MONTANA
ADMINISTRATIVE
REGISTER

DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

NOTICE OF PROPOSED RULEMAKING

MAR NOTICE NO. 2025-156.1

Summary

Amendment of ARM 37.12.401 and 37.57.301 pertaining to newborn screening

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Hearing Date and Time

Thursday, October 30, 2025, at 9:00 a.m.

Virtual Hearing Information

Join Zoom Meeting: https://mt-gov.zoom.us/j/88049735078?pwd=vdOpbY4XkyZO3b12bGibaRXiRQiFQi.1

Meeting ID: 880 4973 5078 and Password: 676305

Dial by Telephone: +1 646 558 8656

Meeting ID: 880 4973 5078 and Password: 676305

Find your local number: https://mt-gov.zoom.us/u/kbRTelCzRq

Comments

Comments may be submitted using the contact information below. Comments must be received by Friday, November 7, 2025, at 5:00 p.m.

Accommodations

The agency will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. Requests must be made by Thursday, October 16, 2025, at 5:00 p.m.

Contact

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Rulemaking Actions

AMEND

The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

37.12.401 LABORATORY FEES FOR ANALYSES

(1) Fees for clinical and environmental analyses performed by the laboratory of the department are set to reflect the actual costs of the tests and services provided.

(2) The department will maintain a list of all tests available from the lab and the price of each test. The department adopts and incorporates by reference the Public Health Laboratory Testing Fee Schedule and the Environmental Laboratory Testing Fee Schedule effective ~~June 1, 2024~~ January 1, 2026, which is available on the web site of the Department of Public Health and Human Services at https://dphhs.mt.gov/publichealth/LaboratoryServices/index, and by mail upon request to the lab at the Department of Public Health and Human Services, Public Health and Safety Division, P.O. Box 6489, Helena, MT 59604-6489.

(3) The fee for a specific lab test will be lowered by the department to a level not exceeding the cost to the department of the test in question whenever a change of analysis method warrants lower fees.

(4) Fees for analyses other than those listed will be established at the level of comparable analyses.

Authorizing statute(s): 50-1-202, MCA

Implementing statute(s): 50-1-202, MCA

37.57.301 DEFINITIONS

As used in this subchapter, the following definitions apply:

(1) "Health care facility" means a hospital or other facility licensed by or located in the state of Montana for the purpose of providing health care services, and which provides primary health care services for newborns at birth.

(2) "Newborn" means an infant in the first 28 days of life.

(3) "Newborn screening tests" are screening tests, procedures, or both for the following conditions:

(a) Acylcarnitine Disorders:

(i) Fatty Acid Oxidation Disorders:

(A) Carnitine uptake defect;

(B) Long-chain L-3-OH acyl-CoA dehydrogenase deficiency;

(C) Medium-chain acyl-CoA dehydrogenase deficiency;

(D) Trifunctional protein deficiency; and

(E) Very long-chain acyl-CoA dehydrogenase deficiency;

(ii) Organic Acidemia Disorders:

(A) 3-hydroxy-3-methylglutaryl-CoA lyase deficiency;

(B) 3-Methylcrotonyl-CoA carboxylase deficiency;

(C) β-ketothiolase deficiency;

(D) Glutaric acidemia type I;

(E) Isovaleric acidemia;

(F) Methylmalonic acidemia (Cbl A,B);

(G) Methylmalonic acidemia (mutase deficiency);

(H) Multiple carboxylase deficiency; and

(I) Propionic acidemia;

(b) Amino Acid Disorders:

(i) Argininosuccinic acidemia;

(ii) Citrullinemia type 1;

(iii) Homocystinuria;

(iv) Maple syrup urine disease;

(v) Classic Phenylketonuria; and

(vi) Tyrosinemia type I;

(c) Biotinidase deficiency;

(d) Classical galactosemia;

(e) Congenital adrenal hyperplasia;

(f) Primary congenital hypothyroidism;

(g) Cystic fibrosis;

(h) Hemoglobinopathies, including:

(i) Hb S/β -thalassemia;

(ii) Hb SC disease; and

(iii) Hb SS disease; and

(i) Critical congenital heart disease, including:

(i) hypoplastic left heart syndrome;

(ii) pulmonary atresia;

(iii) tetralogy of Fallot;

(iv) total anomalous pulmonary venous return;

(v) transposition of the great arteries;

(vi) tricuspid atresia;

(vii) truncus arteriosus;

(j) Severe combined immunodeficiency disease;

(k) Spinal muscular atrophy (SMA); ~~and~~

(l) X-linked adrenoleukodystrophy (X-ALD)<u>; and</u>

<u>(m) Pompe disease</u>.

Authorizing statute(s): 50-19-202, MCA

Implementing statute(s): 50-19-203, MCA

General Reasonable Necessity Statement

The Department of Public Health and Human Services (department) is proposing amendments to ARM 37.12.401 and 37.57.301 regarding newborn screening and the fees charged for such screening panel tests by the department's public health laboratory. The proposed rule amendments add Pompe disease to the required Montana newborn screening testing panel.

ARM 37.12.401 LABORATORY FEES FOR ANALYSES

The department is proposing to amend this rule to adopt and incorporate by reference an updated laboratory test fee list that takes into account the addition of Pompe disease to the newborn screening tests. A copy of the proposed laboratory fee schedule is electronically accessible at: https://dphhs.mt.gov/publichealth/LaboratoryServices/PublicHealthLabTesting. The fee for newborn screening panel tests is currently $150.50. The department is proposing to increase the fee to $161.80 due to the addition of the Pompe disease test. The proposed rule change is necessary to align with the changes being proposed to ARM 37.57.301.

ARM 37.57.301 DEFINITIONS

The department is proposing to amend the definition of the term "newborn screening tests" by adding Pompe disease to the list of required newborn screening panel tests in accordance with the recommendation of the Newborn Screening Advisory Committee made on August 28, 2024. In making its recommendation, the committee relied upon federally recognized standards for newborn screening, including the Recommended Uniform Screening Panel (RUSP) developed by the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

Pompe disease is a type of glycogen storage disease, a genetic condition in which a complex sugar called glycogen builds up in the body's cells. The disease results from the deficiency of a digestive enzyme called acid alpha-glucosidase (GAA). The deficiency of this enzyme leads to an abnormal buildup of glycogen in the lysosomes of cells, resulting in severe muscle weakness, especially in the heart and skeletal muscles. In the United States, Pompe disease affects about 1 in every 40,000 individuals. Without early detection and treatment, the condition is fatal at 1 to 2 years of age.

The proposed rule change is necessary to conform with HRSA's RUSP for all newborns and to update newborn screening to reflect current standards of care for babies born in Montana.

Fiscal Impact

The proposed rule changes affect newborns and their families, birthing hospitals, birthing centers, and small businesses providing direct-entry midwifery services. There are approximately 12,000 babies born in Montana every year. The cost for the addition of the Pompe disease test to the newborn screening panel is $11.30 per test. Given the modest cost of this test, the department does not anticipate these proposed rule changes will have a significant fiscal impact.

Small Business Impact

Pursuant to 2-4-111, MCA, the class of small businesses anticipated to be affected by the proposed rules are those providing birthing care. These affected small businesses primarily consist of those providing midwifery services. The probable significant and direct effect of these proposed rules on these small businesses is the increase in cost of $11.30 for the required newborn screening panel test. Documentation of the small business impact analysis is available upon request.

Bill Sponsor Notification

The bill sponsor contact requirements do not apply.

Interested Persons

The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by the department. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Written requests may be emailed, mailed or otherwise delivered to the contact person above.

Effective Date

The department intends for the proposed rule amendments to be effective January 1, 2026.

Rule Reviewer

Robert Lishman

Approval

Charles T. Brereton, Director

Department of Public Health and Human Services