



# 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 13-11-040 ; 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. The Washington State Board of Health is proposing to add severe combined immunodeficiency (SCID) to the list of mandatory conditions for newborn screening conducted by the Department of Health.

**Hearing location(s):** Washington State Capital Campus  
John A Cherberg Building  
Senate Hearing Room 3  
Olympia, WA

Date: 10/9/2013

Time: 1:30 PM

**Submit written comments to:**

Name: Michael Glass  
Address: 1610 NE 150th Street  
Shoreline WA 98155  
e-mail: <http://www3.doh.wa.gov/policyreview/>  
fax 206-418-5470 by (date) 09/29/2013

**Assistance for persons with disabilities:** Contact

Desiree Robinson by 09/25/2013

TTY (800) 833-6388 or () 711

**Date of intended adoption:** 10/09/2013

(Note: This is NOT the effective date)

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:**

The purpose of the proposal is to amend WAC Chapter 246-650 Sections 010, -020, and -030 to add severe combined immunodeficiency (SCID) 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. Other housekeeping changes are also proposed.

**Reasons supporting proposal:**

SCID is a disabling and deadly disease that, if detected through newborn screening, infants can receive bone marrow transplants or gene therapy before damage is caused by the disorder and the infant can be cured of the condition. The United States Department of Health and Human Services recommends SCID be included in all state's newborn screening programs. Careful review by a Newborn Screening Advisory Committee concluded that SCID meets all of the State Board of Health's Criteria for inclusion on the screening panel. The Board has reviewed and accepted the committee's recommendation.

**Statutory authority for adoption:**

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:

**DATE** 09/04/2013

**NAME** (type or print)

Michelle Davis

**SIGNATURE**

**TITLE**

Executive Director, Washington State Board of Health

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED

**DATE:** September 04, 2013

**TIME:** 9:20 AM

**WSR 13-18-081**

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

Both the Board of Health and the Department of Health are in agreement with the intent and the language of the proposed changes to Chapter 246-650 WAC.

**Name of proponent:** (person or organization) Washington State Board of Health and Department of Health  Private  
 Public  
 Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Michael Glass	1610 NE 150th Street, Shoreline, WA 98155	206-418-5470
Implementation.... Michael Glass	1610 NE 150th Street, Shoreline, WA 98155	206-418-5470
Enforcement..... Michael Glass	1610 NE 150th Street, Shoreline, WA 98155	206-418-5470

**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 impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

**Is a cost-benefit analysis required under RCW 34.05.328?**

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

Name: Michael Glass

Address: 1610 NE 150th Street  
Shoreline, WA 98155

phone 206-418-5470

fax 206-418-5415

e-mail [mike.glass@doh.wa.gov](mailto:mike.glass@doh.wa.gov)

No: Please explain:

**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<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.

(10) "~~((Hemoglobinopathy))~~ 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 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(~~(6)~~) (7).

(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 08-13-073, filed 6/16/08, effective 7/17/08)

**WAC 246-650-020 Performance of screening tests.** (1) Hospitals providing 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(~~(7)~~)i

(ii) Disorders of concern as listed in WAC 246-650-020(2)(~~(7)~~)i

(iii) The requirement for newborn screening(~~(7)and~~)i

(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(~~(7)~~)i 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.

(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 no later than the day after collection or refusal signature.

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

(a) Perform appropriate screening tests for:

(i) Biotinidase deficiency;

(ii) Congenital hypothyroidism;

(iii) Congenital adrenal hyperplasia;

(iv) Galactosemia;

(v) ~~((Homocystinuria;~~

~~(vi))) Hemoglobinopathies;~~

~~((vii) Maple syrup urine disease (MSDU);~~

~~(viii) Medium chain acyl-CoA dehydrogenase deficiency (MCADD);~~

~~(ix) Phenylketonuria (PKU);~~

~~(x)) (vi) Cystic fibrosis;~~

~~((xi))) (vii) The amino acid disorders: Argininosuccinic acidemia (ASA), citrullinemia (CIT), homocystinuria, maple syrup urine disease (MSUD), phenylketonuria (PKU), and tyrosinemia type I (TYR 1) ((according to the schedule in WAC 246-650-030));~~

~~((xii))) (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) according to the schedule in WAC 246-650-030;~~

~~((xiii))) (ix) The organic acid disorders: 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), propionic acidemia (PROP) according to the schedule in WAC 246-650-030;~~

~~(x) Severe combined immunodeficiency (SCID);~~

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

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

AMENDATORY SECTION (Amending WSR 08-13-073, filed 6/16/08, effective 7/17/08)

**WAC 246-650-030 Implementation of screening to detect ((~~amino acid disorders, fatty acid oxidation disorders and organic acid disorders~~)) severe combined immunodeficiency (SCID).** The department shall implement screening to detect ((~~the amino acid disorders, fatty acid oxidation disorders, and organic acid disorders listed in WAC 246-650-020 (2)(a)(xi), (xii) and (xiii))~~)) SCID as quickly as feasible ((~~and not later than September 2008~~)).