



**MONTANA
ADMINISTRATIVE
REGISTER**



DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

NOTICE OF PROPOSED RULEMAKING

MAR NOTICE NO. 2026-28.1

Summary

Amendment of ARM 37.12.401 and 37.57.301 pertaining to newborn screening

Hearing Date and Time

Friday, August 28, 2026, at 11:00 a.m.

Virtual Hearing Information

Join Zoom Meeting

<https://mt-gov.zoom.us/j/87443470543?pwd=5aj0N9nxVFpSgb0zMDJ3xCbaKyubRv.1>

Meeting ID: 874 4347 0543 Password: 944206

Dial by Telephone +1 646 558 8656

Meeting ID: 874 4347 0543 Password: 944206

Find your local number: <https://mt-gov.zoom.us/j/87443470543?pwd=5aj0N9nxVFpSgb0zMDJ3xCbaKyubRv.1>

Join by SIP 87443470543@zoomcrc.com

Join by H.323 (Polycom) 162.255.37.11##87443470543

Comments

Comments may be submitted using the contact information below. Comments must be received by Friday, September 4, 2026, 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 Friday, August 14, 2026, at 5:00 p.m.

Contact

Kendra Fanning
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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 ~~January 1, 2026~~ January 12, 2027, 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);
- (l) X-linked adrenoleukodystrophy (X-ALD); and
- (m) Pompe disease; and
- (n) Acid sphingomyelinase deficiency (ASMD).

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 acid sphingomyelinase deficiency (ASMD) to the required Montana Newborn Screening testing panel.

ARM 37.12.401 LABORATORY FEES FOR ANALYSIS

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 ASMD 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 \$161.80. The department is proposing to increase the fee to \$165.30 due to the addition of the ASMD 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 ASMD to the list of required newborn screening panel tests in accordance with the recommendation of the Newborn Screening Advisory Committee made on September 30, 2025. The committee's recommendation was made unanimously following receipt of testimony from a subject matter expert, the Montana Public Health Laboratory, and a family impacted by ASMD.

ASMD is a type of lysosomal storage disorder, a genetic condition which affects the body's ability to break down and use fats, such as cholesterol and lipids, inside cells. The disease results from a deficiency of an enzyme called acid-sphingomyelinase (ASM). The deficiency of this enzyme leads to an abnormal buildup of fats, which prevents cells from functioning properly and, over time, causes cell death. ASMD can affect the brain, nerves, liver, spleen, bone marrow, and lungs. In the United States, ASMD affects about 1 in every 100,000 live births. Early detection of ASMD through screening of the bloodspot allows for prompt

intervention and treatment initiation prior to irreversible damage, leading to improved care and outcomes for affected individuals.

The proposed rule change is necessary to conform to the advisory committee's recommendation for all newborns and to update newborn screening to reflect current standards of care for babies born in Montana.

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 \$3.50 for the required newborn screening panel test.

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. Such written request 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 12, 2027.

Rule Reviewer

Robert Lishman

Approval

Charles T. Brereton, Director
Department of Public Health and Human Services