



# PROPOSED RULE MAKING

## CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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STATE OF WASHINGTON  
FILED

DATE: May 06, 2020

TIME: 7:59 AM

WSR 20-10-096

Agency: State Board of Health

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 19-15-087 ; 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 Spinal Muscular Atrophy (SMA) to the list of mandatory conditions for which newborn screening is conducted by the Department of Health.

### Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
06/10/2020	11:05 AM	<p>In response to the coronavirus disease 2019 (COVID-19) public health emergency, the State Board of Health will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. A virtual public hearing, without a physical meeting space, will be held instead. Board members, presenters, and staff will all participate remotely. The public may login using a computer or device, or call-in using a phone, to listen to the meeting through the GoTo Webinar application. The public may submit verbal comments during the specified public comment and rules hearing segments.</p> <p>To access the meeting online and register: Registration URL: <a href="https://attendee.gotowebinar.com/register/1641009416538872079">https://attendee.gotowebinar.com/register/1641009416538872079</a></p> <p>You can also dial in using your phone. - Call in: +1 (951) 384-3421</p>	

**Date of intended adoption:** 06/10/2020 (Note: This is **NOT** the **effective** date)

**Submit written comments to:**

Name: Samantha Pskowski  
 Address: PO Box 47990, Olympia, WA 98504-7990  
 Email: <https://fortress.wa.gov/doh/policyreview>  
 Fax: N/A  
 Other: None  
 By (date) 06/05/2020

**Assistance for persons with disabilities:**

Contact Samantha Pskowski  
 Phone: (360) 789-2358  
 Fax:  
 TTY: 711  
 Email: [samantha.pskowski@sboh.wa.gov](mailto:samantha.pskowski@sboh.wa.gov)  
 Other:  
 By (date) 05/29/2020

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** The purpose of this proposal is to amend chapter 246-650 WAC to add SMA to the panel of disorders that every newborn must be tested for, unless so objected by the newborn's parents or guardians due to religious tenets. The United States Department of Health and Human Services included SMA to the Recommended Uniform Screening Panel (RUSP) in July 2018. SMA is a severe condition that results in the breakdown of the skeletal muscles and cardiac and respiratory deficiencies.

**Reasons supporting proposal:** Performing population based screening is the most effective method of early identification of SMA to diagnosis and begin treatment earlier. Delaying diagnosis and treatment can lead to debilitating outcomes and possible early death. The Board and Department of Health have proposed changes to chapter 246-650 WAC to include SMA in order to protect the public's health, safety, and wellbeing through early detection of a debilitating genetic disorder.

**Statutory authority for adoption:** RCW 70.83.030, RCW 70.83.050

**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 and Washington State Department of Health  Private  Public  Governmental

**Name of agency personnel responsible for:**

	Name	Office Location	Phone
Drafting:	Samantha Pskowski	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 789-2358
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: Samantha Pskowski

Address: 101 Israel Road SE, Tumwater, WA, 98504-7990

Phone: (360) 789-2358

Fax: N/A

TTY: 711

Email: samantha.pskowski@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)(e)  
(Dictated by statute)

RCW 34.05.310 (4)(c)  
(Incorporation by reference)

RCW 34.05.310 (4)(f)  
(Set or adjust fees)

RCW 34.05.310 (4)(d)  
(Correct or clarify language)

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 \$81,828.  
(Annual Payroll/Total establishments) \* (0.01) = (556,430.40 \* 1,000) /68) \*(0.01) = \$81,828

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 \$180,600.00.

Total cost of the rule: \$4.30 fee increase per baby \* 84,000 estimated births = \$361,200.00  
\$360,200.00/ 2 = \$180,600.00 (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 68 different establishments so we calculated an average cost per establishment of \$2,655.88.  
\$180,600.00 (total cost to private industry) / 68 (total establishments) = \$2,655.88

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:

<b>Date:</b> 05/05/2020	<b>Signature:</b>    signature here  Place
<b>Name:</b> Michelle A. Davis	
<b>Title:</b> Executive Director	

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

(1) "Amino acid disorders" means 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 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.

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

(9) "Fatty acid oxidation disorders" means 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.

(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<sub>4</sub> in the blood. If undetected and untreated, accumulated galactose-1-PO<sub>4</sub> may cause significant tissue and organ damage often leading to sepsis and death.

(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.

(12) "Newborn" means an infant born in any setting in the state of Washington.

(13) "Newborn screening specimen/information form" means a form provided by the department 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.

(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-CH<sub>3</sub> 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 diagnostic evaluation of the involved infant for a specific congenital disorder.

(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.

(19) "Spinal muscular atrophy (SMA)" means a genetic disorder caused by mutations in the survival motor neuron 1 (SMN1) gene, which impairs the function of the survival motor neuro (SMN) protein. This results in the loss of motor neurons and causes progressive atrophy of skeletal muscles.

(20) "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 19-20-025, filed 9/23/19, effective 10/24/19)

**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 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 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 guardian refuses to allow newborn screening, obtain signatures from parents or guardians on the 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) 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) Spinal muscular atrophy (SMA);

(xiv) X-linked adrenoleukodystrophy (X-ALD).

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

(d) Offer diagnostic and treatment resources to health care providers attending infants with significant screening test 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.