

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

In the matter of the adoption of New )  
Rule I and the amendment of ARM )  
37.114.101, 37.114.105, 37.114.203, )  
37.114.204, 37.114.313, 37.114.314, )  
37.114.526, 37.114.546, 37.114.571, )  
37.114.590, 37.114.1001, and )  
37.114.1015 pertaining to )  
communicable disease control )

TO: All Concerned Persons

1. On September 12, 2019, at 2:30 p.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed adoption and amendment of the above-stated rules.

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 September 4, 2019, to advise us of the nature of the accommodation that you need. Please contact Gwen Knight, 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 dphhslegal@mt.gov.

3. The rule as proposed to be adopted provides as follows:

NEW RULE I MULTIDRUG-RESISTANT ORGANISMS (MDROs) (1) For cases or outbreaks of Multidrug-Resistant Organisms (MDROs), control measurers outlined in the "Interim Guidance for a Public Health Response to Contain Novel or Targeted Multidrug-resistant Organisms (MDROs)," updated January 2019, must be applied and infection control precautions appropriate to the event must be implemented.

(2) The department will provide consultation, assist with investigations, and coordinate responses in healthcare facility and community settings at the request of the local health officer.

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

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

37.114.101 DEFINITIONS Unless otherwise indicated, the following definitions apply throughout this chapter:

(1) through (6) remain the same.

(7) "Directly observed therapy (DOT)" means the method whereby a trained health-care worker or another trained designated person watches a patient swallow each dose of antituberculosis medication and documents it. DOT can include electronic directly observed therapy (eDOT) utilizing a video conferencing application only with express permission from the state TB program.

(8) remains the same.

(9) "Form" means a paper form or electronically submitted information consisting of data elements necessary to implement effective surveillance, investigation, or mitigation of reportable diseases and outbreaks.

(9) through (23) remain the same but are renumbered (10) through (24).

(25) "Multidrug-Resistant Organisms (MDRO)" means microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents.

~~(24)~~ (26) "Outbreak" means ~~an incidence of a disease or infection significantly exceeding the incidence normally observed in a population of people over a period of time specific to the disease or infection in question~~ the occurrence of more cases of a disease than would normally be expected in a specific place or group of people over a given period of time.

(25) through (33) remain the same but are renumbered (27) through (35).

(36) "Toxic Metals" means individual metals and metal compounds that may negatively affect an individual's health and shall include arsenic, cadmium, lead, and mercury for the purposes of these rules.

AUTH: 50-1-202, 50-2-116, 50-17-103, MCA

IMP: 50-1-202, 50-17-103, 50-18-101, MCA

37.114.105 INCORPORATION BY REFERENCE (1) The department adopts and incorporates by reference the following publications:

(a) through (f) remain the same.

(g) The "Interim Guidance for a Public Health Response to Contain Novel or Targeted Multidrug-resistant Organisms (MDROs)", updated January 2019, published by the U.S. Centers for Disease Control and Prevention, which serves as general guidance to state and local health departments and healthcare facilities in relation to the initial response for the containment of novel or targeted MDROs or resistance mechanisms.

(2) To obtain, or for information on how to obtain, any document or publication incorporated by reference, contact the Department of Public Health and Human Services, Public Health and Safety Division, Communicable Disease Control and Prevention Bureau, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951, phone: (406) 444-0919, or by visiting our website at: <https://dphhs.mt.gov/publichealth/cdepi/reporting>.

AUTH: 50-1-202, MCA

IMP: 50-1-202, MCA

37.114.203 REPORTABLE DISEASES AND CONDITIONS (1) The following communicable diseases and conditions are reportable:

(a) through (d) remain the same.

(e) Arsenic poisoning ( $\geq 70$  micrograms per liter ( $\mu\text{g/L}$ ) total arsenic in urine; or  $\geq 35$   $\mu\text{g/L}$  methylated plus inorganic arsenic in urine);

(e) through (g) remain the same but are renumbered (f) through (h).

(i) Cadmium poisoning ( $\geq$  five  $\mu\text{g/L}$  total blood cadmium levels; or  $\geq$  three  $\mu\text{g/L}$  total cadmium in urine);

(j) Candida auris (C. auris);

(h) through (r) remain the same but are renumbered (k) through (u).

~~(s)~~ (v) Escherichia coli, shiga Shiga toxin-producing (STEC);

(t) through (ae) remain the same but are renumbered (w) through (ah).

~~(af)~~ (ai) Lead poisoning (blood levels  $\geq$  five micrograms per deciliter ( $\mu\text{g/dL}$ ) ( $\geq$  five micrograms per deciliter  $\mu\text{g/dL}$  total blood lead levels);

(ag) through (an) remain the same but are renumbered (aj) through (aq).

(ar) Mercury poisoning ( $\geq 200$   $\mu\text{g/L}$  total mercury in urine; or  $\geq 20$   $\mu\text{g}$  elemental mercury/g creatinine in urine; or  $\geq 10$   $\mu\text{g/L}$  elemental, organic, and inorganic blood mercury levels);

(ao) through (av) remain the same but are renumbered (as) through (az).

~~(aw)~~ (ba) Salmonellosis (including Salmonella Typhi and Paratyphi);

(ax) through (bg) remain the same but are renumbered (bb) through (bk).

~~(bh)~~ (bl) Transmissible spongiform encephalopathies (including Creutzfeldt Jakob Disease);

(bi) remains the same but is renumbered (bm).

~~(bj)~~ (bn) Tuberculosis (TB) including latent tuberculosis infection;

(bk) remains the same but is renumbered (bo).

~~(bl) Typhoid fever;~~

(bm) through (bp) remain the same but are renumbered (bp) through (bs).

(2) remains the same.

AUTH: 50-1-202, 50-17-103, 50-18-105, 50-18-106, MCA

IMP: 50-1-202, 50-2-118, 50-17-103, 50-18-102, 50-18-106, MCA

37.114.204 REPORTS AND REPORT DEADLINES (1) remains the same.

(2) A local health officer must transmit by telephone or secure electronic means to the department the information required by ARM 37.114.205(1) and (2) for each suspected or confirmed case of one of the following diseases, within the time limit noted for each:

(a) remains the same.

(b) Information about a case of one of the following diseases must be submitted within seven calendar days after it is received by the local health officer:

(i) through (iii) remain the same.

(iv) Arsenic poisoning ( $\geq 70 \mu\text{g/L}$  total arsenic in urine; or  $\geq 35 \mu\text{g/L}$  methylated plus inorganic arsenic in urine);

(iv) remains the same but is renumbered (v).

(vi) Cadmium poisoning ( $\geq$  five  $\mu\text{g/L}$  total blood cadmium levels; or  $\geq$  three  $\mu\text{g/L}$  total cadmium in urine);

(v) remains the same but is renumbered (vii).

(viii) Candida auris (C. auris);

(vi) through (xxii) remain the same but are renumbered (ix) through (xxv).

(~~xxiii~~) (xxvi) Lead poisoning (blood levels  $\geq$  five micrograms per deciliter,  $\mu\text{g/dL}$  total blood lead levels ( $\mu\text{g/dL}$ ));

(xxiv) through (xxix) remain the same but are renumbered (xxvii) through (xxxii).

(xxxiii) Mercury poisoning ( $\geq 200 \mu\text{g/L}$  total mercury in urine; or  $\geq 20 \mu\text{g}$  elemental mercury/g in creatinine in urine; or  $\geq 10 \mu\text{g/L}$  elemental, organic, and inorganic blood mercury levels);

(xxx) through (xxxiii) remain the same but are renumbered (xxxiv) through (xxxvii).

(~~xxxiv~~) (xxxviii) Salmonellosis (including Salmonella Typhi and Paratyphi);  
(xxxv) through (xliv) remain the same but are renumbered (xxxix) through (xlvii).

(~~xliv~~) (xlviii) Tuberculosis (TB) including latent tuberculosis infection;

(~~xliv~~) Typhoid Fever;

(xlv) through (xlix) remain the same but are renumbered (xlix) through (lii).

(3) remains the same.

(4) For any animal bite exposure that may result in a risk of rabies transmission to a human by a species susceptible to rabies infection, the local health officer must report by secure electronic means to the department documentation of a rabies post-exposure prophylaxis recommendation or administration on a form provided by the department within seven calendar days of the recommendation or administration.

(5) A laboratory that performs testing associated with HIV infection must report:

(a) and (b) remain the same.

(c) HIV nucleic acid tests, RNA or DNA, irrespective of result; and

(d) all test results for assays designed to assess HIV infection subtype and resistance to antiretroviral drugs, including nucleotide sequences, in a format designated by the department; and

(e) submit a specimen utilized for surveillance purposes only, to the department's public health laboratory upon request.

AUTH: 50-1-202, 50-17-103, 50-18-105, MCA

IMP: 50-1-202, 50-17-103, 50-18-102, 50-18-106, MCA

37.114.313 CONFIRMATION OF DISEASE (1) Subject to the limitation in (2), if a local health officer receives information about a case of any of the following diseases, the officer must work with the department to ensure that a specimen from

the case is submitted to the department, when possible, which will be analyzed to confirm the existence or absence of the disease in question, or for further examination associated with use in surveillance or investigation of disease transmission:

(a) through (d) remain the same.

~~(e) Campylobacteriosis;~~

(e) Candida auris (C. auris);

~~(f) Carbapenem-Resistant Enterobacteriaceae (CRE) Organisms;~~

(g) and (h) remain the same.

~~(i) Escherichia coli, shiga~~ Shiga toxin-producing (STEC);

~~(j) Gonorrhea;~~

(k) and (l) remain the same but are renumbered (j) and (k).

~~(m) Human immunodeficiency virus (HIV);~~

(n) through (u) remain the same but are renumbered (l) through (s).

~~(v) (t) Salmonellosis (including Salmonella Typhi and Paratyphi);~~

(w) through (y) remain the same but are renumbered (u) through (w).

~~(z) Syphilis;~~

(aa) remains the same but is renumbered (x).

~~(ab) (y) Tuberculosis disease;~~

(ac) remains the same but is renumbered (z).

~~(ad) Typhoid fever;~~

(ae) through (ag) remain the same but are renumbered (aa) through (ac).

(2) In the event of an outbreak, emergence of an arboviral disease, gastroenteritis, influenza, measles, or pertussis, a communicable disease or a disease of public health importance, specimens must be submitted at the request of the department until a representative sample has been reached as determined by the department.

(3) A laboratory professional or any other person in possession of a specimen from a case of a disease listed in (1)~~(a) through (ag)~~ must submit the specimen to the department upon request.

(4) remains the same.

AUTH: 50-1-202, 50-1-204, MCA

IMP: 50-1-202, 50-1-204, MCA

37.114.314 INVESTIGATION OF A CASE (1) and (2) remain the same.

(3) Whenever the identified source of a reportable disease or a person infected or exposed to a reportable disease who should be quarantined, interviewed, or placed under surveillance is located outside of the jurisdiction of the local health officer, the local health officer must ~~notify~~ coordinate with the department ~~who will then~~ to notify the health officer of the relevant jurisdiction.

AUTH: 50-1-202, 50-2-118, 50-17-103, 50-18-105, MCA

IMP: 50-1-202, 50-2-118, 50-17-103, 50-17-105, 50-18-102, 50-18-107, 50-18-108, MCA

37.114.526 ESCHERICHIA COLI ENTERITIS (SHIGA-TOXIN PRODUCING)

(1) The local health officer or the department must ensure that a child attending day care or child care as defined in ARM 37.95.102 must be excluded from such care until diarrhea resolves and two stool ~~cultures~~ specimens collected at least 24 hours apart, obtained at least 48 hours after antimicrobial therapy has been discontinued, are negative.

AUTH: 50-1-202, 50-2-118, MCA

IMP: 50-1-202, 50-2-118, MCA

37.114.546 LEAD POISONING: ELEVATED BLOOD LEAD LEVELS TOXIC METALS (1) remains the same.

(2) The local health officer must ensure that the following actions are performed when a ~~blood lead level  $\geq$  five micrograms per deciliter is reported~~ biological sample derived from the human body is reported that exceeds reportable toxic metal levels indicated in ARM 37.114.203(1)(e), (i), (ai), and (ar). The health officer or health-care provider must provide:

(a) counseling about the health consequences of lead poisoning their toxic metals exposure;

(b) information about ways to reduce or eliminate lead their exposure(s) to toxic metals exposure; and

(c) referral of the case and household members potentially at risk of exposure to a health-care provider for additional follow-up and ~~blood lead~~ testing as appropriate.

(3) The department will provide consultation, assist with investigations, and coordinate responses in occupational and community settings at the request of the health officer.

AUTH: 50-1-202, MCA

IMP: 50-1-202, MCA

37.114.571 RABIES EXPOSURE (1) through (3) remain the same.

(4) Whenever the circumstances involve a dog, cat, or ferret, the local health officer must:

(a) arrange for the animal to be observed for signs of illness during a ten-day ~~quarantine~~ observation period at an animal shelter, veterinary facility, or other adequate facility, and ensure that any illness in the animal during the confinement or before release is evaluated by a veterinarian for signs suggestive of rabies; and

(b) remains the same.

AUTH: 50-1-202, 50-2-118, MCA

IMP: 50-1-202, 50-2-118, MCA

37.114.590 TYPHOID FEVER SALMONELLA TYPHI (1) remains the same.

AUTH: 50-1-202, 50-2-118, MCA

IMP: 50-1-202, 50-2-118, MCA

37.114.1001 TUBERCULOSIS DIAGNOSIS (1) through (3) remain the same.

(4) A case of latent tuberculosis infection exists if the case meets the laboratory and clinical criteria in (5) and (6).

(5) Laboratory criteria for latent tuberculosis infection:

(a) a positive tuberculin skin test (TST); or

(b) a positive interferon gamma release assay (IGRA).

(6) Clinical criteria for latent tuberculosis infection:

(a) no clinical evidence compatible with TB disease including no signs or symptoms consistent with TB disease; and

(b) chest imaging without abnormalities consistent with TB disease (chest radiograph or CT scan); or

(c) abnormal chest imaging that could be consistent with TB disease with microbiologic testing that is negative for abnormal chest imaging that could be consistent with TB disease with microbiologic testing that is negative for Mycobacterium Tuberculosis Complex and where TB disease has been clinically ruled out.

AUTH: 50-1-202, 50-17-103, 50-17-105, MCA

IMP: 50-1-202, 50-17-103, 50-17-105, MCA

37.114.1015 CASE FOLLOW-UP, REPORTING, AND CONTACT INVESTIGATION (1) through (4) remain the same.

(5) A case of latent tuberculosis must be referred to a health-care provider to rule out active TB disease. Once active TB disease has been ruled out, the individual should be:

(a) educated on risks of conversion to active TB disease; and

(b) referred for treatment for latent tuberculosis infection.

(6) Local health officers must ensure that a latent tuberculosis infection report form, provided by the department, is completed and submitted.

AUTH: 50-1-202, 50-17-103, MCA

IMP: 50-1-202, 50-17-102, 50-17-105, MCA

## 5. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) is proposing to adopt New Rule I and proposing the amendment of ARM 37.114.101, 37.114.105, 37.114.203, 37.114.204, 37.114.313, 37.114.314, 37.114.526, 37.114.546, 37.114.571, 37.114.590, 37.114.1001, and 37.114.1015.

These proposed amendments are necessary in order to keep Montana communicable disease control administrative rules current with changing nationally notifiable disease surveillance investigation and control recommendations. Updated core references reflect changing technologies and knowledge of improved disease specific control measures.

## NEW RULE I

The department is proposing New Rule I to address emerging public health threats linked to healthcare associated infection cases and outbreaks associated with multidrug-resistant organisms.

### ARM 37.114.101

The department is proposing to amend ARM 37.114.101 to update and clarify terms, update referenced materials, address subjective terminology, and to incorporate new terminology.

### ARM 37.114.105

The department is proposing to amend this rule by updating referenced documents and proposing a new reference regarding the management of Multidrug-Resistant Organisms in order to adapt to emerging public health threats.

### ARM 37.114.203

The department is proposing to update this rule to align it with the nationally notifiable disease listing from a disease and terminology standpoint and to better define reportable diseases and outbreaks. The department is proposing to add latent tuberculosis, arsenic poisoning, mercury poisoning, and cadmium poisoning as reportable diseases and conditions under the rule.

### ARM 37.114.204

The department is proposing to update this rule to align with the nationally notifiable disease listing from a disease and terminology standpoint and to better define reportable events while clarifying language. Reporting requirements have been added for latent tuberculosis, arsenic poisoning, mercury poisoning, and cadmium poisoning.

### ARM 37.114.313

The department is proposing to update this rule to align it with the nationally notifiable disease listing from a disease and terminology standpoint and to specify submission requirements for specimens as they relate to reportable diseases and outbreaks.

### ARM 37.114.314

The department is proposing to amend ARM 37.114.314 to clarify investigation coordination between local health jurisdictions and the department.

### ARM 37.114.526



The department is proposing to clarify language in ARM 37.114.526 regarding the submission of biological materials associated with investigation of a case.

ARM 37.114.546

The department is proposing to amend this rule from being lead specific by expanding it to include other "toxic metals" proposed for mandatory reporting (e.g., arsenic and cadmium poisoning) that would be subject to the same types of local health department interventions as lead poisoning.

ARM 37.114.571

Changes in language to ARM 37.114.571 are proposed to clarify requirements for observation as opposed to quarantine to align with Montana Department of Livestock recommendations and requirements.

ARM 37.114.590

The department is proposing to amend this rule to better align with national disease reporting terminology.

ARM 37.114.1001

The department is proposing to amend this rule to address the addition of latent tuberculosis to the list of reportable diseases.

ARM 37.114.1015

The department is proposing to amend this rule to update references and to clarify the processes associated with reporting and case follow-up of reported latent tuberculosis cases.

Fiscal Impact

The department anticipates no fiscal impact regarding the proposed rulemaking.

The proposed rulemaking is estimated to affect: 58 local health jurisdictions (tribal/county), 46 Critical Access Hospitals, 14 Inpatient Hospitals, 3 outpatient hospitals, 84 laboratories, 7,304 physicians, and 2,109 mid-level practitioners.

6. The department intends to make these proposed rules effective as of January 1, 2020.

7. 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: Gwen Knight, 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 dphhslegal@mt.gov, and must be received no later than 5:00 p.m., September 20, 2019.

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

9. 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 7 above or may be made by completing a request form at any rules hearing held by the department.

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 adoption and amendment of the above-referenced rules will not significantly and directly impact small businesses.

/s/ Robert Lishman  
Robert Lishman  
Rule Reviewer

/s/ Sheila Hogan  
Sheila Hogan, Director  
Public Health and Human Services

Certified to the Secretary of State August 13, 2019.