

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES
OF THE STATE OF MONTANA

In the matter of the amendment of) NOTICE OF PUBLIC HEARING ON
ARM 37.12.401 and 37.57.301) PROPOSED AMENDMENT
pertaining to laboratory analyses and)
newborn screening)

TO: All Concerned Persons

1. On May 31, 2024, at 9:00 a.m., the Department of Public Health and Human Services will hold a public hearing via remote conferencing to consider the proposed amendment of the above-stated rules. Interested parties may access the remote conferencing platform in the following ways:

(a) Join Zoom Meeting at: <https://mt-gov.zoom.us/j/86510479190?pwd=VThXN3pCZzRMbXRmVFg1bVVOT0JKdz09>, meeting ID: 865 1047 9190, and password: 235611; or

(b) Dial by telephone: +1 646 558 8656, meeting ID: 865 1047 9190, and password: 235611. Find your local number: <https://mt-gov.zoom.us/u/kbsHetBxtz>.

2. The Department of Public Health and Human Services 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. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on May 17, 2024, to advise us of the nature of the accommodation that you need. Please contact Bailey Yuhas, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail hhsadminrules@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.12.401 LABORATORY FEES FOR ANALYSES (1) remains the same.

(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 ~~December 1, 2023~~ June 1, 2024, which are 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) and (4) remain the same.

AUTH: 50-1-202, MCA
IMP: 50-1-202, MCA

37.57.301 DEFINITIONS As used in this subchapter, the following definitions apply:

- (1) through (3)(i) remain the same.
- (j) Severe combined immunodeficiency disease; ~~and~~
- (k) Spinal muscular atrophy (SMA); ~~and~~
- (l) X-linked adrenoleukodystrophy (X-ALD).

AUTH: 50-19-202, MCA

IMP: 50-19-203, MCA

4. STATEMENT OF REASONABLE NECESSITY

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 X-linked adrenoleukodystrophy (X-ALD) to the list of required newborn screening panel tests.

ARM 37.12.401

The department is proposing to amend ARM 37.12.401 to adopt and incorporate by reference an updated laboratory test fee list that takes into account the addition of X-ALD 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 \$145.00. The department is proposing to revise the fee to \$150.50 due to the addition of the X-ALD test. The proposed rule change is necessary to align with the changes being proposed to ARM 37.57.301.

ARM 37.57.301

The department is proposing to amend the definition of "newborn screening tests" by adding X-ALD to the list of required newborn screening panel tests. X-ALD is one of the primary conditions that the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services has included in the recommended uniform screening panel (RUSP) for newborn screening. Essential requirements for inclusion in the RUSP are that the conditions are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments. Due to technological and medical advances, newborns with X-ALD can be screened in a highly effective manner and babies who are identified soon after birth through newborn screening can survive and lead productive lives. The proposed rule change is necessary to conform with HRSA's RUSP for all newborns and to update

newborn bloodspot 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 12,500 babies born in Montana every year. The cost for the addition of the X-ALD test to the newborn screening panel is \$5.50 per test. Given the modest cost of this test, the department does not anticipate these proposed rule changes will have a significant fiscal impact.

5. The department intends these rule amendments to be effective August 1, 2024.

6. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Bailey Yuhas, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail hhsadminrules@mt.gov, and must be received no later than 5:00 p.m., June 7, 2024.

7. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

8. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. 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 mailed or delivered to the contact person in 6 above.

9. An electronic copy of this notice is available on the department's web site at <https://dphhs.mt.gov/LegalResources/administrativerules>, or through the Secretary of State's web site at <http://sosmt.gov/ARM/register>.

10. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

11. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rules will not significantly and directly impact small businesses.

/s/ Robert Lishman
Robert Lishman
Rule Reviewer

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

Certified to the Secretary of State April 30, 2024.