STATEMENT OF NEED AND REASONABLENESS

In the Matter of Proposed Revisions of Minnesota Rules, chapter, 4605 relating to Communicable Disease Reporting; Revisor ID 4723; OAH Docket # 25-9000-39948

Minnesota Department of Health Infectious Disease Epidemiology, Prevention and Control Division

May, 2024

The State Register notice, this Statement of Need and Reasonableness (SONAR), and the proposed rule will be available during the public comment period on Proposed Revisions, Chapter 4605, Amendment to Rules Governing Communicable Disease Reporting (www.health.state.mn.us/diseases/reportable/rule/change/index.html).

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, braille, or audio. To make a request, contact:

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Acronyms

§	Section
CDC	Centers for Disease Control and Prevention
CSTE	Council of State and Territorial Epidemiologists
DHS	Minnesota Department of Human Services
MDH	Minnesota Department of Health
MDH PHL	Minnesota Department of Health Public Health Laboratory
MMB	Minnesota Management and Budget
SONAR	Statement of Need and Reasonableness

Introduction

The Minnesota Department of Health (MDH, or the department) proposes to amend its rules governing communicable disease reporting (the rules). The intent is to address new and emerging diseases, remove unnecessary provisions, clarify reporting conditions, and address other technical changes.

Minnesota Rules, chapter 4605, are the backbone of MDH's ability to monitor and control communicable[1] diseases in Minnesota. Mandated reporters notify the department of cases, suspected cases, carriers, and deaths from communicable diseases and other significant public health conditions. Medical laboratories also submit clinical materials[2] for many reportable diseases that permit the MDH Public Health Laboratory (MDH PHL) to identify or confirm the disease-causing agent and potentially link cases of disease to a common source. This system of "disease surveillance" is a routine and essential epidemiological practice for monitoring disease, characterizing risk factors, identifying and controlling outbreaks, identifying patterns of disease spread and corresponding prevention and control measures, assessing vaccine effectiveness, and alerting the public and the health care system about health threats.

The department last revised the rules in 2018, and multiple factors have led to proposing the current set of changes. In the last five years, there have been new and emerging communicable diseases not previously seen in Minnesota and the United States. Most notably, the COVID-19 pandemic reflected emergence of a novel virus (SARS-CoV-2) that was easily transmissible from person to person and quickly spread worldwide. Further, clinical and laboratory practices are continually changing. The department needs to update the rules to reflect the current environment and provide flexibility to respond to emerging diseases and changing practices to maintain a strong public health system. These changes are critical for MDH's continued ability to conduct disease surveillance[3] and

[1] In this SONAR, the common term "communicable" refers to infectious diseases that are spread both person-to-person and those that are not.

[2] In this SONAR, "clinical materials" refers to the materials that medical laboratories submit to the MDH Public Health Laboratory for testing. It is defined in Minnesota Rules, part 4605.7000, subpart 3.

[3] This term has been defined as "the continuing scrutiny of all aspects of occurrence and spread of a disease that are pertinent to effective control." Last, John M; A Dictionary of Epidemiology, Oxford Medical Publications, (1983).

investigation that allow it to both identify and control outbreaks and respond promptly to new and emerging communicable diseases, all of which help keep Minnesotans healthy, both medically and economically.

MDH published a Request for Comments on the proposed revisions in the State Register on January 17, 2023, with a comment period that closed on March 20, 2023. The department notified affected parties of the Request for Comments through multiple means. (See Attachment B: Methods of Notifying and Persons Notified of Request for Comments.)

The department proposes the following changes.

(Diseases are reportable within one working day unless specified as immediately reportable)

1. Add the following new diseases and syndromes that are not currently reportable to Minnesota Rules, part 4605.7040:
   - Blue-green algae (Cyanobacteria) and cyanotoxin poisoning.
   - *Capnocytophaga canimorsus.*
   - Carbapenemase-producing carbapenem-resistant *Pseudomonas aeruginosa* (CP-CRPA). Submit clinical materials.
   - Congenital cytomegalovirus (cCMV): cases in infants less than or equal to 90 days of age.
   - Hard tick relapsing fever (*Borrelia miyamotoi*).
   - Multisystem inflammatory syndrome associated with SARS-CoV-2 infection, including in children (MIS-C) and adults (MIS-A).
   - Rat-bite fever *(Streptobacillus moniliformis).*
2. Add the following diseases to Minnesota Rules, part 4605.7040 that are currently reportable under Minnesota Rules, part 4605.7080:
   - *Candida auris*. Submit clinical materials.
   - Carbapenem-resistant *Acinetobacter baumannii* (CRAB). Submit clinical materials.
   - Glanders (*Burkholderia mallei*). Submit clinical materials (immediately reportable).
   - Melioidosis (*Burkholderia pseudomallei*). Submit clinical materials (immediately reportable).
   - SARS- CoV-2 (COVID-19) (unusual case incidence, critical illness, all laboratory confirmed cases). Submit clinical materials.
3. Remove the following diseases from part 4605.7040, making them no longer reportable:
   - *Diphyllobothrium latum* infection, amebiasis (*Entamoeba histolytica/dispar*), and retrovirus infection from the reportable disease list.
4. Changes to diseases currently reportable under Minnesota Rules, part 4605.7040:
   - Replace carbapenem-Resistant “Enterobacteriaceae” with Carbapenem-resistant “Enterobacterales” at part 4605.7040.

- Add a requirement to submit clinical materials for hepatitis A when requested under Minnesota Rules part 4605.7040.
- Add a requirement to submit clinical materials from a normally sterile site for gonorrhea (*Neisseria gonorrhoeae* infection) and upon request under Minnesota Rules part 4605.7040.
- Clarify that *Chlamydia trachomatis* serotypes includes serovars L1, L2, and L3 at Minnesota Rules part 4605.7040.
- Technical Changes:
    - Change blastomycosis (*Blastomyces dermatitidis*) to blastomycosis (*Blastomyces dermatitidis* or *B. gilchristii).*
    - Change brucellosis (*Brucella* spp.) to brucellosis (*Brucella abortus, B. canis, B. melitensis, B. suis).* Submit clinical materials.
    - Change giardiasis (*Giardia intestinalis)* to giardiasis *(Giardia duodenalis).*

5. Additional Changes:
    - Clarify and define that one working day means Monday through Friday and does not include official holidays.
    - Add submission of whole genome sequencing data to the MDH Public Health Laboratory when requested to part 4605.7030.
    - Add hepatitis C to reportable chronic conditions that are perinatally transmissible under part 4605.7044.
    - Clarify the additional information for disease reports under parts 4605.7050 and 4605.7070 consistent with part 4605.7090.

These revised rules are necessary and reasonable to ensure MDH's continued ability to conduct effective disease surveillance and investigation, identify and control outbreaks, and respond promptly to new and emerging communicable diseases, all of which help protect the medical and economic health of Minnesotans.

Statutory Authority

MDH's statutory authority to amend the rules is stated in Minnesota Statutes:

1. **Minnesota Statutes, section 144.12, subdivision 1, states: "The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health." This includes the authority to "control, by rule, . . . the treatment, in hospitals and elsewhere, of persons suffering from communicable diseases, including all manner of venereal disease and infection, the disinfection and quarantine of persons and places in case of those diseases, and the reporting of sicknesses and deaths from them . . . ." (*Id.*, at subd. 1(7)).**
2. **Minnesota Statutes, section 144.05, subdivision 1, establishes the general duties of the commissioner of health ("commissioner") and informs how she is to protect the public health, including in the exercise of the commissioner's rulemaking authority. Among other things, Minnesota Statutes, section 144.05, subdivision 1, paragraph (1), authorizes the commissioner to "conduct... investigations," to "collect and analyze health...data," and to**

"identify and describe health problems." Further, Minnesota Statutes, section 144.05, subdivision 1, paragraph (3), authorizes the commissioner to "[e]stablish and enforce health standards for...reporting of disease."

Under these statutes, MDH has the necessary statutory authority to amend the rules.

Regulatory Analysis

Minnesota Statutes, section 14.131, sets forth eight regulatory factors that state agencies must analyze in a SONAR. Paragraphs (A) through (H) that follow address them. The Rule-by-Rule Analysis, also addresses some of these factors.

(1) Description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Classes of Persons Affected by the Proposed Rule

The existing rules apply to persons and entities required to report communicable diseases and conditions, and to submit clinical materials. The proposed amendments do not change who is required to report but rather what must be reported. These changes affect the following persons and entities:

- Health care providers responsible for reporting (physicians, advanced practice nurses, physician assistants, infection preventionists or other persons designated by a health care facility to report, and all other licensed health care providers who care for a patient who has or is suspected to have a reportable disease or condition).
- Hospitals, nursing homes, medical clinics, and other health care facilities whose personnel must report communicable diseases and conditions.
- Medical laboratories required to report test results and submit clinical materials on reportable diseases and conditions.
- Veterinarians and veterinary laboratories required to report disease and submit clinical materials.
- School nurses.
- Coroners and medical examiners.
- Persons in charge of institutions, schools, child care facilities, and camps. Examples of institutions include, but are not limited to, assisted living facilities, correctional facilities, and shelters.
- The general public and all visitors to the state who either acquire a reportable disease or condition or come in contact with a person who has a reportable disease or condition.
- MDH staff who receive the disease reports.
- Local public health agencies.

Classes of Persons Who Will Bear the Costs of the Proposed Rule

- Mandated reporters.

- Minnesota Department of Health.

Classes of Persons Who Will Benefit from the Proposed Rule

- Minnesota Residents and Visitors: Every person who lives in or visits the state of Minnesota benefits from the proposed rules. MDH's revised communicable disease reporting system will reflect new and emerging communicable diseases and changes in clinical practice, maintaining the agency's ability to properly investigate and control communicable disease and to take the steps necessary to protect the public, including informing the public of a disease threat. For example, since 2019, MDH has had a critical role in solving at least six multi-state foodborne outbreaks involving common foods including peaches, frozen pizza, onions, spinach, and lettuce. In each of these instances, the public was warned to discard the implicated food in order to avoid additional cases of illness. MDH also helps to ensure that people exposed to communicable diseases receive antibiotic or other preventive drug therapy when appropriate. These critical control measures start with a disease report under the rule.
- Mandated Reporters: Mandated reporters also will benefit from updated rules. First, a strong surveillance system means that MDH can quickly alert health care providers about communicable diseases of concern and disseminate guidelines on infection control precautions (to protect hospital and clinic staff), diagnosis, and treatment. When MDH knows about an outbreak, it can play a critical role in ensuring that health care providers have the information necessary to respond. Second, when individual health care providers or facilities are faced with communicable diseases that lack straightforward diagnosis, treatment, or infection control precautions, MDH assists with communicable disease expertise through its staff of nurses, doctors, veterinarians, epidemiologists, disease investigators, and program specialists. MDH also helps with getting assistance from the U.S. Centers for Disease Control and Prevention (CDC). Third, the MDH PHL has the capacity to perform laboratory tests that might not otherwise be available to a health care provider. For example, most Minnesota medical laboratories are not able to test for viral hemorrhagic fevers, such as Lassa Fever and Ebola. The MDH PHL can test for these viruses and convey the results to the initial reporter. Fourth, MDH is able to disseminate aggregate information to clinicians about infectious disease in the state.

(2) The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

Probable costs to the agency of implementation and enforcement

The probable costs to MDH for implementing the proposed rule amendments will be minimal. Existing agency staff will be able to handle reports on the new diseases because most of the new diseases, while significant for public health, will probably occur relatively infrequently. If they were to occur on a large scale, MDH would shift staff from usual daily activities to address the outbreak. There will be one-time costs for developing and distributing educational materials on the new rules to mandated reporters. To the extent possible, MDH will incorporate these educational materials into MDH's regular communication channels. The MDH PHL will receive additional clinical materials because of the new diseases added to the rule. The PHL, however, is already collecting some of these

materials per Minn. Rules Part 4605.7080[4], such as for SARS-CoV-2, glanders, melioidosis, and CRAB. Moreover, since most of the new reportable disease are rare, there should not be much additional work for MDH PHL staff. Existing staff will perform tests on these materials without needing additional state funds. The MDH PHL may have some costs, albeit minimal, for mailers and shipping costs of additional clinical materials.

Probable costs to any other agency of the implementation and enforcement

There should be no cost to any other state agency or to local public health agencies. MDH receives disease reports and clinical materials. Local public health agencies assist MDH in disease investigation, a role that exists under the current rule and would continue under the proposed amendments to the rule.

Anticipated effect on state revenues

The proposed rule amendments will not affect state revenues.

(3) A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

MDH has proposed the least costly and least intrusive methods necessary for achieving the purpose of the rule, namely reporting of communicable diseases (including submission of clinical materials) and other relevant information for disease surveillance, investigation, and control. Reporting of communicable diseases is a basic and essential element for protecting public health. The disease reporting rule is long-standing and this rulemaking is proposing modest amendments to it. Further, over the years and with technology, reporting has often become less burdensome for large disease reporters as progress has been made in automating disease reporting. (This factor also is discussed in the performance-based standard section and in the Rule-by-Rule Analysis. Progress in automated reporting is discussed in more detail in 5.4. below.)

Less Costly Method

Every state requires mandated reporters to report communicable diseases, and, in fact, all states have had some form of reporting since 1901.[5] Such reporting is essential for alerting the public and the health care system to health threats and for communicable disease control. Nationally, there is a list of notifiable (reportable) diseases.[6,7] The Council of State and Territorial Epidemiologists (CSTE) initiated this list in 1950. Today, with input from the CDC, the CSTE makes annual recommendations for changes to the national list. But reporting requirements remain a state, not federal, responsibility.

MDH knows of no less costly method than reporting for achieving the goals of disease surveillance, timely investigation, and control. It would be impossible, to achieve a reliable substitute for monitoring disease in real time (sufficient time to initiate appropriate control measures) other than

[4] Minn, Rules 4605.7080 NEW DISEASES AND SYNDROMES; REPORTING AND SUBMISSIONS. This part of the rule allows the commissioner to require by public notice reporting of newly recognized or emerging diseases and syndromes suspected to be of infectious origin or previously controlled or eradicated infectious diseases if certain criteria are met.

[5] Mandatory Reporting of Infectious Diseases by Clinicians. *MMWR*; June 22, 1990, 39 (RR-9); 1-11,16-17.

[6] https://ndc.services.cdc.gov/search-results-year/.

[7] The CDC collaborates with the Council of State and Territorial Epidemiologists (CSTE) to identify which conditions are nationally notifiable by local, state, and territorial public health departments.

reporting by those who know about a case, suspected case, carrier, or death. Further, even though MDH is increasing the number of diseases that require submitting clinical materials, submission is already required for most of these diseases pursuant to a commissioner's notice under Minnesota Rules, part 4605.7080.[8] If reporters were to submit patient test results without clinical materials, MDH could not conduct critical tests for disease monitoring and investigation such as those for molecular subtyping of the bacteria[9] (which helps MDH link cases to each other and to a common source of infection) and antimicrobial susceptibility testing (which helps MDH monitor antibiotic-resistant pathogens). Without the tools necessary for disease investigation and control, there could be substantial costs and threats to public health, including increased illness and unnecessary death.

MDH kept cost in mind when drafting these proposed amendments. MDH only added what is necessary to ensure that reporters report communicable diseases and conditions of public health significance (including submitting clinical materials) so that we can take timely action to protect the public and prevent unnecessary illness and death. MDH's consideration of both cost and burden is reflected in the fact that we are also proposing to remove three diseases from the reporting list where reporting is no longer warranted. Moreover, we are requiring submission of clinical materials for hepatitis A only upon request, not for each case. Similarly, we are requiring submission of clinical materials for gonorrhea only upon request or from a normally sterile site.

It would be less costly to make no revisions to the rules. This would not, however, achieve the rules' purpose, namely ensuring that communicable diseases and conditions of public health significance are reported to MDH so that the agency can act to protect the public and prevent unnecessary illness and death. This SONAR discusses each proposed amendment in the Rule-by-Rule Analysis. MDH has concluded that no less costly methods exist to accomplish the purpose of the rules and that the proposed amendments are necessary and reasonable.

Less intrusive methods

The two general categories of persons affected by the proposed amendments are mandated reporters and persons whose health information is reported. Mandated reporters did not voice any significant concerns during the Request for Comments period.

Persons whose health information is reported could view the proposed amendments as intrusive because they require reporting of otherwise private health information. MDH places the highest priority on the agency's responsibility to protect private health information. We know that the disease reporting system rests to a large extent on public confidence and reporters' confidence that information reported to us is kept both private and secure. We sent our Request for Comment to the Minnesota Civil Liberties Union (MCLU) and Rainbow Health (formerly the Minnesota AIDS Project). Neither organization raised privacy concerns.

The proposed amendments require reporting of additional information, including reporting of added diseases (part 4605.7040) and submission of clinical materials for specific diseases (part 4605.7040). Justification for each proposed amendment to collect additional information is in the Rule-by-Rule Analysis. However, the changes added by this rulemaking do not represent a change in the disease reporting method and are not more intrusive than the current rule.

[8] Diseases already reportable under Minn. Rules 4605.7080 include CRAB, CRE, glanders, melioidosis and SARS-CoV-2/COVD-19.

[9] Molecular subtyping characterizes strains of disease-causing microorganisms. It is used to identify clusters of disease in the population and to focus outbreak investigations so that the source(s) of infection can be rapidly determined and control measures taken.

Generally, we know of no method for conducting public health surveillance, investigation, and control of communicable diseases, other than via the reporting of private health information. If MDH were only tracking disease trends, one could argue that a less intrusive method might be to require reporting of de-identified health information (i.e., health information without name, address, and other information that could identify the person). MDH, however, monitors disease to contain its spread and limit illness or death in real time. MDH needs identifying information to interview ill people and determine the most likely source of infection. Further, by interviewing people who have a reportable disease (cases), MDH is able to identify their family members and other contacts who might be at risk of disease. MDH can then make recommendations to seek medical attention, obtain prophylaxis (use of drug therapy to prevent disease), or take appropriate infection control precautions. Finally, if MDH only received de-identified information, we would not know when duplicate reports occur, resulting in significant discrepancies between the number of cases reported and the actual number of cases. For example, during the COVID-19 pandemic, MDH matched laboratory test results with case reports, which was critical to counting cases and ensuring against duplicate counts.

A 2008 nationwide foodborne outbreak from a common food source demonstrates the critical importance of individual identifying information. In November and December 2008, MDH received numerous reports of enteric *Salmonella* Typhimurium infection. Through tests on clinical materials coupled with interviews of people reported as ill, MDH determined that ill persons were infected with the same molecular subtype of the bacteria and that its source was a particular brand of peanut butter. The Minnesota cases were part of a large nationwide outbreak, with over 700 laboratory-confirmed infections and nine deaths. In Minnesota alone there were 45 laboratory-confirmed infections and three deaths. This tragic outbreak likely would have gone on for more months had MDH not identified the source. This detection ultimately prevented an untold number of additional illnesses and deaths. Furthermore, far-reaching implications for food safety occurred when the former owner and chief executive and a former employee of the corporation were convicted on federal charges due to this outbreak. This conviction signaled to food producers that they cannot ignore food safety measures. These public health interventions, taken to prevent additional illness, could not have been accomplished without the identifying information in case reports and subsequent interviews with case patients.

Further, reporting identifiable health information under communicable disease reporting requirements is the standard and accepted surveillance method for public health. In fact, federal rules adopted under the Health Insurance Portability and Accountability Act (HIPAA), which set national standards for health information privacy, contain an exemption for surveillance that permits reporting private health information to health departments.[10] Under the Minnesota Government Data Practices Act, (Minnesota Statutes, Chapter 13) health data on individuals is private and MDH can only release such data under Minnesota Statutes, sections 13.04 (release to the subject of the data) and 13.3805 (release for certain public health purposes). MDH has an excellent record of maintaining data privacy.

[10] 45 Code of Federal Regulations, §164.512 of the HIPAA regulations addresses “uses and disclosures for which an authorization or opportunity to agree or object is not required.” Under §164.512 (b)(1)(i), entities covered by HIPAA may disclose protected health information for public health purposes to:
"a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability including, but not limited to the reporting of disease...the conduct of public health surveillance, public health investigations, and public health interventions..."

MDH has concluded that no less intrusive methods are available to accomplish the goals of the rules.

(4) A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the Agency and the reasons why they were rejected in favor of the proposed rule.

Communicable disease reporting requirements are the standard method for performing public health surveillance in every state. Discussions on alternative methods that MDH considered are the following:

1. This SONAR discusses both less costly and less intrusive methods in Factor 3 above.

2. Importantly, an alternative reporting method to use in specified circumstances is already codified under the current rules in Minnesota Rules, part 4605.7046. Under this part, when the commissioner determines that surveillance is necessary for specific public health purposes, the commissioner can require that a limited number of sites (sentinel sites) report to MDH instead of requiring all reporters to report if surveillance using sentinel sites will provide adequate data for epidemiological purposes. With sentinel surveillance,[11] the reporting sites may incur reporting costs, but those reporters not selected for sentinel surveillance do not. For example, currently, MDH conducts sentinel surveillance for respiratory syncytial virus (RSV), extrapulmonary nontuberculous mycobacteria, and nontuberculous mycobacteria which limits the number of persons and entities required to report.

(5) The probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

Most hospitals and some large clinics and long-term care facilities have at least one infection preventionist (IP) on staff who already reports communicable diseases to MDH under the existing rule. MDH works closely with the IPs and other reporters across the state and recognizes the critical work they do in notifying us of communicable diseases, as was demonstrated once again with the volume of reporting needed during the peaks of COVID-19. Some proposed changes might increase their workload, though the increase should not be substantial for any one reporter for the following reasons:

1. Many of the new reportable diseases are anticipated to occur infrequently and those that do occur more frequently are already reportable pursuant to a commissioner's notice under Minnesota Rules, part 4605.7080, such as CRAB, glanders, and melioidosis.

2. Even though MDH is increasing the number of diseases that require submission of clinical materials from medical laboratories, submission is already required for most of these diseases pursuant to a commissioner's notice under Minnesota Rules, part 4605.7080.[12] Laboratories will

[11] "Sentinel surveillance" is a defined term in part 4605.7000, subpart 12 of the rules. It means "monitoring a disease or syndrome through reporting of cases, suspected cases, and carriers, and submission of clinical materials" by selected sites rather than reporting by all mandated reporters.

[12] Diseases already reportable by commissioner's notice under Minn. Rules 4605.7080 include CRAB, CRE, Glanders, Melioidosis and SARS-COV02/COVD-19.

only need to submit clinical materials for hepatitis A when requested. Similarly, laboratories will only need to submit clinical materials for gonorrhea when requested or from a normally sterile site.

3. Even though SARS CoV-2/COVID-19 may not be a disease that occurs infrequently, it has been reportable throughout the pandemic and is currently reportable under Minnesota Rules part 4605.7080. Laboratories have also been required to submit clinical materials since the beginning of the pandemic.

4. MDH has worked hard to use technological advancements to reduce the person time for reporters to submit disease reports. We have worked with reporters on automated reporting in which reports for reportable diseases are generated from electronic medical records and transmitted to MDH. For laboratory reports, 16 hospital laboratories submitted automated reports to MDH in 2016. Today, 102 of 131 hospital laboratories in Minnesota submit automated reports for all reportable diseases to MDH and a total of 340 laboratories submit reports to MDH in this manner, including both hospital-based and non-hospital based medical laboratories. We also have made progress on automated submission of case reports from clinicians. Since 2020, when the national framework became available, MDH has onboarded seven major healthcare organizations (which includes their hospitals and clinics) within Minnesota and four Federally Qualified Health Centers (FQHCs) through electronic Case Reporting (eCR). Currently, we receive reports for monkeypox and COVID-19 from these entities through eCR. The coding for medical record extraction is available to support automated reporting of almost all reportable conditions. Even with the coding in place, coordination and validation is necessary among federal and state partners, and the individual health care entity in order to accomplish automated reporting. The expansion to reporting of additional diseases through this mechanism will continue to increase efficiency for reporters. MDH is prioritizing this expansion. Additionally, MDH has made available reporting methods where reporters without automated reporting are able to submit case report data for some diseases electronically, instead of writing out data and faxing it to the department. MDH staff are also available upon request to assist medical laboratories, hospitals, long-term care facilities, and other reporters with reporting.

   Since MDH published the Request for Comments on January 17, 2023, we have received no concerns about costs from affected parties.

(6) The probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

Probable costs of not adopting the proposed rules

Significant potential costs for not going forward with the proposed rule amendments would be the unnecessary illness or death that could result from the new diseases not being reported and remedial action not being taken. Among the amendments are new reportable diseases and requirements to submit clinical materials. The necessity for reporting the added diseases is detailed in the rule-by-rule analysis. Additionally, the submission of clinical materials enables the MDH PHL to conduct subtyping of strains so that MDH can link cases, identify disease clusters, and identify a common source of illness, which may be an environmental or food source. A delay in recognizing a cluster or outbreak can not only endanger the public's health but can result in negative economic consequences as well.

Additionally, with submission of clinical materials for SARS-CoV-2 (the virus that causes COVID-19), the MDH PHL is able to identify which variants and subvariants are circulating in the state. Data on variants can help inform treatment recommendations and allow MDH to alert clinicians and the public if a variant known to cause more severe disease or better evade immunity is becoming dominant in Minnesota.

An example of the critical importance of clinical materials was illustrated when, in 2021, a Minnesota resident was one of four cases in a multi-state outbreak of melioidosis, a rare but severe disease. Two of the four cases died. The cases were linked to a contaminated aromatherapy spray that was imported from India and sold nationwide. Because clinical specimens were submitted, sequencing was able to match the Minnesota case with cases in other states and to bacteria found in the spray, confirming the source of the outbreak. A product recall was issued, potentially preventing many severe illnesses in Minnesota and across the country.

Portion of costs borne by identifiable categories of affected parties

Under factor 1 of the regulatory analysis, MDH discussed the parties who would benefit from the rule and how they would benefit. Minnesota residents and visitors: every child, adolescent, and adult who lives in Minnesota, and all visitors to the state would benefit. These same persons would bear the greatest burden of sickness, death, and economic costs associated with not adopting up-to-date rules for communicable disease surveillance, investigation, and control.

The discussion under factor 1 also reflects how mandated reporters would benefit from an updated rule. When MDH has timely information on communicable diseases, it can quickly alert health care providers to assess symptomatic patients for a disease that is emerging or for which there is an outbreak (e.g., recent examples of monkeypox and Legionnaires' disease), and disseminate guidelines on infection control precautions (to protect hospital and clinic staff), diagnosis, and treatment. Without an updated reporting rule, especially with HIPAA and reporters wanting explicit legal authority to report, health care providers and their patients could bear the costs of MDH not knowing about a communicable disease event. We anticipate economic costs to mandated reporters from the rule changes will be minimal because the diseases added are either rare or already reportable under Minnesota Rules, part 4605.7080. We did not receive any comments or concerns about increased costs.

(7) An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

Other than the temporary federal reporting requirements for COVID-19 due to the pandemic, there are no federal laws or regulations regarding communicable disease reporting. This is a state function. The proposed updates will not conflict with the temporary federal reporting requirements, which expired on May 11, 2023, with the end of the federal public health emergency.

(8) An assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

No federal regulations on communicable disease reporting conflict with these rules. The federal government does, however, maintain a list of diseases for which it can use federal quarantine

authority (section 361 of the Public Health Service Act (42 U.S. Code § 264)).[13] Currently, all federally quarantinable diseases are in the Minnesota Communicable Disease Rules. Laws requiring reporting of communicable diseases is primarily a state function, while controlling and preventing the spread of communicable diseases involves a state-federal partnership. All 50 states have their own communicable disease reporting rules.

The Communicable Disease Reporting Rule provides Minnesota's only existing regulatory system for reporting communicable diseases. Communicable disease reporting began in Minnesota in the late 1800s, but the rules weren't formally established until the 1900's. MDH and its predecessor agencies have updated the rules periodically to align them with current medical and public health standards.

Additional Statutory Requirements

Performance-based Rules

Minnesota law (Minnesota Statutes, sections 14.002 and 14.131) requires that the SONAR describe how MDH, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting MDH's regulatory objectives and maximum flexibility for the regulated party and MDH in meeting those goals.

MDH staff was guided in developing this proposal by the following questions:

1. Are there special situations we should consider in developing the rules?

2. Are there ways to reduce the burdens of the rules?

3. Do you have any other insights on how to improve the rules?

The objective of the Communicable Disease Reporting Rule is to protect the individual and community from death and illnesses by preventing and controlling communicable disease.

In addition, we regularly review the rules for diseases that no longer necessitate reporting to reduce burden on reporters. In this rulemaking, we are deleting three diseases.

In the proposed changes, we are adding a definition to clarify the term "one working day" so it is used consistently by everyone, and reporters know that they do not have to report on a holiday unless the disease is designated as immediately reportable.

During a prior revision to the rule in 2016, we received a comment from the Association for Professionals in Infection Control and Epidemiology (APIC) Minnesota Chapter requesting that MDH work towards gathering the reportable disease information via electronic health records wherever feasible. They said the goal should be to reduce the manual, labor-intensive reporting and also provide MDH with more comprehensive information. MDH agrees and has taken significant steps in this direction (see Regulatory Analysis, section 5.4. for a discussion of progress in automated and electronic reporting).

[13] Diseases for which federal quarantine authority may be exercised are specified by executive orders of the President upon the recommendation of the Secretary of the U.S. Department of Health and Human Services (HHS), and in consultation with the U.S. Surgeon General. Currently, the list of federally quarantineable diseases includes: Cholera, Diphtheria, Infectious tuberculosis, Plague, Smallpox, Yellow fever, Viral hemorrhagic fevers, Severe acute respiratory syndromes, influenza that can cause a pandemic, and Measles.

True performance-based rules would set specific outcomes and leave the means of achieving those outcomes up to the health care provider. But a true performance-based approach is impossible or impractical for the Communicable Disease Reporting Rule. Allowing mandated reporters to decide what to report and when to report would severely hinder MDH's ability to prevent and control disease and lead to more disease, making it harder to control outbreaks and resulting in more morbidity and mortality. The essence of disease surveillance under the rule is to require prompt and uniform reporting of diseases of public health importance so that MDH can monitor infectious disease in real time, quickly detect and respond to outbreaks including identifying a common source if one exists and identify risk factors for infectious disease threats.

Additional Notice

Minnesota law (Minnesota Statutes, sections 14.131 and 14.23) requires that the SONAR contain a description of the department's efforts to provide additional notice to persons who may be affected by the proposed amendments to the rules.

The additional notice plan consists of the following steps:

1. Mail or email the proposed rules and the dual notice to all persons who have registered to be on the department's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.

2. Post the proposed rules, the dual notice, and the SONAR to Amendment to Rules Governing Communicable Disease Reporting (Amendment to Rules Governing Communicable Disease Reporting (www.health.state.mn.us/diseases/reportable/rule/change/index.html). Individuals can also "subscribe" to receive an alert when the webpage has been updated.

3. Post information on the department's Facebook page and X feed.

4. Provide a copy of the dual notice, the SONAR, the fact sheet containing a summary of the substantive amendments, and a Web link to the proposed rules via e-mail, directly or through MDH subscriber services, such as GovDelivery to various individuals, groups and organizations. MDH will also request, when possible, that these organizations post the information on their website and send it out to their listserv. This list includes, but is not limited to:
    - Health care providers responsible for reporting and health care facilities whose personnel must report communicable diseases and conditions:
        - Infectious disease physicians.
        - MDH's infection preventionist list.
        - Minnesota Academy of Family Physicians.
        - Minnesota Chapter of the American Academy of Pediatrics.
        - Minnesota Council of Health Plans.
        - Minnesota Hospital Association.
        - Minnesota Medical Association.
        - Minnesota Medical Group Management Association. This association serves medical practice executives and their organizations.

    - Minnesota Nurses Association.
    - Physician assistant groups.
- Veterinarians and veterinary labs.
- Coroners and medical examiners.
- Local public health agencies.
- Medical laboratories.
    - MDH's Minnesota Laboratory System list. This list includes approximately 160 laboratories, including public health and private clinical laboratories, as well as veterinary and agriculture laboratories, which serve Minnesota residents.
    - Minnesota Interlaboratory Microbiology Association.
    - MDH's Minnesota Electronic Disease Surveillance System (MEDSS) laboratory notification list.
- Persons in charge of institutions, schools, and childcare facilities.
    - Early childhood providers, including school readiness, ECFE, and screening coordinators.
    - Child care licensors.
    - Child care health care consultants.
    - Minnesota school nurses.
    - Institutes of Higher Education.
    - Leading Age Minnesota.
    - Care Providers of Minnesota.
    - Association of Residential Resources in Minnesota (AARM).
- Long term care facilities, which includes nursing homes, assisted living facilities, and some group homes, through the MDH Compendium.
- Minnesota Department of Human Services and Minnesota Department of Education.

5. Publish information about the proposed changes and where to get further information in publications that reach affected parties, such as association newsletters and journals.

6. Notify the Legislature per Minnesota Statutes, section 14.116. This will include sending the proposed rules, SONAR, and dual notice to the chairs and ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter.

Consultation with Minnesota Management and Budget on Local Government Impact

Minnesota Statutes, section 14.131, requires agencies to consult with Minnesota Management and Budget (MMB) to help evaluate the fiscal impact and benefits of the proposed rules on local governments. MDH did this by sending to the MMB Commissioner copies of the proposed rule and

SONAR before MDH published the *Notice of Intent to Adopt Rules*. A copy of our correspondence with MMB is attached as Attachment C.

Cost of Complying for Small Business or City

As required by Minnesota Statues, section 14.127, the department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city. The only obligation that might be imposed on small businesses or small cities is reporting, and the time commitment to do so in these rare cases is negligible. Any other costs, which will be minimal, will be borne by MDH or mandated reporters as discussed in Section 2 of the Regulatory Analysis. The department has determined that the cost of the rules will not exceed $25,000 for any small business or small city.

Impact on Local Government Ordinances and Rules

The department has considered the requirements of Minnesota Statutes, section 14.128, subdivision 1, which requires that "an agency must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule." MDH conducted this analysis and found that no local government will have to adopt or amend an ordinance or regulation. The Communicable Disease Reporting Rule is regulated at the state, not local level. Even though some local public health agencies assist MDH with disease investigation and control, the commissioner of health ("commissioner") remains responsible under Chapter 144 for protecting public health and establishing standards for reporting of disease.

List of Non-Agency Witnesses

MDH does not intend to call any non-agency witnesses.

Rule-by-rule Analysis

MDH proposes the following amendments to the Communicable Disease Reporting Rule, Minnesota Rules, chapter 4605. MDH has concluded after careful consideration that each amendment is reasonable and necessary to further the goals of the rules.

Part 4605.7000 DEFINITIONS

Subpart 16. Working Day. This amendment adds the definition "working day" to the Communicable Disease Reporting Rule. This addition clarifies that "working day" means Monday through Friday, excluding any holiday as defined under Minnesota Statutes, section 645.44, subdivision 5.

This change is reasonable and necessary to ensure that all reporters apply the same standard when the rule requires them to report the disease within one working day. It clarifies that reporters are not required to report on weekends or specified holidays unless the disease is reportable immediately.

Part 4605.7030 PERSONS REQUIRED TO REPORT

Subpart 3, item C. Medical Laboratories. This amendment requires all laboratories that perform genetic sequencing for any diseases reportable under Minnesota Rules parts 4605.7040, 4605.7046, 4605.7050, 4605.7070 and 4605.7080 to report sequence data to the MDH PHL upon request of the commissioner and in an electronic format specified by MDH. Laboratory technology is continually changing, and it is essential that MDH is able to use the most robust tools available to investigate

disease outbreaks, understand transmission dynamics, and monitor for genetic changes that may impact disease outcomes.

This is reasonable and necessary because currently, the rule only requires laboratories to submit clinical materials,[14] which does not include sequencing data. This change would require medical laboratories that perform genetic sequencing to electronically report this information when the commissioner requests it.

Genetic sequencing is a critical tool in public health monitoring of infectious disease and in identifying and controlling outbreaks.[15] Understanding the importance of this proposed change requires understanding what genetic sequencing means and how sequencing data aids disease outbreak investigation and control. Briefly, sequencing an organism's (such as a virus or bacteria) genome means determining the order of the four chemical building blocks - called "bases" - that make up the DNA/RNA molecule. The sequence tells scientists the kind of genetic information that is carried in a particular DNA/RNA segment. If you know the sequence of the bases in an organism, you have identified its unique DNA/RNA fingerprint, or pattern. Using this type of sequencing, which is called whole genome sequencing (WGS), can help solve disease outbreaks by linking cases of a disease that may not appear to be linked otherwise .[16,17]

For example, as described in detail earlier, in 2021, a Minnesota resident was one of four cases in a multi-state outbreak of melioidosis. WGS was used to match the Minnesota case with cases in other states and to bacteria found in the contaminated product, the source of the outbreak.[18] A product recall was issued, potentially preventing many severe illnesses in Minnesota and across the country.

WGS provides more detailed and precise data for identifying outbreaks than the previously used technology. It is a powerful method for informing public health response decisions. Medical laboratories are recognizing genetic sequencing as a fast and affordable way to obtain high-level information about the virus/bacteria using just one test. This data can then be used by MDH to quickly link cases and implement public health measures to disrupt further spread of severe illness. It

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[14] Clinical materials is defined in Minn. R. 4605.7000, Subd. 3. "Clinical materials" means:

> A. a clinical isolate containing the infectious agent for which submission of material is required; or
>
> B. if an isolate is not available, material containing the infectious agent for which submission of material is required, in the following order of preference:
>
> (1) a patient specimen;
>
> (2) nucleic acid; or
>
> (3) other laboratory material.

[15] Gilchrist, Carol A., et al. "Whole-genome sequencing in outbreak analysis." *Clinical microbiology reviews* 28.3 (2015): 541-563.

[16] Firestone, Melanie J., et al. "First identified cases of SARS-CoV-2 variant P. 1 in the United States—Minnesota, January 2021." *Morbidity and Mortality Weekly Report* 70.10 (2021): 346.

[17] Taylor, Angela J., et al. "Characterization of foodborne outbreaks of Salmonella enterica serovar Enteritidis with whole-genome sequencing single nucleotide polymorphism-based analysis for surveillance and outbreak detection." *Journal of clinical microbiology* 53.10 (2015): 3334-3340.

[18] Gee JE, Bower WA, Kunkel A, Petras J, Gettings J, Bye M, Firestone M, Elrod MG, Liu L, Blaney DD, Zaldivar A, Raybern C, Ahmed FS, Honza H, Stonecipher S, O'Sullivan BJ, Lynfield R, Hunter M, Brennan S, Pavlick J, Gabel J, Drenzek C, Geller R, Lee C, Ritter JM, Zaki SR, Gulvik CA, Wilson WW, Beshearse E, Currie BJ, Webb JR, Weiner ZP, Negrón ME, Hoffmaster AR. Multistate Outbreak of Melioidosis Associated with Imported Aromatherapy Spray. N Engl J Med. 2022 Mar 3;386(9):861-868. doi: 10.1056/NEJMoa2116130. PMID: 35235727; PMCID: PMC10243137.

is important to note that, in requesting sequencing data, MDH is not asking for an individual's DNA but rather, if the medical laboratory is sequencing the virus/bacteria itself, MDH is asking for the viral/bacterial genetic sequencing data.

This change does not require laboratories to perform genetic sequencing. Rather, the change requires laboratories that perform genetic sequencing on a virus or bacteria to submit the sequencing data when the commissioner requests it for a reportable disease.

This change is reasonable and necessary so that MDH can link cases to each other and to an exposure source, as well as characterize pathogen subtypes and strains that are circulating in the state, all of which are critical to controlling and preventing the spread of disease.

Part 4605.7040 DISEASE AND REPORTS; CLINICAL MATERIALS SUBMISSIONS.

These amendments can be divided into two general categories: (1) changes to currently reportable diseases under Minnesota Rules, part 4605.7040; and (2) changes to add new reportable diseases to Minnesota Rules, part Minnesota Rules, Part 4605.7040.

1. Changes to Currently Reportable Diseases in Minn. Rule 4605.7040.

- **Technical Changes**. There are four technical changes.

  The proposed rule adds another fungal species to blastomycosis at item B(4). Currently there is only one species (*Blastomyces dermatitidis)* reportable in Minnesota under part 4605.7040. However, we are now seeing an additional species (*B. gilchristii)* emerge in the state.

  The second change involves a name change. The name is changed from Carbapenem-Resistant "Enterobacteriaceae" to Carbapenem-resistant "Enterobacterales" at part 4605.7040, item B(10). The reason for the change is that, in 2020, the CDC adopted a taxonomy change to use "Enterobacterales" as the name of a new scientific order. "Enterobacteriaceae " are now a family within the "Enterobacterales" order, along with Erwinaceae, Pectobacteriaceae, Yersiniaceae, Hafniaceae, Morganellaceae, and Budvicaceae.[19]

  The third change involves a name change for the organism causing giardiaisis. The name is changed from *Giardia intestinalis* to G*iardia duodenalis* at part 4605.7040, item B(25), because *duodenalis* is now the species name accepted by the scientific community.

  The fourth change clarifies which *Brucella* species must be reported under item A(3). The current rule requires all species of *Brucella* to be reported, even if they do not cause disease. The rule will clarify that only species that cause brucellosis need to be reported, which include *Brucella abortus, B. canis, B. melitensis,* and *B.*suis. The scientific community recently reclassified the genus *Ochrobactrum*—and added it into the genus *Brucella.*[20] However, this genus does not cause brucellosis. Since clinical laboratories *Brucella* species to the MDH PHL, we are concerned that given how the rule is currently written an increasing number of non-pathogenic samples will be sent for testing needlessly. Rewording the rule to specifically include those *Brucella* species of significant concern for human and animal health – *B. abortus, B. canis, B. melitensis*, and *B. suis* would retain our ability to track and test these important pathogens while dramatically reducing reporting of those newly assigned *Brucella* species that are not.

[19] https://www.cdc.gov/hai/organisms/cre/index.html.

[20] https://www.microbiologyresearch.org/content/journal/ijsem/10.1099/ijsem.0.004244?.

- **Diseases Removed from Minnesota Rule 4605.7040.**

  Amebiasis (Entamoeba histolytica/dispar). This disease is being removed from part 4605.7030, at item B(1). Amebiasis is a disease caused by the parasite *Entamoeba histolytica*. It can affect anyone, although it is more common in people who live in tropical areas with poor sanitary conditions. Minnesota has not seen many cases of this disease and surveillance has not been useful from a public health perspective. It is morpohologically indistinguishable from *E. dispar*, which does not cause disease. As a result, virtually all reports of *E. histolytica*/*dispar* received by MDH are due to detection of *E. dispar* and have nothing to do with the patient's illness. Moreover, it was removed from the Nationally Notifiable Disease List because it occurs rarely in this country.

  Diphyllobothrium latum infection. This disease is being removed from item B(17). It is a parasitic intestinal infection that is acquired by eating raw or undercooked fish. Adequately freezing or cooking fish will kill the parasite. Most infections are asymptomatic. This disease is being removed from the list because it is a rare condition, is never identified in the form of outbreaks anymore, and never prompts any disease prevention or control measures. Thus, reporting is not a good use of resources.

  Retrovirus infection. This generic group of infections is being removed from the list of reportable diseases at item B(42). A retrovirus is a virus that uses RNA as its genomic material. Upon infection with a retrovirus, a cell converts the retroviral RNA into DNA, which in turn is inserted into the DNA of the host cell. Many retroviruses are associated with diseases, including HIV infection and some forms of cancer. This non-specific family of infections is being removed from the list because there are no programmatic activities resulting from the reporting of the infection, and there is no requirement to report to the National Notifiable Diseases Surveillance System. Please note that HIV infection is still reportable per Minnesota Rules, 4605.7040, subp. B(25), 4605.7044, 4605.7700, and 4605.7030 subp. 3(C).

- **Other Changes to Diseases Already Included in Minnesota Rules 4605.7040**.

  Hepatitis A. This disease is currently reportable, but reporters are not required to submit clinical materials. This proposed amendment will require submission of clinical materials upon request of the commissioner under item B at renumbered paragraph (30).

  Hepatitis A is an infection of the liver. There are no specific treatments for it, but it can be prevented by vaccination and proper sanitation, such as handwashing. Some people have very severe symptoms and other people have no symptoms at all. A person gets infected when the hepatitis A virus gets into their body, usually via the mouth. Some common ways this can happen are eating or drinking contaminated food or beverages, living in settings without appropriate sanitation or access to handwashing, and using injection or non-injection drugs.

  This amendment is reasonable and necessary because submission of clinical materials will allow whole genome sequencing (WGS) of the virus. WGS is vital in identifying and responding to outbreaks by linking cases of a disease that may not appear to be linked otherwise. For example, in May 2022, MDH identified a hepatitis A case that appeared to be related to consumption of a contaminated food product. The MDH PHL conducted WGS. Those results were then sent to CDC and the sequencing matched an ongoing international outbreak. Minnesota was one of four states, along with Canada, that identified this hepatitis A outbreak and traced it back to fresh organic strawberries. The ability to obtain clinical materials helped

link the cases together in this international outbreak and resulted in the contaminated food item being identified and pulled from the market.

Gonorrhea (Neisseria gonorrhoeae infections). This disease is currently reportable, but reporters are not required to submit clinical materials. This proposed amendment will require submission of clinical materials isolated from a normally sterile site[21] or upon request of the commissioner under item B at renumbered paragraph (26).

Gonorrhea is a sexually transmitted infection (STI) caused by the bacterium *Neisseria gonorrhoeae*. There are more than 200,000 cases per year in the United States. In Minnesota, gonorrhea remains the second most frequently reported STI with 8,161 cases reported in 2022. If left untreated, gonorrhea can spread to sex partners, cause pelvic inflammatory disease, ectopic pregnancy, infertility, and infections in the joints, eyes and anus. During pregnancy, gonorrhea may be passed to a newborn during childbirth, cause serious eye infections and even blindness in newborns, and may infect other organs. Gonorrhea is treatable if a person receives appropriate medication. However, some gonorrhea is becoming harder to treat, as drug-resistant strains are increasing. That means that gonorrhea has progressively developed resistance to the antibiotic drugs prescribed to treat it. It is critical to continuously monitor resistance.

If left untreated, gonorrhea can also sometimes (in less than 3% of cases) result in "disseminated gonorrhea infection" (DGI). DGI occurs when the infection enters the bloodstream and spreads to other sterile sites in the body. This can lead to severe infections that can cause joint pain, tendon pain, small fluid-filled bumps on the skin, fever and chills. Treatment for DGI involves antibiotics and possibly drainage of joint fluid.

CDC treatment guidelines for DGI underline the importance of obtaining and analyzing clinical materials. The current CDC STI Treatment Guidelines state, "If DGI is suspected, NAATs or culture specimens from all exposed urogenital and extragenital sites should be collected and processed, in addition to disseminated sites of infection (e.g., skin, synovial fluid, blood, or CSF). All N. gonorrhoeae isolates should be tested for antimicrobial susceptibility."[22]

Additionally, in situations of suspected treatment failure, clinical materials are required to confirm antimicrobial susceptibility. Upon receipt of results for antibiotic susceptibility, MDH coordinates with the diagnosing provider to ensure adequate treatment for the case and their partners.

The addition of requiring submission of clinical materials is reasonable and necessary to help control gonorrhea and for treatment purposes. Clinical materials are needed to characterize whether certain strains of gonorrhea are more prevalent among DGI cases, to monitor the circulation of resistant strains, and to help inform health care providers about the antibiotics appropriate for treatment.

***Chlamydia trachomatis* infection**, This proposed amendment adds serotypes L1, L2, and L3 to the list at item B(15). Chlamydia is a common sexually transmitted infection (STI) caused by

[21] Sterile sites are typically areas where microorganisms are not found and are often places deeper in the body and more protected from outside infection.

[22] Sexually Transmitted Infections Treatment Guidelines, 2021 (cdc.gov), p 77. https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf.

the bacterium *Chlamydia trachomatis*. Lymphogranuloma venereum (LGV) is a specific type of chlamydial infection caused by serovars L1, L2 and L3, which causes more severe disease with different treatment recommendations than other types of chlamydia. It is important to distinguish between LGV and non-LGV infections in chlamydia case report data. In 2022, the Council of State and Territorial Epidemiologists (CSTE)/CDC updated the chlamydia case definition to include the reporting of chlamydia caused by serovars L1 through L3, indicating lymphogranuloma venereum (LGV) infection and allowing for it to be reported as a separate condition.[23] Chlamydia is a nationally notifiable infection, and all cases should be reported, with a distinction between LGV (chlamydia serotypes L1-3) and non-LGV (other chlamydia) infections.

2. Changes to Add New Reportable Diseases to Minnesota Rules 4605.7040:

MDH proposes to add newly reportable diseases, which are split into four amendment subcategories: (1) Newly Reportable Disease: Report Within One Working Day, (2) Newly Reportable Disease: Report Within One Working Day and Submit Clinical Materials, (3) Currently Reportable Diseases under Minnesota Rules 4605.7080: Report immediately and submit clinical materials; and (4) Currently Reportable Diseases under Minnesota Rules 4605.7080: Report within one working day and submit clinical materials.

Newly Reportable Diseases: Report within one working day.

- **Blue-green algae (Cyanobacteria) and Cyanotoxin poisoning**. This amendment requires reporting of blue-green algae (Cyanobacteria) and cyanotoxin poisoning under item B(5).

  Disease Background. Cyanobacteria, also known as blue-green algae, are aquatic bacteria that are present in water bodies across Minnesota. Exposure to cyanotoxins or algal material can cause cyanobacterial poisoning in humans and animals. Cyanotoxins are among the most powerful natural poisons known. People can develop acute cyanobacterial poisoning after being exposed to cyanotoxin-contaminated waters or algal material. People and animals can come in contact with cyanobacteria and cyanotoxins that are in the environment by drinking water that comes from a lake or reservoir, swimming, or doing other recreational water activities. Specific routes of exposure include ingestion, inhalation, and direct skin contact, with contaminated water. Symptoms experienced during illness depend on the type of toxin present in the water and how a person is exposed. Common symptoms experienced include rash, cough, wheezing, congestion, eye irritation, diarrhea, vomiting, and headache. More severe symptoms may include neurological symptoms or liver damage. Unfortunately, there are no remedies to counteract the effects.

  Surveillance Background and Justification.

  MDH and CDC are working to understand and prevent the health effects associated with cyanobacteria blooms by conducting surveillance on human and animal illnesses that are associated with exposures to blooms in recreational and drinking waters. From 2014 to 2022, MDH received reports of 11 cyanobacteria-associated illnesses. The median age of cases was 10 years (range, 2 to 38 years). All cases were exposed during May through August, with 64% of cases exposed during July.

[23] https://ndc.services.cdc.gov/case-definitions/chlamydia-trachomatis-infection-2022/.

This addition is reasonable and necessary because, while these illnesses remain rare, their potentially severe outcomes can be devastating. Additionally, they can undermine the public's confidence in recreational water activities such as swimming. Reporting is necessary to determine the source of the infection and assess whether others may be at risk to control and prevent further infections.

- **Capnocytophaga canimorsus.** This amendment requires reporting of Capnocytophaga canimorsus (C. canimorous) under item B(8).

  Disease Background. *Capnocytophaga* is a bacteria found in the saliva of some dogs and cats. It does not make dogs or cats sick, but it can cause disease in humans. *Capnocytophaga* is spread to people through bites, scratches, licks, or close contact with a dog or cat. Most people who have contact with a dog or cat do not become sick. People without a spleen, who use alcohol excessively, or with weakened immune systems are at greater risk of becoming ill and developing serious and life-threatening complications. In those who become ill, the bacteria can cause blood infections (septicemia), inflammation of the lining of the heart (endocarditis), kidney failure, and gangrene. Some people may need to have fingers, toes, or even limbs amputated because of complications from severe infection. Death occurs in 30% of people who develop a severe infection and can occur as quickly as 24 to 72 hours after symptoms start. Infections can be treated with antibiotics if recognized early.

  Surveillance Background and Justification. C. canimorous is an emerging pathogen. The primary way to diagnose *Capnocytophaga* infection is by performing cultures of the infected tissue (for sepsis, a blood culture is performed). In Minnesota, about 1-3 cases are identified and reported to MDH annually. Many cases result in death or severe outcomes such as loss of a limb. Making the infection reportable would allow MDH to track the disease more accurately and raise awareness among healthcare providers and the public to recognize and treat the infection quickly and improve outcomes.

  This addition is reasonable and necessary because it would allow MDH to track the incidence and quantify the burden of this emerging, and very serious infection.

- **Congenital cytomegalovirus (cCMV).** This amendment to item B(17) requires reporting of cCMV cases with positive laboratory results collected from infants less than or equal to 90 days of age or from amniotic fluid.

  Disease Background. Congenital cytomegalovirus (cCMV) is an infection that occurs when a fetus is infected with cytomegalovirus, a member of the herpesvirus family. When a pregnant person is infected with CMV (either a primary or recurrent infection) at any time during pregnancy, the virus can be transmitted to the fetus, which may result in a CMV infection in the fetus. Although a CMV infection is typically harmless, resulting in cold-like symptoms for most of the population, cCMV can have serious consequences, including death, in the fetus or newborn.

  Surveillance Background and Justification. CMV is the most common congenital viral infection in the United States, occurring in about 1 in every 200 births.[24] In Minnesota, it is estimated that approximately 300 infants are born with a CMV infection each year. Most infected

[24] https://www.nationalcmv.org/overview.

newborns are asymptomatic, however, approximately 0.5% of infected infants die and about 20% of those that survive will have at least one long-term medical condition and/or complication due to the infection.[25]

CMV infection is also the major infectious cause of disability in newborns in the United States. These disabilities include intellectual disabilities, seizure disorders, and cerebral palsy, but the single most common consequence of congenital CMV is permanent hearing loss. CMV infection is estimated to cause permanent hearing loss in 12.6% of all infections, including 10% of infants with initially asymptomatic infections.[26] Undetected, permanent hearing loss can cause major speech and language delays.[27] Therefore, regular audiologic monitoring and early intervention for CMV-induced hearing loss is of key importance in improving speech and language outcomes for these infants (for example, ability to learn and do well in school).

Although CMV is the most common viral infection of newborns in the United States, only 9% of women are aware of it.[28] Approximately one in three children are infected with (non-congenital) CMV by the age of five and contact with the urine or saliva of young children is the primary risk factor for pregnant women.[29] A consensus group of cCMV experts recommend educating all health care providers and pregnant women about cCMV as the primary control measure. Education should provide recommendations on preventative measures including avoiding contact with saliva of small children (not sharing food or drink, not kissing on the mouth, not putting pacifier, etc. in your mouth) and performing hand hygiene after changing a child's diaper, feeding a young child, or wiping a young child's nose or saliva.[30]

Newborn screening is an important step in identifying infants with cCMV who can benefit from early identification. In February 2022, the commissioner approved the Newborn Screening Advisory Committee's[31] recommendation to add cCMV to the list of diseases for which Minnesota newborns are routinely screened. The MDH newborn screening program began universally screening babies born in Minnesota for cCMV in February 2023 using dried blood spot testing.

Testing using dried blood spots has been shown to identify fewer truly infected infants compared to testing using urine or saliva.[32] Therefore, it is expected that newborn screening

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[25] Dollard SC et al. New estimates of the prevalence of neurological and sensory sequelae and mortality associated with congenital cytomegalovirus infection. Rev Med Virol 2007;17:355-363.

[26] Goderis J et al. Hearing loss and congenital CMV infection: a systematic review. Pediatrics 2014:134(5):972-982.

[27] Cannon WJ et al. Universal newborn screening for congenital CMV infection: what is the evidence of potential benefit? Rev Med Virol 2014 Sep; 24(5):294-307.

[28] https://www.nationalcmv.org/overview.

[29] https://www.nationalcmv.org/overview.

[30] Rawlinson WD et al. Congenital cytomegalovirus infection in pregnancy and the neonate: consensus recommendations for prevention, diagnosis, and therapy. *Lancet Infect Dis* 2017;17:e177-88.

[31] The Advisory Committee on Heritable and Congenital Disorders, also called the Newborn Screening Advisory Committee (NSAC), was established in 2003. The NSAC was created to provide advice and recommendations to the Minnesota Commissioner of Health concerning tests and treatments for disorders found in newborn children (authorizing legislation: https://www.revisor.mn.gov/statutes/cite/144.1255).

[32] Dollard SC et al. Sensitivity of dried blood spot testing for detection of congenital cytomegalovirus infection. JAMA Pediatr 2021 Mar 1;175(3):e205441.

will not identify all cases of cCMV in the state, making reporting by health care providers and laboratories critical to surveillance. Additionally, neighboring states do not currently screen for cCMV as part of their newborn screening panels; some Minnesotans are born outside of Minnesota and therefore would not benefit from early identification of cCMV via newborn screening. Therefore, state-wide reporting of CMV infections is necessary to ensure that all Minnesota babies can benefit from early identification.

Reporting of cCMV is critical to ensure all Minnesota newborns with cCMV can benefit from early intervention and to describe the epidemiology of cCMV in Minnesota including at-risk populations.

This amendment is necessary and reasonable because it allows MDH to evaluate newborn screening performance, estimate the disease burden of cCMV statewide, and monitor trends in severity and prevalence, in order to create targeted education measures to help protect the health of Minnesotans and ensure that Minnesota newborns have the healthiest possible start in life.

- **Hard tick relapsing fever *(Borrelia miyamotoi)*.** This amendment requires reporting of hard tick relapsing fever (*Borrelia miyamotoi*) at item B(29).

  Disease Background. Hard tick relapsing fever caused by *Borrelia miyamotoi (B. miyamotoi)* is an emerging disease transmitted by ticks. It has been increasingly reported as a cause of human infection in the Upper Midwest, the Northeast, the mid-Atlantic, and in Pacific coastal states. Unlike Lyme disease, which is most common in June and July, *B. miyamotoi* infection occurs most commonly in July and August and may be spread by larval blacklegged ticks. The disease is not as well described as other, more established, tickborne diseases but symptoms of this infection are typically non-specific and flu-like. More serious disease is possible in people with weaker immune systems. Unlike Lyme disease, this disease does not usually produce a characteristic skin rash.

  Surveillance Background and Justification. This bacterium was first identified in 1995 in ticks from Japan but has since been detected in two species of North American ticks, the blacklegged or "deer" tick and the western blacklegged tick. These ticks are known to transmit several other diseases, including Lyme disease, anaplasmosis, and babesiosis, which are currently reportable in Minnesota. The first known case of human infection in the United States by *B. miyamotoi* was in 2013, and the first identified case of human infection in Minnesota was in 2016. The CDC reports that to date, there are no comprehensive studies to evaluate treatment regimens, but patients have been successfully treated with antibiotics and dosages used for Lyme disease (www.cdc.gov/ticks/tickbornediseases/lyme.html).

  This amendment is reasonable and necessary because it allows MDH to monitor the incidence and geographic spread of this new and emerging tickborne disease, and help us to better describe the resulting illness. This surveillance will help the department prevent and control the disease and to better communicate accurate information about risk and occurrence to Minnesotans and health care providers.

  Multisystem inflammatory syndrome associated with SARS-CoV-2 infection, including in children (MIS-C) and adults (MIS-A). This addition at item B(43) requires reporting of multisystem inflammatory syndrome associated with SARS-CoV-2 infection, including in children (MIS-C) and in adults (MIS-A).

Disease Background. Multisystem inflammatory syndrome (MIS) associated with SARS-CoV-2 infection is a rare but serious delayed hyperinflammatory condition that can occur several weeks after SARS-CoV-2 infection. MIS in children (MIS-C) occurs in children and teens under 21 years of age, while MIS in adults (MIS-A) occurs in adults aged 21 years and older. There is no confirmatory laboratory test for MIS and exactly how and why some patients get MIS after SARS-CoV-2 infection is still unknown. Typically, symptoms of MIS present two to six weeks after an acute infection. Symptoms of MIS are varied and may include persistent fever, abdominal pain, vomiting, diarrhea, skin rash, headache, and muscle pain. Patients with MIS develop inflammation in different parts of the body ("organ systems") which may include the heart, lungs, kidney, brain, skin, eyes, or gastrointestinal system. This inflammation can occur whether or not the patient had symptoms of COVID-19 during the time of their acute infection with the SARS-CoV-2 virus. Patients with MIS are often critically ill, with the majority requiring critical care. Most patients who develop MIS eventually get better with medical care, including immunomodulatory therapies such as intravenous (IV) immune globulin and steroids, as well as supportive care such as IV fluids and medications to support blood pressure. Mortality from MIS-C in the United States. is <1% with early and appropriate medical care but may be higher in cases of MIS-A.

Surveillance Background and Justification. MIS-C was first reported in the United Kingdom in April 2020, not long after the COVID-19 pandemic was underway in Europe. It has since been reported in many other countries including the United States. MIS-A was subsequently described in case reports in the United States and United Kingdom and is currently thought to be even more rare than MIS-C. MIS is considered a syndrome — a group of signs and symptoms, not a disease diagnosed with a laboratory test. Because much is unknown about it, including how and why it develops, reporting of MIS to identify potential risk factors and further characterize the syndrome, may help to improve our understanding of why some patients develop this life-threatening condition after SARS-CoV-2 infection. The CDC and the National Institutes of Health are working with doctors, health departments, and researchers across the country to learn more about risk factors for MIS and improve diagnosis and treatment.

Since May 2020, the CDC has requested reports (de-identified) of MIS-C and MIS-A from states and jurisdictions. Twelve states have added MIS-C to their reportable disease list (GA, IO, KS, KY, LA, MI, NJ, NY, OR, SC, VT, WI). Since CDC began requesting reports, 9,333 cases of, and 76 deaths due to MIS-C have been reported in the United States. MDH identified its first case of MIS-C in May 2020 and as of December 29, 2022, 226 cases have been identified in the state with no deaths. About 70 cases of MIS-A have been reported to CDC from states and jurisdictions since 2020, including 10 from Minnesota. Throughout the COVID-19 pandemic, trends in MIS-C cases have generally followed trends in reported daily COVID-19 cases over time. Peaks in MIS-C cases generally follow peaks in COVID-19 cases by about a month. COVID-19 vaccination has been found to protect against MIS in children aged 5 to 18.

Because not every state requires reporting of MIS, case numbers likely underestimate the incidence and impact of the syndrome. Early in the pandemic, the incidence of MIS-C in New York State was estimated at 2 cases per 100,000. Since then, the incidence appears to have declined, likely due to a combination of less severe disease with new SARS-CoV-2 variants and higher rates of immunity due to prior infection and vaccination. However, despite the decline

in cases, MIS continues to disproportionately affect males rather than females and patients in racial and ethnic minority groups, including non-Hispanic Black and Hispanic or Latino individuals. The reasons for this are unclear.

CSTE/CDC recently revised its 2020 surveillance case definition for MIS-C, in recognition of the need for a standardized case definition that incorporates known features of MIS-C and better distinguishes it from other hyperinflammatory syndromes in children. The CSTE/CDC updated surveillance case definition went into effect on January 1, 2023. A similar review is underway for cases of MIS-A.

Ongoing surveillance for MIS-C and MIS-A is necessary and reasonable for several reasons. Surveillance is necessary to estimate the disease burden, monitor trends in incidence and severity, and understand the demographic characteristics of patients affected. The epidemiology of MIS is likely to change as new variants emerge and circulate, with potential impacts on clinical care recommendations for providers. Evaluation of disease trends in MIS-C before and after January 1, 2023, will be necessary to understand the impact of the change to CDC's surveillance case definition. Finally, surveillance on the effectiveness of COVID-19 vaccination at preventing MIS will be needed, including data from younger children and adults.

- **Rat-bite fever (*Streptobacillus moniliformis*).** This amendment at item B(48) requires reporting of rat-bite fever (*Streptobacillus moniliformis*).

  Disease Background. Rat-bite fever (RBF) is a rare disease caused by the bacterium *S. moniliformis (S. monlifornis)*. People typically become infected through contact with rodents, often after a bite. A person can also get infected through consumption of food or water contaminated with the urine and droppings of rodents carrying the bacteria. Symptoms due to *S. moniliformis* infection may include chills, fever, vomiting, joint pain or swelling, and rash. Complications of infection include bone and joint infections, abscesses of the abdominal cavity, and infections of the brain, heart, liver or kidneys. Diagnosis is by blood culture. The outlook is excellent with early treatment; if it is not treated, the death rate can be as high as 10-15%.

  People who are at greater risk for RBF infection include those who have pet rats or other rodent-pets at home, especially children, and researchers who work with laboratory rats and other rodents. Pregnant women, and people with compromised immune systems may also be at greater risk.

  Surveillance Background and Justification. The increasing popularity of rats and other rodents as pets, together with the risk of invasive or fatal disease, demands increased attention to rat bite fever as a potential diagnosis. Children with pet rats now account for over 50% of RBF cases in the United States, followed by laboratory personnel and pet shop employees. More than 200 RBF cases have been documented in the United States. In Minnesota, 1 to 2 cases annually are reported to MDH, but this is likely a significant under-representation because RBF is not a reportable disease.

  This amendment is reasonable and necessary because it allows MDH to monitor the incidence of this disease, which will help the department raise awareness among health care providers and the pet owning public.

Newly Reportable Diseases: Report within one working day and submit clinical materials.

- **Carbapenemase-producing carbapenem-resistant *Pseudomonas aeruginosa* (CP - CRPA).** This amendment requires reporting of carbapenemase-producing carbapenem-resistant *Pseudomonas aeruginosa* (CP-CRPA) and submission of clinical materials to the MDH PHL to Minnesota Rules Part 4605.7040, item B(11).

  Disease Background. *Pseudomonas* infection is caused by strains of bacteria found widely in the environment. The most common type causing infections in humans is called *P. aeruginosa*. Carbapenems are a class of antibiotics that were developed to treat bacteria that are resistant to other drugs. Because of the overuse of these antibiotics, some types of *Pseudomonas* have developed resistance to carbapenems, and these bacteria are called carbapenem-resistant *P. aeruginosa* (CRPA). CRPA can cause serious infections in the blood, lungs, or other parts of the body. Healthy people usually do not get CRPA infections, however, in healthcare settings, CRPA infections can occur in patients who are receiving treatment for medical or surgical conditions. Patients who require devices such as ventilators, urinary catheters, or intravenous catheters, and patients who are taking long courses of certain antibiotics are most at risk for CRPA infections.

  While *P. aeruginosa* is widely found in nature, infections with this organism are predominantly healthcare-associated. CRPA can be transmitted by direct contact with an infected person or by contact with contaminated items (e.g., medical equipment) or environmental surfaces (e.g., bed rails, door knobs). Some people carry CRPA bacteria in their bodies without any symptoms. This is called being "colonized." A person might be colonized for a long time before getting sick or might never get sick.

  Treatment options depend on the type of CRPA infection. Some CRPA infections can be treated if the bacteria have not yet developed resistance to certain types of antibiotics. Some types of CRPA produce an enzyme that breaks down carbapenems and similar antibiotics, known as a "carbapenemase" which means the CRPA are even more difficult to treat. Special laboratory tests are needed to identify carbapenemase-producing CRPA (CP-CRPA) and which antibiotics, if any, would be effective for treating the infections.

  Surveillance Background and Justification. CRPA causes an estimated 51,000 health care-associated infections (HAI) in the United States annually and accounts for approximately eight percent of all HAIs reported to the National Healthcare Safety Network (NHSN). Of the 51,000 estimated annual infections, an estimated 6,700 are multi-drug resistant (MDR), meaning the bacteria is non-susceptible (resistant or intermediate resistance) to one or more drugs in at least three different antimicrobial classes. MDR *P. aeruginosa* was described by the CDC in their 2013 list of antimicrobial resistance threats as a serious hazard, meaning it is considered a significant threat to public health.

  The first carbapenemase-producing CRPA in the United States was identified in 2003 and cases continue to increase nationally.

  MDH conducted sentinel surveillance for CRPA in Hennepin and Ramsey Counties from 2016-2018 under Minnesota Rules, part 4605.7046. However, since that time, the state has seen an increase in CP-CRPA statewide including an outbreak of CP-CRPA associated with a contaminated endoscope. Statewide surveillance is necessary to assess the number of cases of CP-CRPA infections in the state, characterize the pathogen, and track the changing

epidemiology of CP-CRPA, including antibiotic resistance patterns, types of infections, demographics, and clinical characteristics of the patients affected and their outcomes. Information from surveillance will be used to inform infection prevention recommendations. In addition, surveillance of CP-CRPA will aid in identification of case clusters that may represent intra-facility or inter-facility transmission, enabling interventions that can prevent further transmission. Because spread can occur rapidly, prompt identification of cases and notification of facilities are essential for control.

This change is reasonable and necessary to prevent and control this drug-resistant bacteria.

Currently Reportable Diseases under Minnesota Rules 4605.7080: Report immediately and submit clinical materials under part 4605.7040, item A.

Note: Even though the following diseases are already reportable through Minnesota Rules, part 4605.7080 under the commissioner's authority for new and emerging diseases, adding them in the general reporting rule part for all reportable diseases under Minnesota Rules, part 4605.7040 is important too. First, if a disease reporter looks at Minnesota Rules, part 4605.7040 online to verify what is reportable and does not see the following diseases because it was only added under 4605.7080, they might not report it. In addition, even though MDH had the authority to add the diseases through 4605.7080, MDH believes it is helpful to also give the public an opportunity to deliberate and participate in the addition.

- **Glanders.** (***Burkholderia mallei*****).** This amendment requires immediate reporting of glanders (*Burkholderia mallei)* and submission of clinical materials to the MDH PHL under item A(7).

  Disease Background. Glanders is a zoonotic bacterial disease caused by *Burkholderia mallei (B. mallei)*. Transmission to humans occurs through contact with tissues or body fluids of infected animals, particularly equines. The bacteria enter the body through cuts or abrasions in the skin and through mucosal surfaces such as the eyes and nose. It may also be inhaled via infected aerosols or dust contaminated by infected animals. Sporadic cases have been documented in veterinarians, horse caretakers, and laboratorians. Cases of human-to-human transmission have not been reported in the United States There have been no naturally occurring cases of glanders in the United States since the 1940s; however, cases continue to be reported sporadically from Africa, Asia, the Middle East, Central America, and South America.[33] Glanders has vague symptoms that could occur in one part of the body or could affect the lungs, blood stream, or lead to chronic infections. Untreated bloodstream infections can be fatal in 7 to 10 days. Because of its rarity, there is limited treatment information, though the bacteria are susceptible to many antibiotics.

  Surveillance Background and Justification. B. mallei is considered an overlap Tier 1 Select Agent, meaning CDC and USDA consider it to pose a potential severe risk to human and animal health and is a re-emerging pathogen in some countries.[34] It is also a category B bioterrorism disease, the second highest priority category because it is moderately easy to

[33] Glanders, Centers for Disease Control and Prevention. https://www.cdc.gov/glanders/index.html

[34] https://www.selectagents.gov/selectagentsandtoxinslist.html.

disseminate, results in moderate morbidity rates and low mortality rates, and requires specific enhancements of diagnostic capacity and enhanced disease surveillance.[35]

Submitting clinical materials is also essential. The primary way to diagnose this infection is by performing testing on the infected tissues. A clinical diagnosis is not often accurate. Because *B. mallei* is a Select Agent, the MDH PHL must test isolates to confirm a diagnosis and the presence of the bacteria. This disease has not occurred naturally in the United States in many decades, and even one case would call for a swift public health response. Submitting clinical materials also aids in characterizing where the person may have been exposed and linking them to other cases, if there were any.

Requiring reporting of glanders, including submission of clinical materials, is necessary and reasonable to prevent and control this dangerous disease that is found in both humans and animals.

- **Melioidosis (*Burkholderia pseudomallei*).** This amendment requires immediate reporting of melioidosis (*Burkholderia mallei)* and submission of clinical materials to the MDH PHL under Minnesota Rules, part 4605.4040, item A(10).

  Disease Background. Melioidosis is a bacterial disease caused by *Burkholderia pseudomallei (B. pseudomallei)*. The bacteria is endemic in many parts of the world including southeast Asia and northern Australia and causes an estimated 165,000 illnesses and 89,000 deaths worldwide.[36] The bacteria was recently found to be endemic along the Mississippi Gulf Coast of the United States, but cases are more commonly identified in people who travel to hyper-endemic countries.[37] A review article from 2015 found that two dozen cases had no travel history outside the Americas suggesting the disease is also prevalent in many countries throughout the Americas.[38]

  Transmission occurs by direct contact with a contaminated source, commonly contaminated soil or water. Person to person transmission is rare, however sexual transmission has been documented.[3] Besides humans, many animal species are also susceptible to *B. pseudomallei* infection and melioidosis can be transmitted between animals and humans, although this is rare. In humans, the symptoms of melioidosis vary depending on the type of infection. Types of melioidosis include pulmonary (lung), bloodstream, local, and disseminated infections.

  B. pseudomallei is designated as a Tier 1 Select Agent because of its high potential threat to public health if it were deliberately misused. Its ease of aerosolization also makes it a risk to clinical laboratory staff working with clinical samples. Melioidosis is on the list of Nationally Notifiable Diseases.

  Surveillance Background and Justification. In Minnesota, four cases of melioidosis have been reported since 2006 (one case in 2006, 2015, 2018, and 2021). One of the cases was

[35] https://emergency.cdc.gov/agent/agentlist-category.asp.

[36] Limmathrurotsakul D, Golding N, Dance DAB, et al. Predicted global distribution of Burkholderia pseudomallei and burden of melioidosis. Nat Microbiol 2016:1; 1-5.

[37] Melioidosis, Centers for Disease Control and Prevention. https://www.cdc.gov/melioidosis/index.html.

[38] Benoit TJ, Blaney DD, Doker TJ, et al. Review article: a review of melioidosis cases in the Americas. Am J Trop Med Hg 2015: 93(6); 1134-1139.

hospitalized for at least 54 days; this case also had a complicated infection involving septic shock, pulmonary infection, splenic abscess, and osteomyelitis. One case had a localized skin infection and did not require hospitalization. There is limited information on the 2006 case and hospitalization status is unknown. The 2021 case developed pneumonia and osteomyelitis and was part of a multi-state outbreak linked to aromatherapy spray imported from an endemic country. All four cases resulted in occupational exposure to the bacteria in the clinical laboratory, requiring 25 laboratorians to undergo serological monitoring for 6 weeks and symptom watch for 21 days.

Melioidosis can be difficult to diagnose because it has a wide range of signs and symptoms and it can be mistaken for other diseases, such as tuberculosis or pneumonia. It also does not have a defined incubation period (days to years). Patients with melioidosis can have a localized infection that can spread to other areas of the body. Mortality rates can range from 19% to over 90% and are highly dependent on presence of certain risk factors, access to health care, early diagnosis, and access to appropriate antibiotic treatment.[39]Melioidosis is treatable usually with an initial regimen of intravenous antibiotics for at least 14 days followed by months of oral antibiotic therapy.

Submitting clinical materials is also essential. As stated above, melioidosis can be difficult to diagnose because its symptoms mirror those of other diseases. Laboratory testing of clinical materials is essential to ensure an accurate diagnosis. The MDH PHL is the only laboratory in the state that can perform confirmatory testing for melioidosis.

This change is reasonable and necessary because reporting of melioidosis, including submission of clinical materials, is necessary and reasonable to prevent and control this dangerous disease.

Currently Reportable Diseases under Minn. Rules 4605.7080: Report within one working day and submit clinical materials under part 4605.7040, item B.

- ***Candida auris (C. auris*).** This amendment adds *Candida auris* and submission of clinical materials to the MDH PHL to Minnesota Rules Part 4605.7040, item B(7).

  Disease Background. *C.auris* is a globally emerging, multidrug-resistant fungal pathogen that causes serious, difficult-to-treat infections and poses a significant threat to public health. *C. auris* infections require treatment with antifungals, which are medications used to kill the organism in the body. Most *C. auris* strains are resistant to at least one antifungal, and some are resistant to all three major classes of antifungals making infections difficult and sometimes impossible to treat. *C auris* can be carried on a patient's skin without causing infection, allowing spread to others. Some common healthcare disinfectants are less effective at eliminating it. *C. auris* strains can develop resistance to antifungal medications and cause outbreaks in healthcare settings that are difficult to control even with enhanced infection control interventions. Most cases of infection result from local spread within healthcare facilities in the same city or state.

  Healthy people usually do not get invasive infections caused by *Candida auris*. Most people who get *C. auris* infections are already sick from other medical conditions and have a

[39] Ketheesan N. Melioidosis - a century of observation and research. James Cook University, Townsville, Australia. 2012.

compromised immune system. Specific risk factors for *C. auris* include recent surgery, diabetes, antimicrobial use, and the presence of invasive devices such as breathing tubes, feeding tubes, and central venous catheters. Infections have been found in patients of all ages, from preterm infants to the elderly, but most infections occur in those over 65 years of age. As *C. auris* is a new and emerging pathogen, further study is needed to identify additional risk factors for *C. auris.* Patients may be colonized with *C. auris*, usually on the skin, prior to an infection occurring. Colonization means that the organism can be found on the body but is not causing any symptoms of disease; however, colonized patients are at increased risk for developing infection if the organism gains access to other body sites.

Surveillance Background and Justification. C. auris was first identified in 2009 in Asia and in the United States in 2016. Over the past few years, health care providers and the CDC have grown increasingly concerned about *C auris*. In 2019, the CDC released a major report on antibiotic resistance, "Antibiotic resistant threats in the United States, 2019."[40] It identified *C auris* as one of five urgent public health threats requiring immediate and aggressive action. If health care officials and public health do not act quickly to control these infections, *C. auris* can rapidly spread, not only in individual health care facilities, but throughout the health care community as patients move from one facility to the next. This highlights the important role for public health in CRE prevention and control efforts. The CDC report outlined public health actions that included new surveillance and prevention measures to track CRE, prevent infections, and halt further spread of resistance.

There have been six cases of *C. auris* reported in Minnesota since 2019. Healthcare-associated outbreaks of *C. auris* have occurred in over 20 countries in addition to the United States.

The MDH PHL is one of seven labs in CDC's Antibiotic Resistance Laboratory Network (ARLN) that is equipped to identify *C. auris,* and clinical laboratories throughout Minnesota are on alert to submit any organism that may be *C. auris* to the MDH PHL for identification.

This testing helps MDH detect outbreaks and assist facilities in investigation and infection control.

Requiring statewide *C. auris* reporting, including submission of clinical materials, is necessary and reasonable to protect the public's health against this urgent threat that looms both in the United States and internationally. These drug resistant infections are difficult to treat, have a high mortality rate, and are easily transmitted to other people. Statewide reporting will allow MDH to detect and control outbreaks, improve infection prevention and control in Minnesota, stay up to date with changing patterns of the disease, and provide actionable information back to our health care facilities.

- **Carbapenem-resistant *Acinetobacter baumannii* (CRAB).** This amendment adds carbapenem-resistant *Acinetobacter baumannii* (CRAB) and submission of clinical materials to the MDH PHL to Minnesota Rules Part 4605.7040, item B(9).

  Disease Background. Carbapenem-resistant *A baumannii (A. baumannii)*, also known as CRAB, is a bacterium that can cause a wide range of infections in humans, such as wound, bloodstream, and urinary tract infections. Such infections are typically healthcare-associated

[40] https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

infections (HAIs), which are infections that patients get while receiving treatment for medical or surgical conditions. Carbapenems are broad-spectrum antibiotics, often considered antibiotics of last resort for treating patients with severe or antibiotic resistant *Acinetobacter* infections. CRAB are resistant to carbapenems and most other available antibiotics, resulting in limited treatment options, poor patient outcomes (e.g., prolonged hospital stays, discharge to long-term care facilities), and high mortality rates. CRAB have emerged globally as a very concerning antibiotic resistance threat.

Healthy people usually do not get CRAB infections or colonization. Most CRAB infections are healthcare-associated infections (HAI) occurring in people who have underlying medical conditions or certain types of healthcare exposure, such as immunocompromising conditions, recent frequent or prolonged stays in health care settings, invasive medical devices (e.g., breathing tubes, feeding tubes, and catheters), open wounds from surgeries, and a history of taking certain antibiotics for long periods of time. Patients with a recent history of receiving healthcare in countries outside the United States with a high prevalence of CRAB may also be at increased risk for CRAB colonization or infection. Colonization means that the organism can be found on the body but is not causing any symptoms or disease; however, colonized patients are at increased risk for infection if colonizing bacteria gain access to body sites like the bladder, lungs, or bloodstream. CRAB-colonized or infected patients can spread the bacteria to other patients by the hands of healthcare workers, through contaminated medical equipment or the healthcare environment.

Surveillance Background and Justification. In 2013, the CDC released its first ever report on antibiotic resistance, *Antibiotic Resistance Threats in the United States, 2013*. It identified CRAB (specifically, multidrug-resistant *Acinetobacter*) as one of 12 serious public health threats that could worsen and become an urgent threat without ongoing public health monitoring and prevention activities. In a 2019 update to this report, CRAB was escalated to threat level urgent because of the growing ease with which the bacteria is able to transfer resistance and the lack of current antibiotics or antibiotics in development to treat CRAB infections.[41] These bacteria are constantly undergoing changes that make antibiotics less effective and sometimes ineffective in treating the infection. If action to control these infections is not taken quickly, CRAB can rapidly become an issue not only in individual healthcare facilities but also across an entire community of inter-connected healthcare settings, highlighting the important role for public health in CRAB prevention and control efforts. Quickly identifying patients with CRAB and implementing infection control interventions are critical to controlling the spread of CRAB in healthcare settings.

In 2017, CRAB caused an estimated 8,500 infections in hospitalized patients and 700 estimated deaths in the United States.[42] In Minnesota, there are approximately 20 CRAB infections reported statewide each year.

CRAB are a challenging threat to hospitalized patients because they frequently contaminate healthcare facility surfaces and shared medical equipment. They can live on a surface for a

[41] CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

[42] CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

long time. If not addressed through infection control measures, including rigorous cleaning and disinfection, outbreaks in hospitals and nursing homes can occur.

Submitting clinical materials is also essential. The MDH PHL tests isolates to determine whether they produce carbapenemase, which many Minnesota labs are unable to do. MDH then communicates the results back to the facility with recommendations for enhanced infection control measures, if necessary. Additional tests include genetic sequencing of the bacteria that can help determine whether infections occurring in different patients came from one source. This helps MDH detect outbreaks and assist facilities in investigation and infection control.

Requiring statewide CRAB reporting, including submission of clinical materials, is necessary and reasonable to protect the public's health. These resistant bacteria are difficult to treat, have a high mortality rate, and are easily transmitted to other people. The ability of some of these bacteria to transfer their resistance to other bacteria is very dangerous and it can create other "superbugs" that can spread. Statewide reporting will allow MDH to detect outbreaks, improve infection prevention and control, stay up to date with changing patterns in the bacteria, and provide actionable information back to our health care facilities.

- **SARS CoV-2/COVID-19.** This amendment adds reporting of unusual case incidence, critical illness and all laboratory confirmed cases of SARS-CoV-2 (COVID-19) and submission of clinical materials to the MDH PHL to Minnesota Rules Part 4605.7040, item B(50).

  Disease Background. COVID-19 is an infectious disease caused by the SARS-CoV-2 virus. SARS-CoV-2 was first identified in China in late 2019, with the first U.S. case identified in January 2020, and the first Minnesota case identified in March 2020. Since its identification, SARS-CoV-2 has caused a generational pandemic with very significant waves of disease globally and in Minnesota over the past three years. SARS-CoV-2 has shown the ability to evolve rapidly with a number of different variants of concern and subvariants emerging since it was first identified.

  In the United States, there have been more than 100 million reported cases of COVID-19 and more than 1 million deaths. Minnesota has had more than 1.8 million reported cases of COVID-19, more than 88,000 hospitalizations, and more than 15,000 deaths.

  SARS-CoV-2 is spread through droplets and virus particles released into the air when an infected person breathes, talks, laughs, sings, coughs or sneezes. Larger droplets may fall to the ground in a few seconds, but tiny infectious particles can linger in the air and accumulate in indoor places, especially where many people are gathered and there is poor ventilation.

  Most people with COVID-19 suffer mild to moderate illness. However, the devastating toll due to serious illness and death from COVID-19 has been experienced in Minnesota and worldwide. Symptoms of COVID-19 can include fever, cough, shortness of breath, chills, headache, muscle pain, sore throat, fatigue, congestion or runny nose, and loss of taste or smell. Other less common symptoms include gastrointestinal symptoms like nausea, vomiting, or diarrhea. These symptoms may appear 2-14 days after an individual is exposed to a person with COVID-19. Not everyone with COVID-19 has all of these symptoms, and some people do not develop symptoms at all despite an infection. Even after recovering from an acute COVID-19 infection, some people continue to have symptoms. Post-COVID conditions or long COVID refers to health problems people experience four or more weeks after being infected with

SARS-CoV-2. Though we still are learning how often long COVID occurs and the duration of symptoms, studies show that 5-30% or more of people who had COVID-19 have symptoms for months, a year, or longer after their initial infection. Long COVID symptoms can range from mild to debilitating. The longer-term effects of COVID-19 can occur even if a person's acute COVID-19 disease was mild or moderate.

SARS-CoV-2 can also cause severe illness in children. While most children will have asymptomatic infection or mild symptomatic illness, severe illness requiring hospitalization, ICU admission or mechanical ventilation may occur. Children with underlying medical conditions are at increased risk for severe illness. In addition, complications of SARS-CoV-2 infection may occur, such as multisystem inflammatory syndrome in children (MIS-C), a rare but serious condition. Children with MIS-C develop inflammation, which can occur in the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs (MIS-C is discussed in more detail in the section that addresses reporting of that syndrome). Children can also develop long COVID.

Pregnant or recently pregnant people are at increased risk of severe COVID illness compared to people who are not pregnant.[43] They are more likely to be admitted to an intensive care unit (ICU) (odds ratio 2.61, 95% confidence interval 1.84-3.71), and receive invasive ventilation (odds ratio 2.41, 2.13-2.71).[44] For pregnant people with COVID-19, the odds of a preterm birth are 1.6 times higher than pregnant people without COVID, and the odds of a maternal death are 6 times higher (95% confidence interval 1.82 to 20.38) than for pregnant people without COVID-19.[45] The data are mixed on the risk of stillbirth for pregnant people who had COVID-19 during pregnancy.[46] Babies born to pregnant people with SARS-CoV-2 infection during pregnancy are admitted to the NICU at a higher rate (odds ratio 2.18, 1.46-3.26)[47] (relative risk 1.86, 1.12-3.08) and are more likely to be low birth weight (relative risk 1.19, 1.02-1.40)[48]

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[43] Centers for Disease Control and Prevention "Pregnant People: At Increased Risk for Severe Illness from COVID-19". https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html Accessed 2/21/23.

[44] Allotey J, Fernandes S, Bonet M, Stallings E, Yap M, Kew T et. al. "Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis". BMJ, Update 2. 7 May 2022. https://www.bmj.com/content/370/bmj.m3320.

[45] Ibid.

[46] One meta-analysis identified an increased risk of stillbirth (odds ratio 1.81, 1.38-2.37), while another meta-analysis found no difference in the risk of stillbirth based on SARS-CoV-2 infection during pregnancy (relative risk 1.08, 0.53-2.16). One CDC study identified that the adjusted relative risk of stillbirth was 4.04 times higher among pregnant people who had COVID-19 documented at delivery during the Delta period (95% confidence interval 3.28-4.97) compared to those without COVID-19 documented. The citations for the data on stillbirths respectively are: Allotey J, Fernandes S, Bonet M, Stallings E, Yap M, Kew T et. al. "Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis". BMJ, Update 2. 7 May 2022. https://www.bmj.com/content/370/bmj.m3320; Smith ER, Oakley E, Grandner GW, et al. Adverse maternal, fetal, and newborn outcomes among pregnant women with SARS-CoV-2 infection: an individual participant data meta-analysis. BMJ Global Health, Jan 2023; (1): e009495. https://pubmed.ncbi.nlm.nih.gov/36646475/; and DeSisto CL, Wallace B, Simeone RM, et al. Risk for Stillbirth Among Women With and Without COVID-19 at Delivery Hospitalization – United States, March 2020-September 2021. MMWR Morb Mortal Wkly Rep 2021; 70: 1640-1645. DOI: http://dx.doi.org/10.15585/mmwr.mm7047e1.

[47] Ilotey J, Fernandes S, Bonet M, Stallings E, Yap M, Kew T et. al. "Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis". BMJ, Update 2. 7 May 2022. https://www.bmj.com/content/370/bmj.m3320.

[48] Smith ER, Oakley E, Grandner GW, et al. Adverse maternal, fetal, and newborn outcomes among pregnant women with SARS-CoV-2 infection: an individual participant data meta-analysis. BMJ Global Health, Jan 2023; 8 (1): e009495. https://pubmed.ncbi.nlm.nih.gov/36646475/.

than babies born to people without a SARS-CoV-2 infection. Despite these risks, in Minnesota, in January 2023, only 55% of births were to fully or partially vaccinated people for COVID-19 – a much lower percentage than the 74% of Minnesotans aged 18-49 years who had at least one dose.

COVID-19 remains a new disease from a scientific and epidemiologic perspective as our knowledge about it continues to evolve. Further, especially earlier in the pandemic, each new variant and subvariant has its own defining set of characteristics and needs to be monitored including for transmissibility, ability to evade immunity, and severity of disease.

Surveillance Background and Justification.

From the start of the pandemic, the data from mandated reporting of COVID-19 infections has been at the heart of the public health response across the United States and in Minnesota. These data are necessary to monitor, prevent, and control disease. The data have allowed for the characterization of the epidemiology of COVID-19 including identifying groups at highest risk of severe outcomes (characteristics of people hospitalized, admitted to the ICU, and deaths) and understanding the circumstances under which SARS-CoV-2 is more likely to spread. Knowledge of the epidemiology of COVID-19 has in turn informed public heath recommendations for the general population and for specific settings, such as long-term care facilities, schools, childcare, shelters, and correctional facilities. Reporting has also allowed for the identification and rapid initiation of public health interventions to contain outbreaks in specific settings and prevent further spread. The data helped inform the initial prioritization of vaccine administration and eligibility for treatment. Data from mandated reporting also made clear racial and ethnic disparities in morbidity and mortality from COVID-19, emphasizing the critical need to ensure resources for harder hit groups. The data have been critical in monitoring fluctuations in disease burden across the state so that Minnesotans know when to exercise caution. Further, disease reporting allowed for case interviews and notification of contacts, and for recommendations for isolation and quarantine to limit spread. It also allows MDH to monitor vaccine breakthrough cases and reinfection with SARS-CoV-2.

The commissioner initiated mandated reporting for SARS-CoV-2/COVID-19 on March 3, 2020. She issued a notification letter under the authority of Minnesota Rules 4605.7050 requiring mandated reporters to report cases, suspected cases, carriers, and deaths due to SARS-CoV-2 to MDH. The letter also required medical laboratories to submit test results and clinical materials upon request. On December 5, 2022, the commissioner issued a public notice under Minnesota Rules 4605.7080 to align reporting requirements with how reporting for COVID-19 had evolved since the beginning of the pandemic. The Commissioner has issued two additional reporting notices for COVID-19 since that time-both were issued under the authority of Minnesota Rules 4605.7080. The first was issued on May 1, 2023, and pertained to reporting of test results, while the second was issued on August 22, 2023, and pertained to reporting by specific community settings including K-12 schools, child care programs, corrections facilities, and shelters. The Commissioner's notices requiring reporting of COVID-19 are at: Reporting of COVID-19/SARS-CoV-2 under the Minnesota Communicable Disease Rules, Chapter 4605.7080 (www.health.state.mn.us/diseases/reportable/rule/process/index.html).

The nature of the pandemic has changed with vaccinations, effective treatments, and more broad infection-induced immunity. However, the emergence of new variants and sub-variants

of SARS-CoV-2 illustrates the critical and continuing need for disease reporting to quickly identify changes in the epidemiology of COVID-19 including changes in disease severity, and vaccine and treatment efficacy. Data from disease reporting is also critical to identifying changes in groups at high risk. Further, reporting helps MDH to identify outbreaks or clusters so that appropriate intervention measures can be quickly implemented. COVID-19 has disproportionately impacted specific populations beyond health-associated risk factors such as chronic conditions and age. The disease has resulted in disproportionate morbidity and mortality among historically disadvantaged communities including the American Indian, Black, Hispanic, and Asian and Pacific Islander communities. Programs were put into place during the pandemic to help mitigate this disproportionate impact, but continued data monitoring is necessary to assess the effect of COVID-19 on these populations. Additionally, SARS-CoV-2 is an important risk factor for health outcomes in pregnancy. COVID-19 disease surveillance in pregnancy depends upon MDH's ability to identify people infected with SARS-CoV-2.

The amendment would require reporting of unusual case incidence, critical illness, and laboratory confirmed cases. This language is the same as for case reporting of influenza under the current reporting rule. Reporting in these situations (excludes cases identified through home tests) enables MDH to identify and quickly investigate clusters where disease characteristics may be changing. These clusters may be due to changes in the properties of the virus (e.g., vaccine or treatment evasion) or in which populations are at higher risk.

Laboratory submission of clinical materials for SARS-Cov-2 is essential so that the MDH PHL can assess which variants and subvariants of SARS-CoV-2 are circulating in Minnesota. If MDH were to see a spike in hospitalizations or cases, we could assess whether a new variant or sub-variant was involved. Further, subtyping of specimens helps us know if cases are linked and if there is a cluster or outbreak that warrants disease investigation and control measures.

This amendment is reasonable and necessary because it allows MDH to monitor COVID-19 in the state and to monitor disease severity, vaccine efficacy, populations at highest risk, and whether the effect of treatment on disease outcomes is changing. These metrics help to inform public health recommendations for disease prevention and control.

Part 4604.7044 CHRONIC INFECTIONS; PERINATALLY TRANSMISSIBLE

This amendment adds hepatitis C to reportable chronic conditions that are perinatally transmissible under Minnesota Rules Part 4605.7044. Hepatitis C is reportable under current Minnesota Rules, part 4605.7040, item B (25), the general rule for disease reporting. Under 4605.7044, health care providers are required to report pregnancy status for people who have certain perinatally transmissible diseases.

In industrialized countries, hepatitis C virus (HCV) is the most common cause of chronic liver disease in children, and transmission from an infected mother to infant at birth (perinatal transmission) is the leading cause of this infection.

As of April 2020, the CDC recommended that prenatal care providers screen all pregnant persons for hepatitis C during every pregnancy. Hepatitis C is a liver infection caused by the hepatitis C virus (HCV).[49] Approximately 40% of people with hepatitis C are unaware of their infection. Testing is the

[49] CDC Recommendations for Hepatitis C Screening Among Adults – United States, 2020. MMWR. 69(2); 1-17, April 10, 2020.

first step to accessing curative treatment. Chronic HCV infection is often asymptomatic, but can lead to cirrhosis and liver cancer. More than half of new hepatitis C infections progress to chronic HCV infection. Without treatment, approximately 15-20% of people living with chronic HCV infection will develop progressive liver fibrosis and cirrhosis.

New cases of hepatitis C are on the rise among reproductive aged adults. Rates of new HCV infections increased by more than 60% from 2015 to 2019. HCV can be transmitted from an infected mother to the child during both pregnancy and childbirth (perinatal transmission). HCV-infected mothers transmit the infection to their baby in 5.8% of pregnancies; the risk of transmission is higher if the mother is co-infected with HIV. Several studies have linked maternal HCV infection with adverse perinatal outcomes, such as intrauterine fetal death and low birthweight. Rates of HCV infection nearly doubled during 2009 - 2014 among people with live births. From 2011-2014, an estimated 29,000 HCV-infected patients gave birth each year. As capacity for viral hepatitis surveillance improves, CDC anticipates that the number of perinatal hepatitis C cases identified and reported will increase.

Currently, there is no intervention during pregnancy to prevent transmission of hepatitis C either in utero or at birth. However, identifying hepatitis C in pregnant people allows them to access treatment following pregnancy and identifies at-risk infants in need of testing and ongoing monitoring. It is also anticipated that hepatitis C treatment will be approved in the near future for use during pregnancy. All children born to HCV-infected women should be tested for hepatitis C. HCV RNA testing can be done as early as 2 months of age and HCV antibody testing can be done starting at 18 months of age.

Over 90 percent of people infected with HCV can be cured with 8-12 weeks of oral therapy. Hepatitis C curative treatment is not currently approved for use during pregnancy; however, once the mother has given birth and completed breastfeeding, it is safe to begin this treatment. Furthermore, treatment is approved for children beginning at 3 years of age.

Based on the information above, the department asserts that this amendment is reasonable and necessary to help control the impact of HCV in the state, especially in young children.

PART 4605.7050 UNUSUAL CASE REPORTING

This amendment adds a subpart 2a that specifies the information a person must report to the commissioner when they have knowledge of any pattern of cases, suspected cases, or increased incidence of any illness beyond the expected number of cases, which may indicate a newly recognized infectious agent, an outbreak, epidemic, or other specified public health threat. Currently, the rule requires the person having knowledge of the case or cases to report but does not specify what information must be reported. The same is true for reports of “unexplained death or unexplained critical illness in a previously healthy individual that may be caused by an infectious agent” under Minnesota Rules, part 4605.7050, subp. 2a.

This amendment will clarify what information must be reported by the person having knowledge. Under the amendment, the person reporting must report the name and date of birth of the person or deceased person and as much information listed under Minn. Rules 4605.7090 as is known. [50] This amendment is a clarification since Minnesota Rules 4605.7090 already states that “[r]eports that are

[50] https://www.revisor.mn.gov/rules/4605.7090/

required under this chapter shall contain as much of the following information as is known" and then provides the required reporting elements.

This amendment is necessary to make clear that reporters are required to report as much information on cases and suspect cases as they know. MDH can only investigate sickness and deaths if we can identify the individuals, interview them or their families, and understand their symptoms, risk factors, and exposures. Without this information, MDH cannot characterize the nature of the potential health threat or even know if cases have characteristics or exposures in common and take the necessary measures to prevent and control the disease.

Based on the information above, the department asserts that this amendment is reasonable and necessary.

PART 4605.7070 OTHER REPORTS

This amendment specifies the information an institution, school, child care facility, or camp must report to the commissioner when they have knowledge of any disease which may threaten the public health. Currently, the rule only requires the person in charge of the institution or the person having knowledge of the disease to report the name and address of any person or deceased person suspected of having the disease to the commissioner.

This change requires that the institution or the person having knowledge of the disease report the name and date of birth of any person or deceased person suspected of having the disease and other information listed under 4605.7090[51] that the commissioner requests as necessary to investigate or control the disease.

Under circumstances where an institution is reporting a suspected case or a decedent, MDH needs to know at least the name and date of birth of the person so we can determine if the case has already been reported to us. If the case or decedent already has a disease report submitted by a health care provider, MDH may not need to collect additional information on that person, though we may need to follow up on potential disease spread at the reporting institution. The amendment also makes clear that the institution is required to provide any other information listed under Minnesota Rules 4605.7090 that the commissioner requests as necessary to investigate or control the disease. This change requires the institution to provide any other information listed under 4605.7090 to MDH upon request, which will address situations where no disease report has already been submitted or there is information missing that is needed to investigate or control the disease.

Based on the information above, this amendment is reasonable and necessary.

Conclusion

Based on the foregoing, the proposed rules are needed and reasonable.

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Brooke Cunningham, MD, PhD
Commissioner
P.O. Box 64975
St. Paul, MN 55164-0975

[51] https://www.revisor.mn.gov/rules/4605.7090/

List of Attachments

1. Attachment A: Glossary of Terms
2. Attachment B: Methods of Notifying and Persons Notified of Request for Comments
3. Attachment C: MMB Letter

Attachment A: Glossary of Terms

antibiotic resistance (AKA drug resistance). Antibiotic resistance is when a bacteria becomes resistant to the antibiotics administered to treat them (the infection).

antibody. An antibody is a protein produced by the body's immune system when it detects harmful substances, called antigens. Examples of antigens include microorganisms (bacteria, fungi, parasites, and viruses) and chemicals.

communicable. Capable of being transmitted from one person or species to another, as a communicable disease; contagious.

epidemiology. The study of the distribution and determinants of disease, injury, and other health-related events.

immunity. Protection from disease. Having antibodies (see above) to a disease makes a person immune. A person who is immune is no longer susceptible. Immunity is achieved through acquiring disease and successfully recovering or passively through vaccination.

immunocompromised. Individuals who are immunocompromised are less capable of battling infections because of an immune response that is not properly functioning. Examples of immunocompromised people are those that have HIV or AIDS, are undergoing chemotherapy or radiation therapy for cancer.

incidence. Incidence is the rate of new cases or events during a specified period.

incubation period. The interval between the time a person is infected with the disease and appearance of the first sign or symptom of that disease.

indirect costs. Include earnings lost due to premature mortality or disability, and loss of earnings for both caregiver and persons with disease.

morbidity rate. The rate at which a disease or illness occurs in a population.

mortality rate. The frequency or number of deaths due to disease divided by the total population.

outbreak. A greater than expected number of cases of a disease occurring around the same time and place, involving people who all got the disease from the same source or from each other.

pathogen. a bacterium, virus, or other microorganism that can cause disease.

prevalence. The number of cases of a disease that are present in a population at a specified time, either at a point in time or over a period of time.

susceptible. Being at risk of contracting a disease by virtue of not having documentation of the number of doses of an immunization against a disease that would render that person immune or not having documented history of disease or not having serologic proof of immunity**.**

Attachment B: Methods of Notifying and Persons Notified of Request for Comments

Mailed the Request for Comments to all persons who had registered to be on the department's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.

Posted the Request for Comment, which had a summary of the proposed changes, and information on the rulemaking process at Amendment to Rules Governing Communicable Disease Reporting (www.health.state.mn.us/diseases/reportable/rule/change/index.html). On the webpage there was also an option for people to "subscribe" to receive an alert when information on the webpage has been updated.

Provided a copy of the Request for Comment, which contained a summary of the proposed changes, and a link to the MDH rulemaking website via email directly or through a listserv, to various individuals. The department also requested that these individuals share this information with colleagues, post the information on their website, and send it to their listservs. This list included:

- Health care providers responsible for reporting and health care facilities whose personnel must report communicable diseases and conditions:
    - Infectious disease physicians.
    - MDH's infection preventionist list.
    - Minnesota Academy of Family Physicians.
    - Minnesota Chapter of the American Academy of Pediatrics.
    - Minnesota Council of Health Plans.
    - Minnesota Hospital Association.
    - Minnesota Medical Association.
    - Minnesota Medical Group Management Association. This association serves medical practice executives and their organizations.
    - Minnesota Nurses Association.
    - Physician assistant groups.
- Veterinarians and veterinary labs.
- Coroners and medical examiners.
- Local public health agencies.
- Medical laboratories.
    - MDH's Minnesota Laboratory System list. This list includes approximately 160 laboratories, including public health and private clinical laboratories, as well as veterinary and agriculture laboratories, which serve Minnesota residents.
    - Minnesota Interlaboratory Microbiology Association.
    - MDH's Minnesota Electronic Disease Surveillance System (MEDSS) laboratory notification list.

- Persons in charge of institutions, schools, and childcare facilities.
    - Early childhood providers, including school readiness, ECFE, and screening coordinators.
    - Child care licensors.
    - Child care health care consultants.
    - Minnesota school nurses.
    - Institutes of Higher Education.
    - Leading Age Minnesota.
    - Care Providers of Minnesota.
    - Association of Residential Resources in Minnesota (AARM).
- Long term care facilities, which includes nursing homes, assisted living facilities, and some group homes, through the MDH Compendium.
- Minnesota Department of Human Services and Minnesota Department of Education.

Attachment C: Minnesota Management and Budget (MMB) Letter

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

April 12, 2024

Ms. Hannah Millang
Executive Budget Officer
Minnesota Management and Budget
658 Cedar St., Ste. 400
St. Paul, MN 55155

Re: **Proposed Amendment to Rules Governing Communicable Disease Reporting, *Minnesota Rules*, Chapter 4605; Revisor's ID Number 4723;**

Dear Ms. Millang:

Minnesota Statutes, section 14.131, requires that an agency engaged in rulemaking consult with the Commissioner of Minnesota Management and Budget "to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government."

Enclosed for your review are copies of the following documents on the above-referenced rule revisions:

1. December 14, 2023, Revisor's draft of the proposed rule; and
2. Draft SONAR.

If you or any other representative of the Commissioner of Minnesota Management & Budget has questions about the proposed rule revisions, please email me at *josh.skaar@state.mn.us*. If necessary, you can also call me at 651-368-0751.

Sincerely,

/s/ Josh Skaar

Josh Skaar
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Rulemaking Coordinator
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Enclosures: