PROPOSED RULE MAKING

CR-102 (June 2012)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: State Board of Health

☐ **Preproposal Statement of Inquiry was filed as WSR ; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR ; or**
☒ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

Title of rule and other identifying information: (Describe Subject)
Chapter 246-650 WAC Newborn screening sample collections and health provider reporting.

Hearing location(s): Washington State Capitol Campus
Cherberg Building, Hearing Room 3
304 15th Avenue
Olympia, WA 98504

Date: 08/13/2014 Time: 1:30 PM

Date of intended adoption: 08/13/2014
(Note: This is **NOT** the **effective** date)

Submit written comments to:
Name: Lain Knowles
Address: Department of Health, Public Health Labs
1610 NE 150th Street, MSTP K17-9
Shoreline, WA 98155-9701
e-mail: http://www3.doh.wa.gov/policyreview/
fax 206-418-5415 by (date) 08/04/2014

Assistance for persons with disabilities: Contact
Melanie Hisaw by 08/04/2014
TTY (800) 833-6388 or () 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The proposal amends the newborn screening chapter 246-650 WAC, so that rules are consistent with changes made by Substitute House Bill (SHB) 2544, chapter 18 Laws of 2014. SHB 2544 amended chapter 70.83 RCW to require each hospital, and all health care providers attending a birth outside of a hospital to collect and submit a sample blood specimen to the department within a specified timeframe. The hospital or health care provider must collect the blood spot specimen for all newborns no more than 48 hours after the birth of the newborn. The department must receive the sample blood specimen within 72 hours after the collection, excluding any day that the Washington state public health laboratory is closed. The bill also adds an annual report for time taken to notify parent(s) when further diagnostic testing is required.

Reasons supporting proposal:
With the exception of those newborn infants whose parents or guardians object to testing because of conflict with their religious tenants and practices, it is important to screen all newborns for the metabolic disorders. Newborn screening saves lives and reduces long-term care costs for affected babies. In 2012, the newborn screening program detected 209 newborns with a metabolic disorder among the 86,180 births in Washington. Early detection of a metabolic disorder helps equip families with the necessary health information and resources.

Statutory authority for adoption:
Chapter 70.83 RCW, SHB 2544 (chapter 18 Laws of 2014)

Statute being implemented:
SHB 2544 (chapter 18 Laws of 2014)

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

DATE 06/*27/2014

NAME (type or print)
Michelle A. Davis

SIGNATURE

Michelle A. Davis

TITLE
Executive Director, State Board of Health

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: June 27, 2014
TIME: 10:21 AM

WSR 14-14-066

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None

Name of proponent: (person or organization) Department of Health

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting.....	Lain Knowles	Department of Health Public Health Labs, 1610 NE 150th Street Shoreline, WA 98155-9701	206-418-5420
Implementation....	Lain Knowles	Department of Health Public Health Labs, 1610 NE 150th Street Shoreline, WA 98155-9701	206-418-5420
Enforcement.....	Lain Knowles	Department of Health Public Health Labs, 1610 NE 150th Street Shoreline, WA 98155-9701	206-418-5420

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

☐ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:
Name:
Address:

phone
fax
e-mail

☒ No. Explain why no statement was prepared.

A small business economic impact statement (SBEIS) was not prepared. Under RCW 19.85.025 and 34.05.310(4)(c), a SBEIS is not required for proposed rules that adopt or incorporate by reference - without material change - federal statutes or regulations, Washington state law, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes A preliminary cost-benefit analysis may be obtained by contacting:
Name:
Address:

phone
fax
e-mail

☒ No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(v) exempts rules the content of which is explicitly and specifically dictated by statute.

AMENDATORY SECTION (Amending WSR 13-24-072, filed 11/26/13, effective 1/1/14)

WAC 246-650-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

For the purposes of this chapter:

(1) "Amino acid disorders" means disorders of metabolism characterized by the body's inability to correctly process amino acids or the inability to detoxify the ammonia released during the breakdown of amino acids. The accumulation of amino acids or their by-products may cause severe complications including mental retardation, coma, seizures, and possibly death. For the purpose of this chapter amino acid disorders include: Argininosuccinic acidemia (ASA), citrullinemia (CIT), homocystinuria (HCY), maple syrup urine disease (MSUD), phenylketonuria (PKU), and tyrosinemia type I (TYR I).

(2) "Board" means the Washington state board of health.

(3) "Biotinidase deficiency" means a deficiency of an enzyme (biotinidase) that facilitates the body's recycling of biotin. The result is biotin deficiency, which if undetected and untreated, may result in severe neurological damage or death.

(4) "Congenital adrenal hyperplasia" means a severe disorder of adrenal steroid metabolism which may result in death of an infant during the neonatal period if undetected and untreated.

(5) "Congenital hypothyroidism" means a disorder of thyroid function during the neonatal period causing impaired mental functioning if undetected and untreated.

(6) "Cystic fibrosis" means a life-shortening disease caused by mutations in the gene encoding the cystic fibrosis transmembrane conductance regulator (CFTR), a transmembrane protein involved in ion transport. Affected individuals suffer from chronic, progressive pulmonary disease and nutritional deficits. Early detection and enrollment in a comprehensive care system provides improved outcomes and avoids the significant nutritional and growth deficits that are evident when diagnosed later.

(7) "Department" means the Washington state department of health.

(8) "Fatty acid oxidation disorders" means disorders of metabolism characterized by the inability to efficiently use fat to make energy. When the body needs extra energy, such as during prolonged fasting or acute illness, these disorders can lead to hypoglycemia and metabolic crises resulting in serious damage affecting the brain, liver, heart, eyes, muscle, and possibly death. For the purpose of this chapter fatty acid oxidation disorders include: Carnitine uptake defect (CUD), long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHADD), medium-chain acyl-CoA dehydrogenase deficiency (MCADD), trifunctional protein deficiency (TFP), and very long-chain acyl-CoA dehydrogenase deficiency (VLCADD).

(9) "Galactosemia" means a deficiency of enzymes that help the body convert the simple sugar galactose into glucose resulting in a buildup of galactose and galactose-1-PO_4 in the blood. If undetected and untreated, accumulated galactose-1-PO_4 may cause significant tissue and organ damage often leading to sepsis and death.

(10) "Hemoglobinopathies" means a group of hereditary blood disorders caused by genetic alteration of hemoglobin which results in

characteristic clinical and laboratory abnormalities and which leads to developmental impairment or physical disabilities.

(11) "Organic acid disorders" means disorders of metabolism characterized by the accumulation of nonamino organic acids and toxic intermediates. This may lead to metabolic crisis with ketoacidosis, hyperammonemia and hypoglycemia resulting in severe neurological and physical damage and possibly death. For the purpose of this chapter organic acid disorders include: 3-OH 3-CH3 glutaric aciduria (HMG), beta-ketothiolase deficiency (BKT), glutaric acidemia type I (GA 1), isovaleric acidemia (IVA), methylmalonic acidemia (CblA,B), methylmalonic acidemia (*mutase deficiency*) (MUT), multiple carboxylase deficiency (MCD), and propionic acidemia (PROP).

(12) "Newborn" means an infant born in ((~~a hospital~~)) any setting in the state of Washington ((~~prior to discharge from the hospital of birth or transfer~~)).

(13) "Newborn screening specimen/information form" means the information form provided by the department including the filter paper portion and associated dried blood spots. A specimen/information form containing patient information is "health care information" as ((~~defined by the Uniform Health Care Information Act, RCW 70.02.010(7)~~)) used in chapter 70.02 RCW.

(14) "Significant screening test result" means a laboratory test result indicating a suspicion of abnormality and requiring further diagnostic evaluation of the involved infant for the specific disorder.

(15) "Severe combined immunodeficiency (SCID)" means a group of congenital disorders characterized by profound deficiencies in T- and B- lymphocyte function. This results in very low or absent production of the body's primary infection fighting processes that, if left untreated, results in severe recurrent, and often life-threatening infections within the first year of life.

AMENDATORY SECTION (Amending WSR 13-24-072, filed 11/26/13, effective 1/1/14)

WAC 246-650-020 Performance of screening tests. (1) Hospitals ((~~providing~~)) and other providers of birth and delivery services or neonatal care to infants shall:

(a) Inform parents or responsible parties, by providing a departmental information pamphlet or by other means, of:

(i) The purpose of screening newborns for congenital disorders;

(ii) Disorders of concern as listed in WAC 246-650-020(2);

(iii) The requirement for newborn screening;

(iv) The legal right of parents or responsible parties to refuse testing because of religious tenets or practices as specified in RCW 70.83.020; and

(v) The specimen storage, retention and access requirements specified in WAC 246-650-050.

(b) Obtain a blood specimen for laboratory testing as specified by the department from each newborn ((~~prior to discharge from the hospital or, if not yet discharged,~~)) no later than ((~~five days of age~~)) forty-eight hours following birth.

(c) Use department-approved newborn screening specimen/information forms and directions for obtaining specimens.

(d) Enter all identifying and related information required on the specimen/information form following directions of the department.

(e) In the event a parent or responsible party refuses to allow newborn screening, obtain signatures from parents or responsible parties on the department specimen/information form.

(f) Forward the specimen/information form with dried blood spots or signed refusal to the Washington state public health laboratory so that it will be received no later than ((~~the day after collection or refusal signature~~)) seventy-two hours following collection of the specimen, excluding any day that the state laboratory is closed.

(2) Upon receipt of specimens, the department shall:

(a) Record the time and date of receipt;

(b) Perform appropriate screening tests for:

(i) Biotinidase deficiency;

(ii) Congenital hypothyroidism;

(iii) Congenital adrenal hyperplasia;

(iv) Galactosemia;

(v) Hemoglobinopathies;

(vi) Cystic fibrosis;

(vii) The amino acid disorders: Argininosuccinic acidemia (ASA), citrullinemia (CIT), homocystinuria, maple syrup urine disease (MSUD), phenylketonuria (PKU), and tyrosinemia type I (TYR 1);

(viii) The fatty acid oxidation disorders: Carnitine uptake defect (CUD), long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHADD), medium chain acyl-coA dehydrogenase deficiency (MCADD), trifunctional protein deficiency (TFP), and very long-chain acyl-CoA dehydrogenase deficiency (VLCADD);

(ix) The organic acid disorders: 3-OH 3-CH3 glutaric aciduria (HMG), beta-ketothiolase deficiency (BKT), glutaric acidemia type I (GA 1), isovaleric acidemia (IVA), methylmalonic acidemia (CblA,B), methylmalonic acidemia (*mutase deficiency*) (MUT), multiple carboxylase deficiency (MCD), propionic acidemia (PROP);

(x) Severe combined immunodeficiency (SCID);

((~~(b)~~)) (c) Report significant screening test results to the infant's attending physician or family if an attending physician cannot be identified; and

((~~(c)~~)) (d) Offer diagnostic and treatment resources of the department to physicians attending infants with presumptive positive screening tests within limits determined by the department.

(3) Once the department notifies the attending health care provider of significant screening test results, the attending health care provider shall notify the department of the date upon which the results were disclosed to the parent or guardian of the infant. This requirement expires January 1, 2020.

AMENDATORY SECTION (Amending WSR 03-24-026, filed 11/24/03, effective 12/25/03)

WAC 246-650-040 Report~~s~~ to the board and the public. (1) The department shall report to the board annually the following information concerning tests conducted ((~~pursuant to~~)) under this section:

((~~(1)~~)) (a) The costs of tests as charged by the department;

((~~(2)~~)) (b) The results of each category of tests, by county of birth and ethnic group, as reported on the newborn screening form and, if available, birth certificates; and

((~~(3)~~)) (c) Follow-up procedures and the results of such follow-up procedures.

(2) The department shall compile an annual report for the public that includes:

(a) The compliance rate of each hospital meeting the deadlines established under RCW 70.83.020 for newborn screenings;

(b) The performance rate of each individual hospital;

(c) The extent to which health care providers are promptly informing parents and guardians about infant screening tests that indicate a suspicion of abnormality that requires further diagnostic evaluation.

(3) The reports must be made available in a format that does not disclose the identifying information related to any infant, parent or guardian, or health care provider.

(4) The report must be posted in an accessible location on the department of health's web site.

(5) Subsections (2) through (4) of this section expire January 1, 2020.