PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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DATE: July 02, 2019
TIME: 9:53 AM

WSR 19-14-103

Agency: State Board of Health

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 17-22-104 **; 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).**

☐ **Proposal is exempt under RCW .**

Title of rule and other identifying information: (describe subject) Chapter 246-650 WAC, Newborn Screening. The Washington State Board of Health (Board) is proposing to amend the newborn screening (NBS) rules to add Pompe disease and Mucopolysaccharidosis type I (MPS I) to the list of mandatory conditions for newborn screening conducted by the Department of Health; create a new section outlining critical congenital heart disease screening requirements to align with RCW 70.83.090; and to improve clarity and usability of the rule.

Hearing location(s):			
Date:	**Time:**	**Location:** (be specific)	**Comment:**
08/14/2019	1:30pm	John A Cherberg Building, Senate Hearing Room 4 304 15th Avenue SW Olympia, WA 98504	

Date of intended adoption: 08/14/2019 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Alexandra Montano
Address: PO Box 47990 Olympia, WA 98504-7990
Email: https://fortress.wa.gov/doh/policyreview
Fax: 360-236-4088
Other:
By (date) 07/24/2019

Assistance for persons with disabilities:

Contact Alexandra Montano
Phone: (360) 236-4106
Fax:
TTY: (360) 833-6388 or 711
Email: alexandra.montano@sboh.wa.gov
Other:
By (date) 07/24/2019

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the proposal is to amend chapter 246-650 WAC to add Pompe disease and Mucopolysaccharidosis type I (MPS I) to the panel of disorders that every newborn must be tested for unless the parents or guardian object on the grounds that such tests conflict with their religious tenets and practices. Pompe disease was added to the U.S. Department of Health and Human Services Recommended Uniform Screening Panel (RUSP) in 2015 and MPS I was added to the RUSP in 2016. Pompe disease and MPS I are both severe conditions that can result in significant physical or mental morbidity or death if not detected and treated early. Early diagnosis of these conditions through newborn screening is essential to both save the lives and improve the quality of life of affected infants and their families.

In addition, the proposed rule creates a new section outlining critical congenital heart disease screening requirements as described in RCW 70.83.090, and improves the clarity and usability of the rule by ensuring that definitions are complete and up-to-date and consistent terms are used throughout the rule.

Reasons supporting proposal: Population-based newborn screening is the best way to ensure that newborns with Pompe disease and MPS I are identified and can receive treatment before the condition causes irreversible damage or death. In order for universal screening of these conditions to occur in Washington, chapter 246-650 WAC must be amended to include these conditions. Aligning the rule with RCW 70.83.090 to address requirements for critical congenital heart disease screening will also provide clarity and consistency for stakeholders.

Statutory authority for adoption: RCW 70.83.050, RCW 70.83.090

Statute being implemented: RCW 70.83.020

Is rule necessary because of a:

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

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None.

Name of proponent: (person or organization) Washington State Board of Health ☐ Private ☐ Public ☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Alexandra Montano	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 236-4106
Implementation:	John Thompson	1610 NE 150th Street, Shoreline, WA 98155	(206) 418-5531
Enforcement:	John Thompson	1610 NE 150th Street, Shoreline, WA 98155	(206) 418-5531

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name: Alexandra Montano
Address: PO Box 47990 Olympia, WA 98504-7990
Phone: (360) 236-4106
Fax: (360) 236-4088
TTY: (360) 833-6388 or 711

Email: alexandra.montano@sboh.wa.gov
Other:

☐ No: Please explain:

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's analysis showing how costs were calculated. The cost threshold for the industry of direct health and medical insurance carriers (NAICS Code: 524114) is $79,165.
(Annual Payroll/Total establishments) * (0.01) = (593,741 * 1,000) /75) *(0.01) = $79,165

Half of births in Washington are covered by Medicaid and it is assumed that the other half are covered by private insurance. The total cost of the rule to private industry would be $471,833.25.
Total cost of the rule: $10.50 fee increase per baby * 89,873 estimated births = $943,666.50
$943,666.5 / 2 = $471,833.25 (half of the births are Medicaid, half are private insurance)

We do not have a way of knowing how many babies will be covered by each of the 75 different establishments so we calculated an average cost per establishment of $6,291.11.
$471,833.25 (total cost to private industry) / 75 (total establishments) = $6,291.11

Therefore, the average cost of the rule per establishment does not exceed the average cost threshold for the industry and does not require a SBEIS.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: 07/02/2019	**Signature:**  Place signature here
Name: Michelle A. Davis	
Title: Executive Director, Washington State Board of Health	

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

WAC 246-650-001 Purpose. The purpose of this chapter is to establish board rules to detect, in newborns, congenital disorders leading to developmental ((~~impairment~~)) or physical disabilities as required by RCW 70.83.050 and to provide protections for the confidentiality of information and human biological specimens submitted pursuant to these requirements.

AMENDATORY SECTION (Amending WSR 18-01-024, filed 12/8/17, effective 3/1/18)

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 intellectual disability, coma, seizures, and possibly death. For the purpose of this chapter amino acid disorders include:~~)) argininosuccinic acidemia (ASA), citrullinemia type I (CIT), homocystinuria (HCY), maple syrup urine disease (MSUD), phenylketonuria (PKU), and tyrosinemia type I (TYR I), which may cause severe complications including intellectual disability, coma, seizures, and possibly death.

(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) "Critical congenital heart disease" means an abnormality in the structure or function of the heart that exists at birth, causes severe, life-threatening symptoms, and requires medical intervention within the first year of life.

(7) "Cystic fibrosis" means a life-shortening ((~~disease~~)) disorder 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)~~)) (8) "Department" means the Washington state department of health.

((~~(8)~~)) (9) "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). These disorders can lead to hypoglycemia and metabolic crises resulting in serious damage affecting the brain, liver, heart, eyes, muscle, and possibly death.

((~~(9)~~)) (10) "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)~~)) (11) "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 any setting in the state of Washington.

(13) "Newborn screening specimen/information form" means ((~~the information~~)) a form provided by the department ((~~including~~)) for collecting a newborn's dried blood spots and information used to screen for congenital disorders under this chapter. This includes the filter paper portion and associated dried blood spots. ((~~A specimen/information form containing patient information is "health care information" as used in chapter 70.02 RCW.~~))

(14) "Mucopolysaccharidosis I (MPS-I)" means a multisystem disorder caused by mutations in the alpha-L-iduronidase gene in which a lysosomal enzyme is deficient, leading to accumulation of mucopolysaccharides (a type of carbohydrate) and other metabolites. This includes Hurler, Hurler-Scheie, and Scheie syndromes.

(15) "Organic acid disorders" means 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). These disorders can lead to metabolic crises resulting in severe nerve damage, physical damage, and possibly death.

(16) "Pompe disease" means a neuromuscular disorder caused by mutations in the acid glucosidase gene which result in reduced or absent activity of the acid alpha glucosidase enzyme.

(17) "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~~)) a specific congenital disorder.

((~~(15)~~)) (18) "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.

((~~(16)~~)) (19) "X-linked adrenoleukodystrophy (X-ALD)" means a peroxisomal disorder caused by mutations in the ABCD1 gene located on the X chromosome. If untreated this can lead to adrenocortical deficiency, damage to the nerve cells of the brain, paralysis of the lower limbs, mental decline, disability, or death.

AMENDATORY SECTION (Amending WSR 18-01-024, filed 12/8/17, effective 3/1/18)

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

(a) Inform parents or ((~~responsible parties~~)) guardians, 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~~)) guardians 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 no later than 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 newborn screening specimen/information form following directions of the department.

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

(f) Forward the newborn screening 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 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);~~
~~(xi) X-linked adrenoleukodystrophy (X-ALD)~~)) Amino acid disorders;
(ii) Biotinidase deficiency;
(iii) Congenital hypothyroidism;
(iv) Congenital adrenal hyperplasia;
(v) Cystic fibrosis;
(vi) Fatty acid oxidation disorders;
(vii) Galactosemia;
(viii) Hemoglobinopathies;
(ix) Mucopolysaccharidosis type I (MPS-I);
(x) Organic acid disorders;
(xi) Pompe disease;
(xii) Severe combined immunodeficiency (SCID);
(xiii) X-linked adrenoleukodystrophy (X-ALD).

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

(d) Offer diagnostic and treatment resources ((~~of the department~~)) to ((~~physicians~~)) health care providers attending infants with ((~~presumptive positive~~)) significant screening test((~~s~~)) results 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.

NEW SECTION

WAC 246-650-035 Screening for critical congenital heart disease. (1) Prior to a hospital discharge of a newborn, the hospital shall ensure that:

(a) A licensed health care provider perform critical congenital heart disease screening on the newborn using pulse oximetry according to recommended American Academy of Pediatrics guidelines;

(b) Record the results of the critical congenital heart disease screening test in the newborn's medical record; and

(c) If the screening test indicates a suspicion of abnormality, refer the newborn for appropriate care and report the test results to the newborn's attending health care provider and parent, parents, or guardian.

(2)(a) Except as provided in (b) of this subsection, a health care provider attending a birth outside of a hospital shall, between twenty-four and forty-eight hours after the birth of the newborn:

(i) Perform critical congenital heart disease screening on the newborn using pulse oximetry according to recommended American Academy of Pediatrics guidelines;

(ii) Record the results of the critical congenital heart disease screening test in the newborn's medical record; and

(iii) If the screening test indicates a suspicion of abnormality, refer the newborn for appropriate care and report the test results to the newborn's attending health care provider and parents or guardians.

(b) If the health care provider does not perform the test required in (a) of this subsection because he or she does not possess the proper equipment, the health care provider shall notify the parents or guardians in writing that the health care provider was unable to perform the test and that the newborn should be tested by another health care provider no sooner than twenty-four hours after the birth, but no later than forty-eight hours after the birth.

(3) A health care provider may not test a newborn as required by this section if the parents or guardians object to the test based on religious beliefs.

AMENDATORY SECTION (Amending WSR 14-21-017, filed 10/2/14, effective 11/2/14)

WAC 246-650-040 Reports to the board and the public. (1) The department shall report to the board annually the following information concerning tests conducted under ((~~this section~~)) WAC 246-650-020:

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

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

(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 in meeting the deadlines established under RCW 70.83.020 for newborn screenings; and

(b) The performance rate of each individual hospital((~~;~~

~~(c) The time taken by health care providers to notify parents and guardians after being notified by the department about infant screening tests that indicate a suspicion of abnormality that requires further diagnostic evaluation. Notification times will be summarized and reported in increments of days~~)).

(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.~~))

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

WAC 246-650-050 Privacy and security of newborn screening specimen/information forms. The newborn screening specimen/information form submitted to the department pursuant to WAC 246-650-020 becomes the property of the state of Washington upon receipt by the Washington state public health laboratory. The department shall protect the privacy of newborns and their families and assure that all specimen/information forms submitted for screening are protected from inappropriate use or access. A newborn specimen/information form contains health care information that is confidential under chapter 70.02 RCW.

(1) Storage: The newborn screening specimen/information forms shall be kept at ambient temperature in secured storage to preserve their confidentiality and prevent access by unauthorized persons.

(2) Retention/destruction: The newborn screening specimen/information form shall be retained until the child is twenty-one years old in accordance with the requirements for hospitals specified in RCW 70.41.190. After this time the ((~~form will be destroyed~~)) department shall destroy the form.

EXCEPTION FOR PARENTAL REQUEST: Upon request of a parent or guardian (or a patient who is over the age of eighteen years), the department ((~~will~~)) shall destroy the newborn screening specimen/information form only after all required screening tests have been performed and if the patient's screening/clinical status related to these tests is not in question.

(3) Access: Access to stored newborn screening specimen/information forms ((~~shall~~)) must be restricted to department employees and those contractors or others approved by the department as necessary to meet specific program needs. Access is contingent upon compliance with all applicable federal and state laws, regulations, and policies safeguarding the privacy and confidentiality of medical information. The department shall assure that those granted access understand the confidentiality requirements and have a signed confidentiality agreement on file.

(4) Release: Dried blood spot samples and specimen information may only be released when required by state or federal law or under the following conditions:

(a) A sample from a specimen and copies of associated identifying information (patient information and testing results, if requested) may be released to:

(i) A health care provider at the request of the patient or ((~~their~~)) his or her legal representative after completing and signing a written request form approved by the department. The release form must be provided to the director of newborn screening before the request will be fulfilled.

(ii) A researcher with the written, informed consent of the patient or ((~~their~~)) the patient's legal representative as part of a research project that has been reviewed and approved by the ((~~DOH/DSHS~~

~~human subjects research~~)) Washington state institutional review board and the secretary or designee of the department ((~~of health~~)).

(iii) A named person in a legally executed subpoena following review and approval of the state attorney general.

(iv) A person to whom release is mandated by order of a court of competent jurisdiction.

(b) Anonymous samples may be released if the department determines that the intended use has significant potential health benefit and that each of the following criteria have been met:

(i) The investigation design is adequate to assure anonymity will be preserved.

(ii) All newborn screening tests have been completed and the status of the infant is resolved.

(iii) At least one fully adequate spot will remain after the anonymous sample has been taken.

(iv) Sufficient resources (personnel) are available for extracting the samples.

(v) The ((~~DOH/DSHS human subjects research~~)) Washington state institutional review board has reviewed and approved the investigation. This requirement may be waived by the department for a very small (i.e., less than 100 sample) pilot study where the intent is to evaluate a testing tool, as opposed to an evaluation where the intent is to measure some characteristic of a population.

(5) Notification: The department shall notify parents or guardians of the specimen storage, retention/destruction and access requirements through the department's newborn screening informational pamphlet.

AMENDATORY SECTION (Amending WSR 99-20-036, filed 9/29/99, effective 10/30/99)

WAC 246-650-990 Screening charge. The department has authority under RCW 43.20B.020 to require a reasonable charge from parents, guardians, or responsible parties for the costs of newborn screening. The charge is to be collected through the facility where the specimen was obtained.

AMENDATORY SECTION (Amending WSR 05-20-108, filed 10/5/05, effective 11/5/05)

WAC 246-650-991 Specialty clinic support fee. ((~~(1)~~)) The department has the authority under RCW ((~~70.83.040~~)) 70.83.023 to collect ((~~a~~)) an eight dollar and forty cent fee for each infant screened to fund specialty clinics that provide treatment services for ((~~hemoglobin diseases, phenylketonuria,~~)) congenital ((~~adrenal hyperplasia, congenital hypothyroidism and other~~)) disorders defined by the state board of health under RCW 70.83.020, and may also be used for purposes of funding activities in subsection (2) of this section. This fee is to be collected in conjunction with the screening charge described in WAC 246-650-990.

((~~(2) The specialty clinic support fee is $3.50. It is to be collected in conjunction with the screening charge from the parents or other responsible party through the facility where the screening specimen is obtained.~~

~~(3) However, effective through June 30, 2007, the department will collect an additional $3.10 to fund specialty clinics that provide treatment services for other disorders defined by the board under RCW 70.83.020.~~))