposed amendments to OAR 333-024-1080 “Newborn Screening: Result Reporting and Follow-up”: Update of language for clarity and to reflect the definition outlined in OAR 333-024-1010(6) “kit”.

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 kit 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 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 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
AMEND: 333-024-1110

RULE SUMMARY: Proposed change to OAR 333-024-1110 “Newborn Screening: Failure to Comply”: Update of rule effective date to be in alignment with the effective date of the other rules in OAR 333-024 “Newborn Screening”. No proposed changes to rule text.

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