DEPARTMENT OF HEALTH

*Protecting, Maintaining and Improving the Health of All Minnesotans*

December 17, 2018

TO: Policy and Funding Committees and Divisions with Jurisdiction over the Minnesota Department of Health

[A complete list of addressees is at the end of the letter.]

RE: In The Matter of the Proposed Repeal of Obsolete Rules of the Department of Health Revisor's ID Number R-4325

Dear Legislators:

The Minnesota Department of Health intends to repeal the following rules that it has identified as obsolete:

**Mobile Home Parks and Recreational Camping Areas rule:** Part 4630.2000. The fees contained
in the rules have been superseded by statute.

**Tuberculosis Testing rules:** Certain parts, subparts, and portions of Chapters 4640; 4655; 4658; 4664; 4665; and 4675. Minnesota no longer has the tuberculosis hospitals that the rules used to govern and the TB tests required are no longer used.

**Newborn Screening rules.** Certain parts, subparts, and portions of Chapters 4615.0300, 4615.0400, 4615.0500, 4615.0600, and 4615.0700. The language is either obsolete, unnecessary, or duplicative. In 2014, the Legislature added explicit sections to the newborn screening statutes that supersede the rules (*Minnesota Statutes*, section 144.125 to 144.128).

**Rules relating to Chapter 4670—Local Public Health Agencies; Merit System.** The Legislature, by *Minnesota Laws* 2014, chapter 192, repealed the chapter's statutory authority, *Minnesota Statutes*, section 144.071. The entire chapter is therefore no longer enforceable and its remaining rules parts, subparts, and items are now either obsolete, unnecessary, or duplicative.

**Environmental Laboratory Accreditation rules:** Certain parts, subparts, and portions of Chapters 4630 and 4740. In 2009, the Legislature amended Minnesota Statutes, sections 144.98 and 144.99, requiring the commissioner to accredit labs according to national laboratory standards and charge the fees stated in the amended statute. This repeal removed the outdated state requirements to avoid confusion about what standards apply to the accredited labs.

If 25 or more people submit a written request, the Department will have to meet the requirements of sections 14.131 to 14.20 for rules adopted after a hearing or the requirements of sections 14.22

to 14.28 for rules adopted without a hearing, including preparing a statement of need and reasonableness and the opportunity for a hearing.

The Department is publishing the Notice of Intent to Repeal Obsolete Rules in the December 17, 2018 *State Register*, and are now mailing the Notice under Minnesota Statutes, section 14.3895, subdivision. 3.

As required by section 14.3895, subdivision 3, the Department is sending you a copy of the notice and the Revisor's draft of the proposed rules that repeal these obsolete rules.

If you have any questions about these rules, please contact me at (651) 201-5748.

Yours very truly,

Patricia Winget

Patricia Winget
MDH Rules Coordinator and Legal Counsel

CC: Melissa Finnegan
Director: MDH Office of Legislative Relations

**This is a complete list of addressees for MDH's 2018-2019 Obsolete Rules Repeal.**

**Senate Health and Human Services Finance and Policy Committee**

Senator Michelle Benson
Minnesota Senate
95 University Avenue W.
3109 Minnesota Senate Bldg.
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Senator Tony Lourey
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**Senate Environment and Natural Resources Policy and Legacy Finance Committee**

Senator Carrie Ruud
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Senator Chris Eaton
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**Senate State Government Finance and Policy and Elections Committee**

Senator Mary Kiffmeyer
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**Senate Human Services Reform Finance and Policy Committee**

Senator Jim Abeler
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**Senate Environment and Natural Resources Finance Committee**

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**House Health and Human Services Finance Committee**

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**House Environment and Natural Resources Policy and Finance**

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100 Rev. Dr. Martin Luther King Jr. Blvd.
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Representative Sheldon Johnson
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**House Commerce and Regulatory Reform Membership Committee**

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# Minnesota Department of Health

**Divisions of Environmental Health, Public Health Laboratory, Infectious Disease Epidemiology, Prevention and Control, and Health Improvement**

**NOTICE OF INTENT TO REPEAL OBSOLETE RULES**

**Proposed Repeal of Rules identified in the Department of Health's 2018 Obsolete Rules Report. OAH Docket Number 82-9000-35714; Revisor ID Number R-4325; Rules Governing:**

**Camps and Manufactured Home Parks, Minnesota Rules 4630.2000 [Environmental Health Division].**

**Newborn Screening, Minnesota Rules 4615.0300; 4615.0400; 4615.0500; 4615.0600; 4615.0700 [Public Health Laboratory Division].**

**Tuberculosis Testing, Minnesota Rules 4640.0100, subpart 12; 4640.4400–4640.6000; 4655.3000; 4655.4700, subpart 1; 4658.0450, subpart 1, item H; 4658.0800, subpart 4, items E and F; 4658.0810; 4658.0815; 4658.0850; 4664.0190, subpart 3, item L; 4664.0290, subparts 1–6; 4664.0290, subpart 8, items A–F; 4665.1200, item A; 4675.0500, item I [Infectious Disease Epidemiology, Prevention and Control Division].**

**Local Public Health Agencies; Merit System, Minnesota Rules, Chapter 4670: 4670.0100, subparts 1, 1a, 2, 3, 3a, 4, 5, 6, 7, 7a, 7b, 8, 9, 10, 11, 12, 12a, 13, 13a, 14, 14a, 15, 16, 17, 17a, 17b, 18, 19a, 20, 21, 22, 23, 25, 26, 26a, 27, 28, 29, 30, 31, 32, 33, 34, 34a, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 48a, 49, and 50; 4670.0200; 4670.0300; 4670.0310; 4670.0320; 4670.0400; 4670.0500; 4670.0600; 4670.0610; 4670.0700; 4670.0810; 4670.0820; 4670.0830; 4670.0900; 4670.0910; 4670.0920; 4670.0930, subparts 1 and 2; 4670.0940; 4670.0950; 4670.1000; 4670.1010; 4670.1020; 4670.1110; 4670.1120; 4670.1130; 4670.1140; 4670.1200, subparts 1, 3, 3a, and 5; 4670.1210; 4670.1300; 4670.1310; 4670.1320; 4670.1330; 4670.1340; 4670.1500; 4670.1700; 4670.1800; 4670.1900; 4670.1910; 4670.1920; 4670.1930; 4670.1940; 4670.1950; 4670.1960; 4670.1970; 4670.1980; 4670.2000; 4670.2100; 4670.2200; 4670.2300; 4670.2400; 4670.2500; 4670.2510; 4670.2520; 4670.2530; 4670.2540; 4670.2550; 4670.2600; 4670.2610; 4670.2620; 4670.2630; 4670.2640; 4670.2650; 4670.2660; 4670.2670; 4670.2680; 4670.2690; 4670.2700; 4670.2710; 4670.2800; 4670.2810; 4670.2900; 4670.2910; 4670.2920; 4670.2930; 4670.2950; 4670.2960; 4670.2980; 4670.3200; 4670.3300; 4670.3500; 4670.3510; 4670.3520; 4670.3530; 4670.3550; 4670.3600; 4670.3700; 4670.3800; 4670.4010; 4670.4030; 4670.4100; 4670.4110; 4670.4120; 4670.4130; 4670.4140; 4670.4150; 4670.4200; 4670.4210, subpart 1; 4670.4220, subpart 1; and 4670.4230, subpart 1 [Health Improvement Division].**

**Accrediting Environmental Laboratories, Minnesota Rules 4740.2010, subpart 39; 4740.2050, subpart 1; 4740.2050, subpart 1, item C; 4740.2050, subpart 1, item D**

**(1)–(2); 4740.2050, subpart 1, item D (3)–(6), and item E; 4740.2050, subpart 2, item C; 4740.2050, subpart 3; 4740.2050, subpart 7, item B; 4740.2050, subpart 7, item D; 4740.2050, subpart 10 (5); 4740.2050, subpart 12, item A; 4740.2050, subpart 12, item C; 4740.2050, subpart 12, item F; 4740.2050, subpart 16, item A; 4740.2050, subpart 16, item D; 4740.2060, subpart 2, item C; 4740.2060, subpart 3, item C; 4740.2060, subpart 4, item C; 4740.2060, subpart 5, item C; 4740.2065, subpart 8; 4740.2070, subparts 2, 3, 5, 6; 4740.2070, subpart 7, items A, B, and D; 4740.2070, subpart 8, items A, B, and C; 4740.2087, subpart 2, items A and C; 4740.2089, item C; 4740.2100, subpart 4, item A; 4740.2100, subpart 5, item B; 4740.2100, subpart 9, item A [Environmental Health Improvement Center Division].**

**Introduction.** The Minnesota Department of Health (MDH) intends to repeal obsolete rules under the rulemaking process in the Administrative Procedure Act, *Minnesota Statutes*, section 14.3895. You may submit written comments on the proposed repeal of obsolete rules until Friday, February 22, 2019.

**Agency Contact Person.** You must submit comments or questions on the rules to Patricia Winget, Minnesota Department of Health, 625 North Robert Street, P.O. Box 64975, Saint Paul, MN 55164; telephone: (651) 201-5748; fax: (651) 201-4986; or email: *patricia.winget@state.mn.us*.

**Subject of the Repeal of Obsolete Rules and Statutory Authority.** The Department proposes to repeal the following obsolete, unnecessary, or duplicative rules, the Department identified in MDH's 2018 Obsolete Rules Report under *Minnesota Statutes*, section 14.05, subdivision 5:

**1. Rules relating to Chapter 4630—Camps and Manufactured Home Parks.** Part 4630.2000 is obsolete, unnecessary, or duplicative. In 2009, the Legislature added licensing fees to the camps and manufactured home park statutes under *Minnesota Statutes*, section 327.15, superseding 4630.2000 and making the rule part superfluous. *See Minnesota Laws* 2009, chapter 79, article 10, section 40.

**2. Rules relating to Chapter 4615—Newborn Screening.** The language is either obsolete, unnecessary, or duplicative. In 2014, the Legislature added explicit sections to the newborn screening statutes that supersede the rules (*Minnesota Statutes*, section 144.125 to 144.128):

- Part 4615.0300 is obsolete and duplicative because most of the duties stated are defined in *Minnesota Statutes*, section 144.125.

- Part 4615.0400 is obsolete because it duplicates language included in *Minnesota Statutes*, section 144.125 and is unnecessary.

- Part 4615.0500 is obsolete because it does not include all conditions currently on the screening panel and does not reflect parents' rights to opt out for any reason. It also duplicates language in *Minnesota Statutes*, section 144.125.

- Part 4615.0600 is obsolete because it prescribes basic, standard MDH practice that is integral to operating the program.

- Part 4615.0700 is obsolete as it does not require reporting of all conditions currently on the screening panel and includes an incorrect reporting address.

**3. Rules relating to Chapter 4640—Tuberculosis Testing.** The language is either obsolete, unnecessary, or duplicative because Minnesota no longer has tuberculosis hospitals and the testing requirements are outdated. In 2013, the Legislature enacted *Minnesota Laws*, chapter 45, which includes new statutes that supersede them:

- Part 4640.0100, subparts 12, and other phrases relating to tuberculosis in subparts 3, 10, and 11 are obsolete because they relate to definitions for hospital licensing and operation rules for tuberculosis hospitals, which Minnesota no longer has.

- Part 4640.4400–4640.6000 are obsolete as they relate to hospital licensing and operation rules that govern staff of tuberculosis hospitals, which Minnesota no longer has.

- Part 4655.3000, these requirements for specific tests for nursing and boarding care home employees are now obsolete because *Minnesota Statutes*, sections 144A.04 and 144.56, subdivision 2c, superseded them.

- Part 4658.0450, subpart 1, item H, is now obsolete as the penalties refer to parts 4658.0810 and 4658.0815, which are superseded by *Minnesota Statutes*, section 144A.04.

- Part 4655.4700, subpart 1, specifically requires a now-obsolete testing method as part of a required physical exam of boarding care home residents upon admission.

- Part 4658.0800, subpart 4, items E and F, are now obsolete because *Minnesota Statutes*, section 144A.04 supersedes them.

- Part 4658.0810, nursing home providers no longer use this resident tuberculosis program, making the part obsolete and superseded by *Minnesota Statutes*, section 144A.04.

- Part 4658.0815, nursing home providers no longer use this resident tuberculosis program, making this part therefore obsolete and superseded by *Minnesota Statutes*, section 144A.04.

- Part 4658.0850, is now obsolete since these penalties refer to parts 4658.0810 and 4658.0815, which the Department is repealing. *Minnesota Statutes*, section 144A.04, supersedes it.

- Part 4664.0190, subpart 3, item L, is now obsolete because *Minnesota Statutes*, section 144A.752, subdivision 4, supersedes it.

- Part 4664.0290, subparts 1–6, hospice providers no longer use these types of infection control requirements, so the subparts are therefore obsolete because *Minnesota Statutes*, section 144A.752, subdivision 4, supersedes them.

- Part 4664.0290, subpart 8, items A–F, hospice providers no longer use these types of infection control requirements. Thus the items are therefore obsolete and *Minnesota Statutes*, section 144A.752, subdivision 4, supersedes them.

- Part 4664.0290, subpart 8, hospice providers no longer use these types of infection control requirements. The subpart is therefore obsolete and *Minnesota Statutes*, section 144A.753, subdivision 4, supersedes it.

- Part 4665.1200, item A, supervised living facilities are no longer required to follow this provision and the item is therefore obsolete and *Minnesota Statutes*, section 144.50, subdivision 6a, supersedes it.

- Part 4675.0500, item I, governs outpatient surgical centers medical staff. The item is obsolete because *Minnesota Statutes*, section 144.55, subdivision 3(c), supersedes it.

**4. Rules relating to Chapter 4670—Local Public Health Agencies; Merit System.** The Legislature, by *Minnesota Laws* 2014, chapter 192, repealed the chapter's statutory authority, *Minnesota Statutes*, section 144.071. The entire chapter is therefore no longer enforceable and its remaining rules parts, subparts, and items are now either obsolete, unnecessary, or duplicative.

**5. Rules relating to Chapter 4740—Accrediting Environmental Laboratories.** The language is either obsolete, unnecessary, or duplicative. In 2009, the Legislature amended *Minnesota Statutes*, sections 144.98 and 144.99, requiring the commissioner to accredit labs according to national laboratory standards and charge the fees stated in the amended statute:

- Part 4740.2000 is obsolete because current fees are found in Minnesota Statutes, section 327.15.

- Part 4740.2010, subpart 39, is obsolete since the defined term "notarial officer" is no longer used in 4740.2050, subpart 1, but is defined in statutes elsewhere.

- Part 4740.2050, subpart 1, item A, contains the phrase "according to subpart 3," which is an outdated reference.

- Part 4740.2050, subpart 1, item C, the phrase beginning "The laboratory must apply…" is obsolete because MDH is converting the lab certification program's application to an online form using an electronic signature. This item is obsolete.

- Part 4740.2050, subpart 1, item D (1) to (2), is obsolete because *Minnesota Statutes*, section 144.98, supersedes these requirements.

- Part 4740.2050, subpart 1, item D (3) to (6) and item E, are obsolete because *Minnesota Statutes*, section 144.98, subdivision 6, supersedes these requirements.
- Part 4740.2050, subpart 2, item C, with the phrase beginning "With each change in location…" is obsolete because the information required is now included in laboratory documentation required with the application under *Minnesota Statutes*, section 144.98.

- Part 4740.2050 subpart 3, is obsolete because *Minnesota Statutes*, section 144.998, subdivision 3a(b) supersedes these requirements.

- Part 4740.2050, subpart 7, item B, is obsolete or duplicative because the required items are listed in national standards and adopted in *Minnesota Statutes*, section 144.98, subdivision 2a.

- Part 4740.2050, subpart 7, item D, is obsolete because *Minnesota Statutes*, section 144.98, subdivision 7, supersedes these requirements.

- Part 4740.2050, subpart 10, item B (5), contains the phrase "at the frequency specified in part 4740.2070," which is obsolete. The standards now contained in *Minnesota Statutes*, section 144.98, subdivision 2a, govern frequency.

- Part 4740.2050, subpart 12, item A, contains the phrase "unless a reciprocity agreement exists," which is obsolete. The standards now contained in *Minnesota Statutes*, section 144.98, subdivision 2a, govern reciprocity.

- Part 4740.2050, subpart 12, item A, the phrase beginning "Fees include the on-site…" is obsolete because these fees and their frequency of payment are requirements that *Minnesota Statutes*, section 144.98, subdivision 6(d), supersedes. The standards no longer contain reciprocal agreements and thus on-site-inspection fees do not apply.

- Part 4740.2050, subpart 12, item C, is obsolete because these requirements for approval of reciprocity agreements are obsolete since by *Minnesota Statutes*, section 144.98, subdivision 6(d) there are no longer reciprocity agreements.

- Part 4740.2050, subpart 12, item D(2), contains the phrase "not to include an on-site inspection fee for out-of-state laboratories," which is obsolete. The standards now contained in *Minnesota Statutes*, section 144.98, subdivision 6(d), govern

inspection fees. The standards no longer contain reciprocal agreements and thus on-site-inspection fees do not apply.

- Part 4740.2050, subpart 12, item F, the phrase "…except the fee for out-of-state inspection under subpart 16, item D" is obsolete because the requirements for approval of reciprocal agreements are in national standards now governed by *Minnesota Statutes*, section 144.98, subdivision 6(d).

- Part 4740.2050, subpart 12, item F, the last sentence beginning "Only fixed-base laboratories located within…" is obsolete because the requirements for approval of reciprocal agreements are in national standards now governed by *Minnesota Statutes*, section 144.98, subdivision 6(d).

- Part 4740.2050, subpart 16, item A, contains the phrase "…subdivision 3," which is obsolete because the entire section 144.98 now applies.

- Part 4740.2050, subpart 16, item D, is obsolete because the item conflicts with the national standards contained in *Minnesota Statutes*, section 144.98, subdivision 2a.

- Part 4740.2060, subpart 2, item C; subpart 3, item C; subpart 4, item C; and subpart 5, item C; are identical items that contain the phrase "…as required under part 4740.2050, subpart 16, item C." This cited subpart 16 relates to fees, which are governed by *Minnesota Statutes*, section 144.98.

- Part 4740.2065, subpart 8, is obsolete because the required items are listed under national standards (adopted in *Minnesota Statutes*, section 144.98).

- Part 4740.2070, subparts 2, 3, 5, 6 and subpart 7, items A, B, and D, address proficiency test studies. These are obsolete because the national standards now listed in *Minnesota Statutes*, section 144.98, subdivision 2a, now control, eliminating the need for these references.

- Part 4740.2070, subpart 8, items A, B, and C, are obsolete as the required items here are now listed under national standards adopted in *Minnesota Statutes*, section 144.98, subdivision 2a.

- Part 4740.2087, subpart 2, items A and C, are obsolete requirements for because these requirements for handling laboratory samples are now governed by national standards adopted in *Minnesota Statutes*, section 144.98, subdivision 2a.

- Part 4740.2089, item C, is obsolete as these required items for keeping records for standards, reagents, and bacteriological media are contained under the national standards adopted in *Minnesota Statutes*, section 144.98, subdivision 2a.

- Part 4740.2100, subpart 4, item A, the second sentence is obsolete because the national standards adopted in *Minnesota Statutes*, section 144.98, subdivision 2a, do not include these requirements for matrix spikes.

- Part 4740.2100, subpart 5, item B, the phrase "before sample preparation or extraction" is obsolete because the national standards adopted in *Minnesota Statutes*, section 144.98, subdivision 2a, do not include these procedures for sample testing.

- Part 4740.2100, subpart 9, item A, is obsolete as the national standard obsolete because the national standards adopted in *Minnesota Statutes*, section 144.98, subdivision 2a, includes a broader list of technologies affected by selectivity. Consequently, this item is out of date.

The agency identified the proposed obsolete rules in its annual obsolete rules report under *Minnesota Statutes*, section 14.05, subdivision 5. The statutory authority to repeal the obsolete rules appears in *Minnesota Statutes*, section 14.3895. A copy of the proposed obsolete rules to be repealed is published in the State Register and attached to this notice as mailed. A free copy of the rules is available upon request from the agency contact person listed above. The proposed obsolete rules to be repealed may be viewed at the Minnesota Department of Health's website: *http://www.health.state.mn.us*

**Comments.** You have until 4:30 p.m. on Friday, February 22, 2019, to submit written comment in support of or in opposition to the proposed repeal of obsolete rules and any part or subpart of the repeal. Your comment must be in writing and the agency contact person must receive it by the due date. The Department encourages comment. Your comment should identify the portion of the proposed obsolete rules to be repealed addressed and the reason for the comment. In addition, you are encouraged to object to the repeal of any part or subpart. You must also make any comments on the legality of the proposed rules during this comment period.

**Request for Hearing.** In addition to submitting comments, you may also request that a hearing be held on the rules. You must make your request in writing to the agency contact person. The agency contact person must receive the request by 4:30 p.m. on Friday, February 22, 2019. Your written request must include your name and address. You must identify the portion of the proposed repealed rules to which you object or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and the agency cannot count it for determining whether it must hold a public hearing. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

**Effect of Requests.** If 25 or more people submit a written request, the agency will have to meet the requirements of *Minnesota Statutes*, sections 14.131 to 14.20 for rules adopted after a hearing or the requirements of *Minnesota Statutes*, sections 14.22 to 14.28 for rules adopted without a hearing, including the preparation of a statement of need and reasonableness and the opportunity for a hearing.

**Modifications.** The agency might modify its choice of these designated rules or parts proposed for repeal (e.g. fixing a typo or deciding not to repeal a rule because the rule is discovered not to be obsolete), based on comments and information submitted to the agency. If the final rules to be repealed are identical to the rules originally published in the State Register for repeal, then the agency will publish a notice of adopting the repealers in the State Register. If the final rules to be repealed are different from the rules originally published in the State Register for repeal, then the agency must publish a copy of the changes in the State Register. If the proposed repeal of obsolete rules affects you in any way, the agency encourages you to participate in the rulemaking process.

**Alternative Format.** Upon request, the agency can make this Notice available in an alternative format, such as large print, Braille, or audio. To make such a request, please contact the agency contact person at the address or telephone number listed above.

**Lobbyist Registration.** *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You may direct questions regarding this requirement to the Campaign Finance and Public Disclosure Board at: Suite 190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 296-5148 or 1-(800)-657-3889.

**Repeal and Review of Obsolete Rules.** The agency may repeal the obsolete rules at the end of the comment period. The agency will then submit rules and supporting documents to the Office of Administrative Hearings for review for legality. You may ask to be notified of the date that the agency submits the rules. If you want to be so notified, or want to receive a copy of the repealed obsolete rules, or want to register with the agency to receive notice of future rule proceedings, submit your request to the agency contact person listed above.

December 5, 2018

Jan K. Malcolm, Commissioner
Minnesota Department of Health

**Department of Health**

**Proposed Permanent Rules Repealing and Eliminating Certain Health-Related Requirements**

## 4640.0100 DEFINITIONS.

Subpart 1. **Scope.** For the purpose of ~~these rules~~ this chapter, the terms used in subparts 2 to 12 have the meanings given them in this part.

Subp. 2. [Repealed by amendment, L 1977 c 305 s 39]

Subp. 3. **Chronic disease hospital.** A "chronic disease hospital" is a hospital, the primary purpose of which is to provide the services and facilities for the diagnosis, treatment, and rehabilitation of patients with chronic illness. "Chronic disease" refers to illness or disability which is either permanent or recurrent, which may require long periods of medical supervision or care as well as special rehabilitative services, as distinguished from acute illness which is usually of short duration and self-limiting in nature. Nursing homes and boarding care homes as classified and defined in parts 4655.0090 to 4655.1060, and hospitals devoted exclusively to the care of patients ~~with tuberculosis or~~ with mental illness are not "chronic disease hospitals."

*[For text of subps 4 to 9, see M.R.]*

Subp. 10. **Specialized hospital.** A "specialized hospital" is a hospital providing primarily for one type of care, such as a hospital for persons with a mental illness, a psychiatric hospital, ~~a tuberculosis hospital,~~ a chronic disease hospital, or a maternity hospital. The specialized hospital shall meet the applicable regulations for a general hospital of corresponding size and all regulations pertaining to such specialized services as are provided by the hospital.

Subp. 11. **Specialized unit.** When a general hospital provides ten or more beds in a segregated unit for a specialized type of care, such as psychiatric, ~~tuberculosis,~~ chronic disease, or nursing home, such a unit is a "specialized unit" of the general hospital. The

services provided in a nursing home unit are not hospital services. For licensing purposes, one license shall be issued to a general hospital having one or more specialized units, when such units are adjacent to or located on property adjoining that of the general hospital. Separate licenses shall be required for institutions which are maintained on separate premises even though they are under the same management. The total bed capacity, including bassinets, shall be used in determining the license fee.

Subp. 12. [See repealer.]

**4655.4700 PHYSICIANS' EXAMINATIONS AND ORDERS.**

Subpart 1. **Physical examination at admission.** Each patient or resident shall have an admission medical history and complete physical examination performed and recorded by a physician within five days prior to or within 72 hours after admission. The medical record shall include: the report of the admission history and physical examination; the admitting diagnosis and report of subsequent physical examinations; ~~a report of a standard Mantoux tuberculin test or, if the Mantoux test is positive or contraindicated, a chest X ray within three months in advance of admission and as indicated thereafter;~~ reports of appropriate laboratory examinations; general medical condition including disabilities and limitations; instructions relative to the patient's or resident's total program of care; written orders for all medications with stop dates, treatments, special diets, and for extent or restriction of activity; physician's orders and progress notes; and condition on discharge or transfer, or cause of death.

*[For text of subps 2 to 4, see M.R.]*

**4658.0450 CLINICAL RECORD CONTENTS.**

Subpart 1. **In general.** Each resident's clinical record, including nursing notes, must include:

*[For text of items A to G, see M.R.]*

~~H. a report of a tuberculin test within the three months prior to admission, as described in part 4658.0810;~~

~~I.~~ H. reports of laboratory examinations;

~~J.~~ I. dates and times of all treatments and dressings;

~~K.~~ J. dates and times of visits by all licensed health care practitioners;

~~L.~~ K. visits to clinics or hospitals;

~~M.~~ L. any orders or instructions relative to the comprehensive plan of care;

~~N.~~ M. any change in the resident's sleeping habits or appetite;

~~O.~~ N. pertinent factors regarding changes in the resident's general conditions; and

~~P.~~ O. results of the initial comprehensive resident assessment and all subsequent comprehensive assessments as described in part 4658.0400.

*[For text of subp 2, see M.R.]*

Subp. 3. **Nursing services.** The clinical record must contain the recording requirements of parts ~~4658.0515~~ 4658.0520 to 4658.0530.

*[For text of subps 4 to 6, see M.R.]*

Subp. 7. **Social services.** The clinical record must contain the recording requirements of parts ~~4658.1015~~ 4658.0450 and ~~4658.1020~~ 4658.1005.

**4658.0800 INFECTION CONTROL.**

*[For text of subps 1 to 3, see M.R.]*

Subp. 4. **Policies and procedures.** The infection control program must include policies and procedures which provide for the following:

*[For text of items A to D, see M.R.]*

E. a resident health program including an immunization program~~, a tuberculosis program as defined in part 4658.0810,~~ and policies and procedures of resident care practices to assist in the prevention and treatment of infections;

F. the development and implementation of employee health policies and infection control practices~~, including a tuberculosis program as defined in part 4658.0815~~;

*[For text of items G to I, see M.R.]*

**4658.0850 PENALTIES FOR INFECTION CONTROL RULE VIOLATIONS.**

Penalty assessments will be assessed on a daily basis for violations of parts 4658.0800 to 4658.0820 and are as follows:

A. part 4658.0800, $300;

B. part 4658.0805, $300; and

~~C. part 4658.0810, $200;~~

~~D. part 4658.0815, subparts 1 and 2, $200;~~

~~E. part 4658.0815, subpart 3, $50;~~

~~F. part 4658.0815, subpart 4, $300; and~~

~~G.~~ C. part 4658.0820, $100.

**4664.0190 HEALTH INFORMATION MANAGEMENT.**

*[For text of subps 1 and 2, see M.R.]*

Subp. 3. **Content.** A hospice provider must ensure that each hospice patient's record contains:

*[For text of items A to K, see M.R.]*

L. documentation of tuberculosis screening of residential hospice patients~~, as required by part 4664.0290, subpart 6~~; and

*[For text of item M, see M.R.]*

*[For text of subps 4 to 8, see M.R.]*

**4664.0290 INFECTION CONTROL.**

Subpart 1. [See repealer.]

Subp. 2. [See repealer.]

Subp. 3. [See repealer.]

Subp. 4. [See repealer.]

Subp. 5. [See repealer.]

Subp. 6. [See repealer.]

*[For text of subp 7, see M.R.]*

Subp. 8. **Fines.** For ~~each~~ a violation of ~~the following subparts~~ subpart 7, the stated fine shall be ~~assessed:~~ $300.

~~A. subpart 1, $100;~~

~~B. subpart 2, $500;~~

~~C. subpart 3, $50;~~

~~D. subpart 4, $500;~~

~~E. subpart 5, $100;~~

~~F. subpart 6, $500; and~~

~~G. subpart 7, $300.~~

**4665.1200 STAFF HEALTH.**

The licensee shall ~~assure~~ ensure that:

~~A. all staff shall, prior to employment and annually thereafter, show freedom from tuberculosis by a report of either a standard Mantoux tuberculin test or a chest X-ray. If the Mantoux test is positive or contraindicated, a chest X-ray shall be taken. The results of these tests shall be reported in writing and made a part of the staff member's personnel record;~~

~~B.~~ A. any staff member with a communicable disease shall not be permitted to work in the facility until such time that a physician certifies that the staff member's condition will permit a return to work without endangering the health of other staff and residents;

~~C.~~ B. the facility administrator may require that a staff member have a medical examination when a reasonable suspicion of communicable disease exists; and

~~D.~~ C. personnel records shall be available for inspection by department employees.

**4675.0500 MEDICAL STAFF.**

The medical director and the medical staff ~~shall be~~ are responsible to the governing body for patient and staff policies and for medical procedures and services relative to admission, treatment, and related emergency treatment. The medical staff shall:

A. Establish written policies for the admission and treatment of patients for surgery, including but not limited to~~:~~ subitems (1) to (5).

*[For text of subitems (1) to (5), see M.R.]*

*[For text of items B to H, see M.R.]*

~~I. Assure that all employees, prior to employment and at least annually thereafter show freedom from tuberculosis by means of a standard Mantoux tuberculin test and/or a chest X-ray test as medically indicated. The results shall be reported in writing and made a part of each employee's personnel record.~~

**4740.2050 APPLICATION FOR CERTIFICATION.**

Subpart 1. **Base certification requirements.**

A. A laboratory may request to be certified by the commissioner for the use of methods to test the analytes eligible for certification ~~according to subpart 3~~.

*[For text of item B, see M.R.]*

C. A laboratory must apply on a form that is provided by the commissioner. ~~The laboratory must supply the following information:~~

~~(1) the name of the laboratory;~~

~~(2) the physical location, postal mailing address, and electronic mailing address of the laboratory;~~

~~(3) the owner of the laboratory;~~

~~(4) the names and telephone numbers of a designated contact person and the laboratory director;~~

~~(5) the names of at least one managing agent with signature attested by a notarial officer; and~~

~~(6) the names of supervisory professional staff responsible for the analyses.~~

~~D. An application for certification must include:~~

~~(1) the form required under item C;~~

~~(2) the applicable fees, including a nonrefundable base certification fee and fees for each test category in which the laboratory seeks certification;~~

~~(3) a quality assurance manual meeting the standards of part 4740.2085;~~

~~(4) a laboratory procedures manual meeting the standards of part 4740.2065;~~

~~(5) if the application is an initial request for certification, the most recent proficiency testing result for each field of testing for which the laboratory seeks certification. The proficiency testing samples must be from an approved provider and be analyzed within one year prior to the date that the application is received by the commissioner; and~~

~~(6) a list of the laboratory's detection limits and reporting limits for each field of testing for which the laboratory is requesting certification.~~

~~E. Except as provided for mobile laboratories in subpart 2, a laboratory that owns or manages laboratory facilities at different locations must submit a separate application for each laboratory location.~~

~~F.~~ D. Applications for renewal of certification must be received no later than 90 days before the expiration of certification. The application must meet the criteria of this subpart. If a laboratory fails to submit a renewal application within 90 days before the expiration of certification, the commissioner must notify the regulatory authorities that receive data that the laboratory did not apply to renew its certification. The laboratory must not report results as certified after its certification expires.

Subp. 2. **Requirements for mobile laboratories.**

*[For text of items A and B, see M.R.]*

C. A mobile laboratory must designate which fields of testing, equipment, and personnel are associated with the mobile laboratory. Changes to the numbers and types of equipment within the mobile laboratory may require reapplication according to subpart 1. ~~With each change in location, the mobile laboratory must verify that the information provided to the commissioner as required in subpart 1, item D, subitem (6), remains applicable.~~

Subp. 3. [See repealer.]

*[For text of subps 4 to 6, see M.R.]*

Subp. 7. **Awarding certification.**

*[For text of item A, see M.R.]*

~~B. The certificate and scope of certification must include:~~

~~(1) the logo of the Minnesota Department of Health;~~

~~(2) the name of the laboratory;~~

~~(3) the address of the laboratory;~~

~~(4) the laboratory identification number; and~~

~~(5) the expiration date of the certification.~~

~~C.~~ B. If a laboratory's scope of certification changes, the commissioner shall issue a new certificate and scope of certification.

~~D. A laboratory's certification is valid for two years from the date of awarding base certification or renewal of base certification, unless conditions warrant suspension or revocation by the commissioner under subparts 9 and 10.~~

~~E.~~ C. A laboratory must return its certificate to the commissioner upon suspension or revocation of certification.

~~F.~~ D. A certified laboratory must not misrepresent its certification on any document, including laboratory reports, catalogs, advertising, business solicitations, proposals, quotations, or other materials.

~~G.~~ E. A laboratory must make available its current certificate and corresponding scope of certification upon the request of a client, certification authority, or regulatory agency. The laboratory must not supply a copy of its current certificate without the accompanying copy of its scope of certification.

*[For text of subps 8 and 9, see M.R.]*

Subp. 10. **Revocation.**

*[For text of item A, see M.R.]*

B. Grounds for partial or total revocation of certification are:

*[For text of subitems (1) to (4), see M.R.]*

(5) failure to complete proficiency testing studies and maintain a history of successful proficiency testing studies ~~at the frequency specified in part 4740.2070~~;

*[For text of subitems (6) and (7), see M.R.]*

*[For text of items C to F, see M.R.]*

*[For text of subp 11, see M.R.]*

Subp. 12. **Reciprocity and laboratories in other states.**

A. A laboratory in another state may request certification in Minnesota. In addition to following the application process under subpart 1, the laboratory must submit the appropriate fees with its application~~, unless a reciprocity agreement exists~~. ~~Fees include the on-site inspection fee for out-of-state laboratories.~~

*[For text of item B, see M.R.]*

~~C. A certification program is not considered substantially equivalent if:~~

~~(1) inspections of certified laboratories are performed at intervals exceeding three years;~~

~~(2) the certifying agency does not require an acceptable corrective action response from the laboratory as required under subpart 6; or~~

~~(3) the certifying agency is not the primary authority for necessary enforcement actions, such as suspension or revocation of the laboratory's certification.~~

~~D.~~ C. When a reciprocal agreement exists, the commissioner shall certify an out-of-state laboratory that:

(1) submits an application meeting the requirements of subpart 1;

(2) submits the appropriate fees~~, not to include an on-site inspection fee for out-of-state laboratories;~~

(3) provides a copy of current certification from the reciprocal state or private or federal agency; and

(4) provides a copy of the certifying authority's most recent inspection report.

~~E.~~ D. A laboratory certified under this subpart must notify the commissioner within 30 days after any enforcement action is taken by the reciprocal certifying authority.

~~F.~~ E. Laboratories certified under reciprocity agreements are subject to parts 4740.2010 to 4740.2120~~, except the fee for out-of-state inspection under subpart 16, item D. Only fixed-base laboratories located within the boundaries of the state represented by the certifying authority may apply under a reciprocal agreement~~.

~~G.~~ F. The commissioner shall provide a list of reciprocity agreements upon request.

*[For text of subps 13 to 15, see M.R.]*

Subp. 16. **Payment of fees.**

A. All applications or requests to change the scope of certification submitted to the commissioner for approval must be accompanied by the fee specified in Minnesota Statutes, section 144.98~~, subdivision 3~~.

*[For text of item B, see M.R.]*

C. When a laboratory requests a variance according to subpart 13, the request must be accompanied by applicable fees according to Minnesota Statutes, section 144.98~~, subdivision 3~~.

~~D. When a laboratory in another state requests certification in Minnesota, the laboratory must submit all applicable fees with its application, to include an out-of-state inspection fee according to Minnesota Statutes, section 144.98, subdivision 3, unless a reciprocity agreement exists between the commissioner and the certifying authority of the state in which the fixed-base laboratory is located.~~

~~E.~~ D. Payment of fees must be in the form of a check, money order, or electronic transfer of funds. When payment is in the form of an electronic transfer of funds, proof of deposit must be verifiable before the date the fees are due to the commissioner.

*[For text of subp 17, see M.R.]*

**4740.2060 METHODS REQUIRED FOR CERTIFICATION.**

*[For text of subp 1, see M.R.]*

Subp. 2. **Clean water program.**

*[For text of items A and B, see M.R.]*

C. The laboratory must submit a copy of the approval for alternate methods to the commissioner along with an application, as required under part 4740.2050~~, subpart 1, and fees as required under part 4740.2050, subpart 16, item C~~.

*[For text of item D, see M.R.]*

Subp. 3. **Safe drinking water program.**

*[For text of items A and B, see M.R.]*

C. The laboratory must submit a copy of the approval for ~~alternative~~ alternate methods to the commissioner along with an application, as required under part 4740.2050~~, subpart 1, and fees as required under part 4740.2050, subpart 16, item C~~.

*[For text of item D, see M.R.]*

Subp. 4. **Resource conservation recovery program.**

*[For text of items A and B, see M.R.]*

C. The laboratory must submit a copy of the approval of alternate methods to the commissioner along with an application, as required under part 4740.2050~~, subpart 1, and fees as required under part 4740.2050, subpart 16, item C~~.

*[For text of item D, see M.R.]*

Subp. 5. **Underground storage tank program.**

*[For text of items A and B, see M.R.]*

C. The laboratory must submit a copy of the approval for alternate methods to the commissioner along with an application, as required under part 4740.2050~~, subpart 1, and fees as required under part 4740.2050, subpart 16, item C~~.

*[For text of item D, see M.R.]*

*[For text of subp 6, see M.R.]*

**4740.2070 PROFICIENCY TESTING REQUIREMENTS.**

*[For text of subp 1, see M.R.]*

Subp. 2. [See repealer.]

Subp. 3. [See repealer.]

*[For text of subp 4, see M.R.]*

Subp. 5. [See repealer.]

Subp. 6. [See repealer.]

Subp. 7. **Evaluation of results.**

~~A. A laboratory must demonstrate acceptable performance, as determined by the approved provider, for each field of testing reported.~~

~~B. A laboratory may use one PT sample to analyze and report results for multiple methods under multiple test categories.~~

~~C.~~ A laboratory may not request from the PT provider a revised report when the revisions to the report are due to any error on the part of the laboratory.

~~D. For the purpose of initial or continuing certification, the commissioner shall deem unacceptable any reported results not meeting the criteria under this subpart.~~

Subp. 8. [See repealer.]

*[For text of subp 9, see M.R.]*

Subp. 10. [See repealer.]

*[For text of subp 11, see M.R.]*

**4740.2087 SAMPLE HANDLING, RECEIPT, AND ACCEPTANCE.**

*[For text of subp 1, see M.R.]*

Subp. 2. **Sample receipt protocols.** The following items must be verified and the results documented:

~~A. all samples that require thermal preservation are considered acceptable if the arrival temperature is within the range required by the approved method or within 2 degrees Celsius of the temperature required by the applicable permit, program, or rule;~~

~~B.~~ A. all samples that require chemical preservation are considered acceptable if the laboratory verifies that the preservation meets the requirements of the approved method. A laboratory must implement procedures for checking chemical preservation before sample preparation or analysis except for methods where postanalysis preservation checks are required to ensure that sample integrity is not compromised. When specified in permit, program, or rule, chemical preservation must be verified upon receipt; and

~~C. bacteriological samples from chlorinated water systems do not require an additional chlorine residual check in the laboratory if:~~

~~(1) sufficient sodium thiosulfate is added to each container to neutralize at minimum 5 milligrams per liter of chlorine for drinking water and 15 milligrams per liter of chlorine for wastewater samples;~~

~~(2) one container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 milligrams per liter chlorine or 15 milligrams per liter chlorine, as appropriate, and the check is documented; or~~

~~(3) chlorine residual is verified by the collector and the recorded concentration is less than or equal to 0.1 mg/L; and~~

~~D.~~ B. a laboratory must maintain chronological records, either paper-based or electronic, such as a log book or database, to document receipt of all samples, including the number and types of containers received for each field of testing. The records must include:

(1) the client and project name, if applicable;

(2) the date and time of laboratory receipt;

(3) a unique laboratory-assigned identification code;

(4) the signature, initials, or equivalent electronic identification of the person making the entries;

(5) the field identification code, which identifies each container, linked to the laboratory-assigned identification code in the sample receipt log;

(6) the date and time of sample collection, linked to the sample container and to the date and time of receipt in the laboratory;

(7) the requested field of testing, linked to the laboratory-assigned identification code; and

(8) any comments resulting from inspection for sample rejection, linked to the laboratory-assigned identification code.

*[For text of subp 3, see M.R.]*

**4740.2089 STANDARDS, REAGENTS, AND BACTERIOLOGICAL MEDIA.**

*[For text of items A and B, see M.R.]*

~~C. All containers of reagents, standards, and bacteriological media must be assigned a unique identification linked to records containing the documentation required in this part.~~

**4740.2100 QUALITY CONTROL CRITERIA FOR CHEMISTRY EXCEPT RADIOCHEMISTRY.**

*[For text of subps 1 to 3, see M.R.]*

Subp. 4. **Matrix spike and matrix spike duplicates.**

A. The frequency of the analysis of matrix spikes and matrix spike duplicates must be determined as part of a systematic planning process or as specified by the required approved method. ~~Where no requirement is stated, the laboratory must prepare and analyze at least one matrix spike and one matrix spike duplicate with each batch.~~ The matrix spikes must be prepared from samples contained in the batch.

*[For text of items B and C, see M.R.]*

Subp. 5. **Surrogate spikes.**

*[For text of item A, see M.R.]*

B. Except when the matrix precludes their use, or when not available, surrogate compounds must be added to all samples, standards, and blanks for all appropriate test methods ~~before sample preparation or extraction~~.

*[For text of items C and D, see M.R.]*

*[For text of subps 6 to 8, see M.R.]*

Subp. 9. **Selectivity.**

~~A. This subpart applies to volatile organic compounds and other organic compounds.~~

~~B.~~ A. Absolute retention time and relative retention time aid in identifying components in chromatographic analyses and evaluating the effectiveness of a chromatographic medium to separate constituents. A laboratory must develop and document acceptance criteria for retention time windows if the acceptance criteria are not specified in the approved method.

~~C.~~ B. A confirmation must be performed to verify the compound identification when positive results are detected on drinking water. The confirmations must be performed on organic tests, such as pesticides, herbicides, or acid-extractable compounds, or when recommended by the analytical test method, except when the analysis involves the use of a mass spectrometer or Fourier transform infrared spectrometer (FTIR). All confirmations must be documented.

~~D.~~ C. A confirmation must be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously

tested. The confirmations must be performed on organic tests, such as pesticides, herbicides, or acid-extractable compounds, or when recommended by the analytical test method, except when the analysis involves the use of a mass spectrometer or Fourier transform infrared spectrometer. A confirmation is not required on positive results for samples analyzed for diesel range organics and gasoline range organics under the underground storage tank program. All confirmations must be documented.

~~E.~~ D. A laboratory must document acceptance criteria for mass spectral tuning. The laboratory must ensure that the tuning criteria meets the specifications in the approved method or as established by the client, whichever is more stringent.

*[For text of subps 10 and 11, see M.R.]*

**TERM CHANGES.** The revisor shall make any necessary cross-reference changes to Minnesota Rules and Minnesota Statutes as a result of the repealed sections in this rule. The revisor shall make necessary grammatical changes and changes to sentence structure as a result of the cross-reference changes.

**REPEALER.** (a) Minnesota Rules, parts 4615.0300; 4615.0400; 4615.0500; 4615.0600; 4615.0700; 4630.2000; 4640.0100, subpart 12; 4640.4400; 4640.4500; 4640.4600; 4640.4700; 4640.4800; 4640.4900; 4640.5000; 4640.5100; 4640.5200; 4640.5300; 4640.5400; 4640.5500; 4640.5600; 4640.5700; 4640.5800; 4640.5900; 4640.6000; 4655.3000; 4658.0810; 4658.0815; 4664.0290, subparts 1, 2, 3, 4, 5, and 6; 4740.2010, subpart 39; 4740.2050, subpart 3; 4740.2065, subpart 8; and 4740.2070, subparts 2, 3, 5, 6, 8, and 10, are repealed.

(b) Minnesota Rules, parts 4670.0100, subparts 1, 1a, 2, 3, 3a, 4, 5, 6, 7, 7a, 7b, 8, 9, 10, 11, 12, 12a, 13, 13a, 14, 14a, 15, 16, 17, 17a, 17b, 18, 19a, 20, 21, 22, 23, 25, 26, 26a, 27, 28, 29, 30, 31, 32, 33, 34, 34a, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 48a, 49, and 50; 4670.0200; 4670.0300; 4670.0310; 4670.0320; 4670.0400; 4670.0500; 4670.0600; 4670.0610; 4670.0700; 4670.0810; 4670.0820; 4670.0830; 4670.0900;

4670.0910; 4670.0920; 4670.0930, subparts 1 and 2; 4670.0940; 4670.0950; 4670.1000; 4670.1010; 4670.1020; 4670.1110; 4670.1120; 4670.1130; 4670.1140; 4670.1200, subparts 1, 3, 3a, and 5; 4670.1210; 4670.1300; 4670.1310; 4670.1320; 4670.1330; 4670.1340; 4670.1500; 4670.1700; 4670.1800; 4670.1900; 4670.1910; 4670.1920; 4670.1930; 4670.1940; 4670.1950; 4670.1960; 4670.1970; 4670.1980; 4670.2000; 4670.2100; 4670.2200; 4670.2300; 4670.2400; 4670.2500; 4670.2510; 4670.2520; 4670.2530; 4670.2540; 4670.2550; 4670.2600; 4670.2610; 4670.2620; 4670.2630; 4670.2640; 4670.2650; 4670.2660; 4670.2670; 4670.2680; 4670.2690; 4670.2700; 4670.2710; 4670.2800; 4670.2810; 4670.2900; 4670.2910; 4670.2920; 4670.2930; 4670.2950; 4670.2960; 4670.2980; 4670.3200; 4670.3300; 4670.3500; 4670.3510; 4670.3520; 4670.3530; 4670.3550; 4670.3600; 4670.3700; 4670.3800; 4670.4010; 4670.4030; 4670.4100; 4670.4110; 4670.4120; 4670.4130; 4670.4140; 4670.4150; 4670.4200; 4670.4210, subpart 1; 4670.4220, subpart 1; and 4670.4230, subpart 1, are repealed.