Protecting, maintaining and improving the health of all Minnesotans

July 14, 2016

sonars@lrl.leg.mn

Legislative Reference Library
645 State Office Building
100 Constitution Avenue
St. Paul, Minnesota 55155

Re: In The Matter of the Proposed Rules of the Department of Health Communicable Disease Reporting, Minnesota Rules, Chapter 4605; Revisor's ID Number R-4362

Dear Librarian:

The Minnesota Department of Health intends to adopt rules relating to the Communicable Disease Reporting, Minnesota Rules, Chapter 4605. We plan to publish a Dual Notice in the July 18, 2016, State Register.

The Department has prepared a Statement of Need and Reasonableness. As required by Minnesota Statutes, sections 14.131 and 14.23, the Department is sending the Library an electronic copy of the Statement of Need and Reasonableness at the same time we are mailing our Notice of Intent to Adopt Rules.

If you have questions, please contact me at 651-201-5520.

Yours very truly,

Patricia Freeman
Legal Counsel/Rule Writer
Minnesota Department of Health

Enclosure: Statement of Need and Reasonableness

STATEMENT OF NEED AND REASONABLENESS (SONAR)

COMMUNICABLE DISEASE REPORTING RULE

MDH Minnesota Department *of* Health
INFECTIOUS DISEASE EPIDEMIOLOGY, PREVENTION AND CONTROL

Proposed Amendment to Rules Governing Minnesota Communicable Disease, Minnesota Rules 4605.

Note: A glossary of terms can be found in Attachment A. Relevant diseases are described in the SONAR text in relation to discussion of them.

June 24, 2016, 2016

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STATEMENT OF NEED AND REASONABLENESS (SONAR)

COMMUNICABLE DISEASE REPORTING RULE

I. INTRODUCTION

The Minnesota Department of Health (MDH) is proposing amendments to the current Communicable Disease Reporting Rules (the rules). These rules are the backbone of MDH's ability to monitor and control communicable[1] disease in Minnesota. Under the rules, mandated reporters notify MDH of cases, suspected cases, carriers, and deaths from communicable diseases and other significant public health conditions. Medical laboratories submit clinical materials[2] under the rules 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 an epidemiological practice for monitoring the spread of disease to establish patterns of how diseases spread. The main role of disease surveillance is to predict, observe, and minimize the harm caused by outbreak, epidemic, and pandemic situations. It also increases knowledge about which factors contribute to such circumstances.

MDH has not revised the current rules comprehensively since 2004, but in the last 12 years communicable diseases not previously seen in the United States have appeared (such as Zika, Ebola, and chikungunya). Additionally, clinical practices have changed. Thus MDH needs to update these rules to reflect the current environment and provide flexibility for emerging diseases and clinical-practice standards.

MDH's proposed amendments update the rules to address new and emerging infectious diseases and help ensure a strong public health system. Further, the proposed amendments address the regulatory climate that the federal Health Insurance Portability and Accountability Act (HIPAA)[3] created. Communicable disease reporters increasingly seek explicit reporting provisions that protect them when they provide MDH with health information. Revised rules are critical for MDH's continued ability to conduct effective surveillance[4] and disease investigation, identify outbreaks, and respond promptly to new and emerging communicable diseases, all of which keep Minnesotans both medically and economically healthy.

MDH began work on potential revisions to the rules in August 2015. The agency published a Request for Comments in the State Register on September 28, 2015 with a closing date of December 4, 2015. MDH notified affected parties of the Request for Comments through multiple means. (See *Attachment B: Methods of Notifying and Persons Notified of Request for Comments*)

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. For this rule, it is defined in Minnesota Rules 4605.7000, Subp. 3.

3 Among other requirements, HIPAA creates federal standards for the privacy of health information.

4 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).

II. ALTERNATIVE FORMAT REQUEST

Upon request, MDH can make this SONAR available in an alternative format, such as large print, Braille, or cassette tape. To make a request, contact Patricia Segal Freeman, Minnesota Department of Health, P.O. Box 64975, St. Paul, Minnesota 55164-0975, Phone: (651) 201-5414, 1-877-676-5414, Fax (651) 201-5666 or commdisrule@state.mn.us.

III. STATUTORY AUTHORITY FOR MODIFYING THE RULES

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

A. 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."

B. Minnesota Statutes, section 144.05, subdivision 1, establishes the general duties of the commissioner of health ("commissioner"). Under Minnesota Statutes, section 144.05, subdivision 1, paragraph (a), the commissioner is authorized 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 (c), authorizes the commissioner to "[e]stablish and enforce health standards for...reporting of disease."

   Minnesota Statutes, section 144.05, subdivision 1, states:

   Subdivision 1. **General duties.** The state commissioner of health shall have general authority as the state's official health agency and shall be responsible for the development and maintenance of an organized system of programs and services for protecting, maintaining, and improving the health of the citizens. This authority shall include but not be limited to the following:

   a. Conduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems;

   b. Plan, facilitate, coordinate, provide, and support the organization of services for the prevention and control of illness and disease and the limitation of disabilities resulting therefrom;

   c. Establish and enforce health standards for the protection and the promotion of the public's health such as quality of health services, reporting of disease, regulation of health facilities, environmental health hazards and personnel;

   d. Affect the quality of public health and general health care services by providing consultation and technical training for health professionals and paraprofessionals;

   e. Promote personal health by conducting general health education programs and disseminating health information;

f. Coordinate and integrate local, state, and federal programs and services affecting the public's health;

g. Continually assess and evaluate the effectiveness and efficiency of health service systems and public health programming efforts in the state; and

h. Advise the governor and legislature on matters relating to the public's health.

Under these statutes, MDH has the necessary statutory authority to amend the rules. This rulemaking amends existing rules and thus, Minnesota Statutes, section 14.125, does not apply.

IV. 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. Section VI, the Rule-by-Rule Analysis, also addresses some of these factors.

A. A 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.

1. 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, or camps;
- 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;
- Minnesota Department of Health staff that receive the disease reports; and
- Local public health agencies.

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

   - Mandated reporters
   - Minnesota Department of Health

3. 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 diseases and changes in clinical practice, maintaining the agency's ability to properly investigate and control communicable disease. Reporting and investigation enable MDH to put control measures in place that protect the public. An example is the action MDH took in 2008 to halt the sale of peanut butter that caused 45 salmonellosis cases in Minnesota, including three deaths. Even though the outbreak was national, MDH investigators were the first to identify the outbreak's source, preventing an untold number of illnesses and deaths and stopping the sale and consumption of the product. MDH also ensures that people exposed to communicable diseases receive antibiotic prophylaxis (preventive drug therapy) when appropriate. These critical control measures start with a disease report under the rules.

   - 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 federal Centers for Disease Control and Prevention (CDC). Third, the MDH Public Health Laboratory (PHL) has the capacity to perform laboratory tests that might not otherwise be available to a health care provider. For example, not all Minnesota medical laboratories are able to test for MERS-CoV.[5] The MDH PHL can test for this virus and convey the results to the initial reporter. Fourth, MDH disseminates aggregate information to assist clinicians in their practice. For example, MDH annually issues an antibiogram[6] reflecting the results of antibiotic

[5] CoV means the coronavirus. So MERS-CoV is MERS caused by the coronavirus.

[6] The antibiogram is a chart reflecting the susceptibility of common pathogens to antimicrobial (antibiotic) drugs. By using the antibiogram, a clinician can obtain information about which antibiotics are currently most effective against selected communicable diseases in Minnesota.

susceptibility tests (measuring the effectiveness of antibiotics) on clinical materials submitted to the MDH PHL. This tool guides clinicians in prescribing antibiotics that are effective for common pathogens and is increasingly important because of the growing problem of antibiotic resistance.

B. 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.

1. 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. The PHL, however, is already collecting some of these materials per Minn. Rules Part 4605.7080[7], such as Carbapenem-resistant Enterobacteriaceae (CRE). Moreover, since most of the new reportable disease are rare, there should not be a lot of extra work. Existing staff will perform tests on these materials without needing additional state funds. The MDH PHL also may have some costs, albeit minimal, for mailers and shipping costs of additional clinical materials.

2. Probable costs to any other agency of 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.

3. Anticipated effect on state revenues

The proposed rule amendments will not affect state revenues.

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[7] 4605.7080 NEW DISEASES AND SYNDROMES; REPORTING AND SUBMISSIONS

C. 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[8] for disease surveillance, investigation, and control. Those required to report and what they are required to report are the basic essentials for protecting people's health. (This factor is also is discussed in the performance-based standard section and in the Rule-by-Rule Analysis.)

1. Less costly methods

Every state in the United States requires mandated reporters to report communicable diseases and, in fact, all states have had some form of reporting since 1901.[9] Such reporting is at the heart of communicable disease control. Nationally, there is a list of notifiable (reportable) diseases.[10,11] 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 without federal communicable disease reporting laws, reporting requirements are solely a state responsibility.

MDH knows of no less costly method than reporting for achieving the goals of communicable disease surveillance, timely investigation, and control. It would be difficult, if not impossible, to achieve a reliable substitute for monitoring disease in real time (sufficient time to initiate appropriate control measures) other than reporting by those who know about a case, suspected case, carrier, or death. Further, even though increasing the number of diseases that require submitting clinical materials adds some cost, there similarly is no substitute for achieving the goals of these rules. 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[12] (helps MDH link cases to a common source of infection) and antimicrobial susceptibility

[8] Information for inclusion in disease reports is set forth in the current rules in part 4605.7090. Several amendments are made to this part in the proposed rules.

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

[10] http://wwwn.cdc.gov/nndss/data-collection.html

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

[12] 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.

(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.

It should be noted that 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 to MDH (including submitting clinical materials) so that we can take timely action to protect the public and prevent unnecessary illness and death. For example, MDH currently conducts sentinel surveillance[13] for invasive methicillin-resistant Staphylococcus aureus (MRSA) among Hennepin and Ramsey Counties residents. MDH had considered statewide surveillance for invasive MRSA. Because of the added burden and expenses on providers, staff decided not to add this requirement. Staff felt they could achieve their goals with sentinel surveillance. Moreover, MDH removed two diseases, Reye syndrome and rheumatic fever, because cases of these diseases have decreased tremendously and no longer pose a public health threat that needs to be monitored.

The least costly method would be 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.

2. 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. One commenter questioned the rationale for collecting viral load information on hepatitis B and C; staff responded. (See response at the bottom of pages 18-19.) Another person questioned why MDH is collecting urine antigen for *Streptococcus pneumoniae*; again, staff responded. (See Streptococcal disease discussion on page 34.) MDH knows of no other such issues that reporters have.

Persons whose health information is reported could view the proposed amendments as intrusive because they require reporting of otherwise private health information. The 2004 rule changes, however, were much broader and more intrusive than these proposed changes. In 2004, we also specifically consulted with both representatives from the Minnesota Civil Liberties Union (MCLU) and a representative from the Minnesota AIDS Project (MAP), who

[13] Sentinel surveillance 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.

were on our advisory committee; neither of them raised issues about the intrusiveness of the 2004 proposed rules. Likewise, we have not heard concerns from either of those groups during this rulemaking endeavor about our proposed changes.

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.

Generally, we know of no method for conducting public health surveillance, investigation, and control of communicable diseases, other than reporting 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 (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 simply must have identifying information to interview ill people and determine the most likely source of infection. Further, by interviewing case patients, 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 duplicated reports occur, resulting in huge discrepancies between the number of cases reported and the actual number of cases.

A 2008 foodborne outbreak demonstrates the critical importance of individual identifying information. In November and December of 2008, MDH received multiple reports of enteric Salmonella Typhimurium infection. Through tests on clinical materials coupled with case interviews, MDH determined that ill persons were infected with the same molecular subtype of the bacteria and that its source was peanut butter produced by the Peanut Corporation of America. 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 national outbreak likely would have gone on for many 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 Peanut Corporation of America 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 and interviews with case patients.

Further, reporting identifiable health information under communicable disease reporting requirements is the standard and accepted surveillance method. In fact, federal rules adopted under HIPAA, which set national standards for health

information privacy, contain an exemption for surveillance that permits reporting private health information to health departments.[14] 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.

MDH has concluded that no less intrusive methods are available to accomplish the goals of the rules and that the proposed amendments for collection of additional private health information are necessary and reasonable.

D. 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 U.S. state. Discussions on alternative methods that MDH considered are the following:

1. This SONAR discusses both less costly and less intrusive methods (See Factor "C" above.)

2. Importantly, an alternative reporting method to use in specified circumstances is already codified under the current rules in part 4605.7049. Under this part, when the commissioner determines that surveillance is necessary for specific public health purposes, he can require that a limited number of sites (sentinel sites) report to the Department instead of requiring all reporters to report. With sentinel surveillance,[15] the reporting sites incur reporting costs, those reporters not affected do not. The MRSA example in Factor C.1. on page seven demonstrates this alternative method. MDH staff also considered requiring reporting of

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[14] 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..."

[15] "sentinel surveillance" is defined term in part 4605.7000, subpart 12 of the current 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.

Carbapenem-resistant Acinetobacter (CRA) statewide but decided that using sentinel surveillance would be sufficient.

E. The probable costs of complying with the proposed rule, including the portion of the total costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

1. Probable costs of complying with the proposed rule

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. Some proposed changes might increase their workload, though the increase should not be substantial for any one reporter since the new reportable diseases are infrequent. In addition, some facilities[16] are already reporting these proposed reportable diseases through sentinel surveillance so this will not be an additional burden on them. Of the proposed new diseases: (1) reporters already report them in practice, (2) reporters already report them because of a public notice published under part 4605.7080 of the existing rules (carbapenem-resistant Enterobacteriaceae), or (3) the disease is anticipated to occur infrequently, or possibly never. MDH staff are available upon request to assist hospitals, long-term care facilities, and other reporters with reporting. MDH listed most of the proposed reportable diseases in its Request for Comments that it published on September 28, 2015.[17]

The amendments also would require that reporters submit clinical materials for most of the newly reportable diseases and for some diseases reportable under the existing rules.[18] Most proposed requirements for clinical-materials submission apply to diseases that occur infrequently. Of the newly reportable diseases, four would entail submitting clinical materials, which would only occur infrequently, as already mentioned. MDH also eliminated the requirement to submit clinical materials for HIV/AIDS.

2. The portion of the costs borne by identifiable categories of affected parties

- Mandated Reporters: Under regulatory analysis factor A, MDH listed the categories of affected parties. MDH anticipates that hospitals and medical laboratories will bear the largest portion of additional cost, which should be minimal.

[16] For example, Hennepin and Ramsey counties are currently reporting CRE.

[17] Zika virus was added after the Request for Comments was published.

[18] See part 4605.7040 of the proposed rules.

- Government Entities: MDH is the government entity affected by any additional costs under the proposed rules. We anticipate that costs for MDH will be minimal. This is discussed under factor B of the regulatory analysis.

F. 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.

1. 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 taken. Among the amendments are new reportable diseases and a requirement to submit clinical materials for certain new diseases and for one disease that is currently reportable. For example, Ebola is not currently reportable. Under the proposed rule, it would be. If MDH confirmed a case of Ebola, it would quickly identify contacts and ensure all infection control measures were taken. Similarly, without these additional requirements submitting clinical materials, MDH might not receive crucial evidence, impeding disease investigation activities and endangering the public's health.

   A delay in recognizing an outbreak could result in negative economic consequences as well. Extending the Ebola example further, a combination of astute clinicians and reports to MDH could curtail Ebola's spread, helping to avoid the severe economic consequences of treating potentially exposed people, disrupting the state's health care delivery system, and causing patient suffering and expense.

2. Portion of costs borne by identifiable categories of affected parties

   Under factor A 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.

   Mandated reporters and their patients: The discussion under factor A reflects how mandated reporters would benefit from an updated rule. When MDH has timely information on communicable disease, it can quickly alert health care providers 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 permission to report, health care providers and their patients could bear the costs of MDH's not knowing about a communicable disease event.

G. 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.

There are no federal regulations regarding communicable disease reporting. This is a state function.

H. 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 Minnesota's Communicable Disease Reporting rule. The federal government does, however, maintain a list of diseases that people can be quarantined for having (Executive Order 13295[19]). Currently all these federal listed diseases, except one (viral hemorrhagic fevers), are in the Minnesota Communicable Disease Rules. The department is proposing to add viral hemorrhagic fevers to its rules. Reporting communicable diseases is mostly 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 current communicable disease reporting rule provides Minnesota's only existing regulatory system for reporting communicable diseases. Alerting health authorities to take swift action not only saves lives and helps prevent the spread of these diseases, but also reduces health care costs. 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 standards based on new scientific research. This proposed change continues that process that, by extension, protects all Minnesotans from vaccine-preventable diseases and so they remain healthy.

[19] http://fas.org/irp/offdocs/eo/eo-13295.htm

V. ADDITIONAL STATUTORY REQUIREMENTS

A. 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 reviewed 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?

Many comments from the 2004 rulemaking remain relevant. In 2004, some advisory committee members commented that the one-working-day reporting requirement[20] in the still-existing rule is not always followed. They asked whether MDH could prioritize reporting by "tiered timeframes" by first categorizing diseases according to reporting urgency and then establishing a timeframe for each category. Another member commented that complying with the one-working-day rule is a struggle. MDH said then that it would be very difficult to create tiered timeframes for reporting. This is because, even with a specific disease for which two-day reporting, or more, might be acceptable, there are circumstances where protecting the public's health would require one-day reporting for that disease.

Having multiple time frames for disease reporting would present a challenge and could potentially lead to more cases. For example, in 2011, a large scale measles outbreak could have occurred but measles being an immediately reportable disease, prevented this from happening. That year, MDH promptly received reports of two cases, each from a different hospital. At the time, it may not have seemed important to report a single case immediately or within one working day. However, by putting together interview information from both cases, MDH identified an outbreak and acted promptly. MDH alerted people who had potential exposure to measles, recommended vaccination, and also alerted the medical community.

The one-working-day requirement has always been in the rule. MDH recognizes that reporting does not always occur in that time period. MDH strongly believes, however, that disease reporting does not lend itself to multiple timeframes because (1) for every disease on the reporting list, unpredictable circumstances arise when one-day reporting is essential; (2) having multiple timeframes for each disease would unduly complicate

[20] Under the existing rules, some diseases are reportable to the Commissioner of Health immediately by telephone and all other diseases are reportable within one working day (part 4605.7030 of the existing rules and part 4605.7040, subpart B of the proposed rules). The proposed rule does not change this framework.

operating under the rule; and (3) as in the measles example, any one reporter might not immediately perceive the importance of prompt reporting that might become obvious when pattern of reports emerges from reports that MDH receives from across the state. MDH often connects reports from different reporters to identify an outbreak. Thus, MDH concluded that the benefit of one-working-day reporting outweighs the benefits of creating multiple timeframes for disease reporting because the latter could endanger the public's health, and would not accomplish the goals of the rules.

MDH 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 that the goal should be to reduce the manual, labor-intensive reporting and also provide MDH with more comprehensive information. MDH is working in this direction but it has been impeded by lack of resources. However, many disease reports are reported electronically.

B. Additional Notice

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

MDH submitted an additional notice plan to the Office of Administrative Hearings, which reviewed and approved it on June 29, 2016] by Administrative Law Judge James Mortenson.

The additional notice plan consists of the following steps:

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

2. Posting the proposed rules, the dual notice, the SONAR, and a fact sheet containing a summary of the substantive amendments on MDH's Communicable Disease Rule website at http://www.health.state.mn.us/divs/idepc/dtopics/reportable/newrule/index.html.

3. Providing 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 and workspace[21] to various individuals, groups and organizations. MDH will also request, when

[21] The MDH Workspace is a password protected portal used by department staff, local health departments, and other emergency preparedness and response partners for planning and response work. MDH used the Workspace when it sent out the Request for Comments and it went to 721 contacts.

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
- Persons in charge of institutions, schools, and childcare facilities
  - Early childhood providers, including school readiness, ECFE, and screening coordinators
  - Childcare licensors
  - Childcare Resource and Referral Agencies
  - Childcare health care consultants
  - Minnesota school nurses

4. Publishing information such as the dual notice, a summary of proposed changes, and where people can get further information in publications that reach affected parties, such as association newsletters and journals, etc.

5. Notifying the Minnesota Legislature per Minnesota Statutes, section 14.116 and Minnesota Statutes, sections 121A.15, subdivision 12(2)(b) and 135A.14, subdivision 7(d). This will include sending the proposed rules, SONAR, dual notice, and summary of substantive amendments to the chairs and ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter.

C. Consultation with the Minnesota Department of Finance on Local Government Impact

Minnesota Statutes, section 14.131, requires agencies to consult with the Department of Finance to help evaluate the fiscal impact and benefits of the proposed rules on local governments. MDH delivered a copy of the proposed rules and SONAR to the Executive Budget Officer on April 27, 2016.

MDH does not anticipate local agencies will incur costs as a result of the proposed rules because the system already exists (See B.2. of the Regulatory Analysis on page 5). Local jurisdictions will benefit from an updated system of communicable disease surveillance, investigation, and control. This is because they can help to better protect residents in their jurisdiction when disease outbreaks are detected early.

D. Cost Determination for Small Business or Small 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 city is reporting and the time commitment to do so in these rare cases is negligible. Since any other costs, which will be minimal, will be borne by MDH or mandated reporters as discussed in Section IV.E., the department has determined that the rules will not exceed $25,000 for any small business or small city.

E. Section 14.128 Analysis

Minnesota Statutes, section 14.128 requires agencies to determine whether a local government will have to adopt or amend an ordinance or other regulation to comply with a proposed agency rule and submit this determination for ALJ approval. 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 remains responsible under chapter 144 for protecting public health and local regulations for communicable disease reporting would not be appropriate.

F. List of Non-Agency Witnesses

If the rules go to a public hearing, MDH anticipates having the following non-agency witnesses testify in support of the need for and reasonableness of the proposed amendments to the rules:

1. An infectious disease physician or nurse
2. An infection preventionist

VI. RULE-BY-RULE ANALYSIS

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

Note: The Department corrected previous spelling errors in the rules.

PART 4605.7000 DEFINITIONS.

These proposed definitions provide a common vocabulary for MDH and communicable disease reporters to understand each other and apply consistently, thus ensuring thorough disease surveillance, investigation, and control.

4605.7000, Subpart 4a. Community Health Board. This technical amendment conforms the rule to current statutory law. Under the current rule, 4605.7000, subpart 9, "'Board of Health' means authorized administrators, officers, agents, or employees of the county, multicounty, or city board of health organized under Minnesota Statutes, sections 145A.09 to 145A.14." In 2015, Minnesota Chapter 145 was revised and the term Board of Health was replaced with "Community Health Board."

4605.7000, Subpart 6a. Health Care Practitioner. This amendment replaces "physician" in 4605.7000, subpart 11, with the term "Health Care Practitioner." In 2014, the legislature expanded the scopes of practice for a Minnesota licensed physician assistant (PA) and a Minnesota licensed advanced practice registered nurse (APRN), which includes a certified nurse midwife. Consequently, many PAs and APRNs could have primary responsibility for the care and treatment of a person diagnosed with a disease that is reportable under the communicable disease reporting rules. This proposed amendment, which is consistent with the definition in Minnesota Statutes, section 151.01, updates this definition to correspond to this broadened scope of practice and ensure that these health care providers have notice that they carry the same responsibility as Minnesota licensed physicians.

For consistency MDH replaced the term physician with health care practitioner where ever it appears in the rules.

Repealer. Minnesota Rules 4605.7000, subparts 9 and 11 are repealed and replaced with subparts 4a and 6a as explained above.

PART 4605.7030 PERSONS REQUIRED TO REPORT

4605.7030, Subpart 3. Medical laboratories.

This amendment requires all laboratories to report to the Minnesota Department of Health (MDH) all hepatitis C virus (HCV) and hepatitis B virus (HBV) viral-detection laboratory test results. Currently, laboratories are only required to report HIV viral-detection laboratory test results.

Viral-detection test results are one step in public health monitoring viral diseases. Understanding the importance for this proposed change requires understanding the sequence for finding patients with the disease, treating the disease, measuring the results, and preventing further transmission. Briefly, the system works as follows, using HCV as an example:

First, a patient is diagnosed with an HCV infection. Next, the patient enters treatment and receives direct-acting antiviral therapy (drugs). The drug therapy often results in clearing hepatitis C from the patient's body. The patient's caregivers and MDH monitor the amount of virus in the patient's body through testing. Epidemiologists call the amount of virus present the "viral load." Successful treatment cures hepatitis C and the viral load will continue to be "undetectable" and the patient is no longer infectious. Accordingly:

Patient cured of hepatitis C through drug therapy= Undetectable Viral Load → Patient Cannot Transmit HCV

Conversely, if a patient is re-infected and the viral load rises, that patient becomes infectious again. Thus data from test results give MDH important measures of detected and undetected viral loads that MDH uses to measure the burden hepatitis C represents and to evaluate programs to prevent and treat hepatitis C in Minnesota.

MDH proposes to require that laboratories report all viral-detection test results, whether HBV or HCV is detected or not. As described above, the viral load detection tests for HBV and HCV inform health care providers how much HBV or HCV virus is in the body.

It is important that laboratories report all viral detection test results, even those tests that don't detect any virus (undetectable) because with the current available medications for treating HCV many individuals living with HCV infection will be cured and have undetectable results. The new case definitions for hepatitis C differentiate between current HCV infection; and past HCV infection and undetectable HCV-viral-load-detection test results are an essential component for case classification.[22] In addition, any efforts to assist those with HCV infection with access to HCV-related treatment or care are dependent on the ability of MDH to identify those who are currently infected.

HBV viral load testing is also becoming increasingly common. Undetectable HBV-viral-load-detection test results are useful in helping to identify women who may need assistance getting into HBV-related care during pregnancy to prevent transmission from mother to child. If undetectable HBV-viral-load-detection test results are not reported, MDH assumes that this testing was not done and might refer the individual for unnecessary follow-up testing.

MDH received one question from a laboratorian regarding the reason for collecting this information. Staff explained the reasoning for the change and also clarified what MDH would do with reports on persons with no evidence of past or present infection prior to or at the time of

[22] The case definition is based on a position statements approved by the Council of State and Territorial Epidemiologists (CSTE). This updated case definitions change the national criteria for which de-identified cases we need to report to CDC. The previous case definition categorized current and past infections the same way.

report. If we receive an undetectable viral-load-detection test results for hepatitis B or C on a person with no previous record of infection and no current evidence of infection, those records will be destroyed either by shredding or permanent removal from our system. MDH received no other comments in this area.

This change is reasonable and necessary to ensure individuals are treated appropriately and help prevent the spread of these diseases.

4605.7040 Disease and Reports; Clinical Materials Submissions.

These amendments can be divided into two general categories: (A) changes to currently reportable diseases and (B) changes to add new reportable diseases.

A. Changes to Currently Reportable Diseases:

- **Enteric Escherichia coli infection (E coli).** This change to 4605.7040, item B (17) clarifies that the category "enteric *Escherichia coli* infection" encompasses all E. coli infections that cause enteric (or intestinal) symptoms, such as diarrhea, abdominal discomfort, nausea, and vomiting. When MDH originally added *E coli* to the list, MDH intended that reporters would report all pathogenic *E. coli* infections that cause enteric symptoms. The types of *E. coli* currently listed in parentheses are examples of the most commonly encountered *E. coli* infections and not intended to be an all-inclusive list. Laboratory testing was then limited to *E. coli* O157. In the last decade, however, testing practices have changed dramatically. Clinical laboratories can now identify Shiga toxin-producing *E. coli* (enterohemorrhagic *E. coli*, which causes bleeding) and other pathogenic types of *E coli* strains, such as enteropathogenic, enterotoxigenic, enteroinvasive and enteroaggrevative *E. coli*. As testing practices continue to evolve, future tests quite likely will identify other types of *E. coli* that cause enteric illness, such as diffusely adherent *E. coli*. These future testing methods might also prompt an overhaul of *E. coli* classifications as we more precisely identify individual *E. coli* types. Updating this language will more clearly direct reporters to report all diarrhea-causing *E. coli*. All examples listed above are well documented causes of diarrhea, including outbreaks.

- **Human Immunodeficiency Virus (HIV).** This change to 4605.7040, item (27) removes the requirement to submit clinical materials for HIV and acquired immunodeficiency syndrome (AIDS).

  In 2004, MDH required that reporters "submit clinical materials" for HIV/AIDS because MDH Public Health Laboratory (PHL) had then received a CDC-funded Cooperative Agreement for the following activities:
  - Evaluating dried blood spots (DBS) for use as a specimen type for surveillance of atypical strains of HIV;
  - Monitoring the prevalence of atypical strains of HIV among persons newly diagnosed with HIV; and
  - Developing a framework for implementing atypical HIV strain surveillance.

MDH no longer needs these clinical materials. Clinical diagnostics have since improved making the requirement to examine them obsolete. Plus, the CDC funding has ended. Thus the MDH PHL cannot process any clinical materials beyond those from the limited facilities who have a contract or grant-based arrangement with the MDH PHL to perform diagnostic testing for HIV. Therefore this change is reasonable and necessary.

- **Mumps**. Currently, mumps is reportable but submitting clinical materials to the MDH PHL is not. This change adds the requirement to submit clinical materials for mumps under part 4605.7030 (38).

  Mumps was rampant in the United States during the early and middle parts of the 20th century. Since the mumps vaccine was introduced in 1967, however, reported cases have drastically decreased from 152,000 in 1968 to a low of 229 cases in 2012.[23,24] Incidence in the United States fluctuates annually from several hundred to several thousand cases, depending on whether large outbreaks are occurring. Though the mumps component of the Measles, Mumps Rubella (MMR) vaccine is effective (88% after two doses of vaccine), outbreaks still occur in close-contact settings such as schools, colleges, and camps.[26] Large resurgences of mumps in 2006, 2009, and 2010 have reminded health professionals that mumps has not disappeared.[27] Maintaining high vaccination rates and good surveillance for mumps is crucial to control mumps outbreaks and stop the spread of this highly communicable disease.

  The Department's reason for requiring that reporters submit clinical materials for mumps is three-fold:
  - First, mumps surveillance is complicated. The symptoms of mumps are very similar to other diseases. For example, influenza A, parainfluenza virus types 1 and 3, Epstein Barr virus, coxsackie A virus, cytomegalovirus, herpes simplex virus, lymphocytic choriomeningitis virus, acute bacterial suppurative parotitis and certain drug reactions can also present with symptoms similar to mumps. As a result, a health care provider may not be able to diagnose mumps by these clinical symptoms alone.
  - Second, the current test most health care providers order to confirm mumps is not very accurate.[25] This means that the test gives results that are highly likely to be either falsely positive or falsely negative. Because of this, the Council for State and Territorial Epidemiologists (CSTE) has added a positive PCR lab test result to the case definition for a confirmed mumps case.[26] A PCR test requires clinical materials. At present, the MDH PHL has a reliable PCR test for mumps and currently requests that providers submit specimens for PCR, but this is not required and not always done. Because it is not required, some health care

[23] CDC. Mumps Cases and Outbreaks. Accessed 10/23/15: http://www.cdc.gov/mumps/outbreaks.html.

[24] CDC. VPD Surveillance Manual, 5th Edition, 2012. Mumps: Chapter 9-1

[25] In epidemiological terms, this means they are neither very sensitive nor specific tests.

[26] CDC. National Notifiable Disease Surveillance System (NNDSS) Accessed 10/28/15: http://wwwn.cdc.gov/nndss/conditions/mumps/case-definition/2012/

providers might not provide the clinical materials. This requirement will allow us to get clinical materials when necessary.

- Third, since mumps is not as common as it once was, many health care providers are not familiar with the disease or its epidemiology. In situations where the clinical presentation and epidemiological information do not clearly support a mumps diagnosis, MDH needs clinical materials to verify laboratory results to determine what control measures, such as alerting the public and notifying contacts, need to be taken.

MDH needs reliable diagnoses to act. Therefore it is necessary and reasonable that MDH require reporters collect and submit clinical materials for mumps so MDH can prevent and control this disease to protect all Minnesotans.

- **Rocky Mountain spotted fever**. This technical change brings the terminology used for this disease up to date. Rocky Mountain spotted fever will now be listed under 4605.7040 item (45) as "Spotted fever rickettsiosis" to better reflect the broad spectrum of tick-borne rickettsial bacteria that may cause human disease. The symptoms and immune reactions caused by various spotted fever group rickettsioses (SFGR) are often difficult to distinguish from one another based on available laboratory techniques. Some human illnesses currently attributed to Rocky Mountain spotted fever might actually be caused by other SFGR. In addition to the species found in the United States, numerous other tick-borne SFGRs have been described internationally, putting travelers with exposure to ticks at risk for these pathogens. Broadening the reporting rule to refer to spotted fever rickettsiosis rather than just Rocky Mountain spotted fever enables MDH to more accurately describe illnesses occurring in Minnesota residents and better prevent and control the disease.

- **Tuberculosis**. This proposed technical change clarifies that all TB cases, including suspected cases, are reportable.

  Minnesota Rules, part 4605.7030, Persons Required to Report Disease, states that physicians and other reporters must report a case, suspected case, carrier, or death from any diseases listed in part 4605.7040. TB is listed in part 4605.7040.

  At the same time, under the list of reportable diseases, Part 4605.7040, it says, "(54) tuberculosis (*Mycobacterium tuberculosis* complex) (pulmonary or extrapulmonary sites of disease, including laboratory confirmed or clinically diagnosed disease)."

  To properly treat someone suspected to have TB or who does have TB, the practitioner must consult with MDH or LPH. This ensures optimum treatment and prevents transmitting TB to someone. These two parts, however, have caused confusion. Part 4605.7030 says that "suspected cases" must be reported while part 4605.7040 seems to imply that only laboratory confirmed or clinical diagnosed disease need to be reported. As a result, some health care providers have misunderstood Part 4605.7040 and not reported suspect cases, thinking that only laboratory confirmed and clinically diagnosed cases must be reported. As a result, some providers start treating a suspected case before consulting with MDH or local

public health (LPH). It is crucial that the practitioner consult with MDH or LPH on the best course of treatment before starting treatment to ensure there are no to detrimental health outcomes for the TB patient and prevent further disease spread.

MDH added the phrase "including laboratory confirmed or clinically diagnosed disease" during the last communicable disease rulemaking changes in 2004 because many providers were not then reporting all TB cases, especially those that were clinically diagnosed. MDH wanted to ensure that all these cases were reported. Since then, some practitioners have interpreted the change to imply that suspected cases don't need to be reported even though 4605.7030 requires it.

MDH is proposing removing "laboratory confirmed" to clarify that 4605.7030 applies and that all cases, including suspected cases, need to be reported. MDH is leaving in the phrase "including clinically diagnosed" to explicitly spell this out and ensure that providers report these cases.

- **Varicella and Zoster**. This proposed technical change separates varicella (chickenpox) and zoster (shingles) into two separate disease categories under part 4605.7040, Disease and Reports. The Department is making this change because using the term "varicella zoster disease" for both diseases confuses some reporters. Although caused by the same virus, the conditions are clinically distinct, and the reporting requirements are significantly different. Separating the two conditions and using the specific terms for each will improve clarity and resulting effectiveness.

B. Changes to Add New Reportable Diseases:

MDH proposes to add newly reportable diseases, which are split into three amendment subcategories:

- Newly Reportable Disease: Report Immediately and Submit Clinical Materials
- Newly Reportable Disease: Report Within One Working Day
- Newly Reportable Disease: Report Within One Working Day and Submit Clinical Materials

Newly Reportable Diseases, Report immediately and submit clinical materials.

- **Free-living amebic infection (including at least: *Acanthamoeba* spp., *Naegleria fowleri, Balamuthia* spp., *Sappinia* spp[27]).** This amendment requires reporters immediately report free-living amebic (FLA) infection and submit clinical materials

[27] Spp means species.

to the MDH PHL. MDH needs immediate reporting so it can initiate an investigation to determine the source of the infection, whether there are additional people who are sick, and whether others may be at risk. Clinical materials for this disease are necessary for diagnostic testing to ensure a definitive diagnosis, guide treatment, and assist with disease investigation.

Disease Background. Naegleria is an ameba commonly found in warm freshwater and soil. Only one species of *Naegleria* infects people, *Naegleria fowleri*. It causes a very rare but severe brain infection called primary amebic meningoencephalitis[28] (PAM), which is often fatal.

Naegleria fowleri infects people by entering the body through the nose. This typically occurs when people go swimming or diving in warm fresh water places, like lakes and rivers. In very rare instances, *Naegleria* infections may also occur when contaminated water from other sources enters the nose. Once the ameba enters the brain, it usually causes a fatal infection called primary amebic meningoencephalitis (PAM). After symptoms begin, the disease can move quickly and cause death within five days.

*B. mandrillaris (*a species of *Balamuthia*) is found worldwide in fresh water and soil year-round. It causes chronic encephalitis called granulomatous amebic encephalitis (GAE). It can also affect other organs including skin, lung, adrenal glands, kidney and pancreas. The mean time from symptom onset to death for *B. mandrillaris* infection is 74 days.

Acanthamoeba spp. are thought to be ubiquitous in the environment, and like *B. mandrillaris*, cause GAE as well as disseminated infections.

Sappinia spp. can be found around the world. They are usually found in elk and buffalo feces, places where farm animals are known to eat, soil containing rotting plants, and fresh water sources in. It was previously thought that this FLA could not cause disease (was nonpathogenic) until the first case of amebic encephalitis caused by *Sappinia diploidea* was reported in 2001 in Texas (Gelman, B.B., et al., *Amoebic encephalitis due to Sappinia diploidea.* JAMA, 2001. 285(19): p. 2450-1). This remains the only report of amebic encephalitis caused by *Sappinia* spp. The case-patient recovered completely suggesting that *S. diploidea* might be less virulent than other FLA.

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[28] An inflammation of the brain and its membranes

The epidemiology of amebic meningoencephalitis and encephalitis caused by *Naegleria fowleri*, *Balamuthia mandrillaris*, *Acanthamoeba* species, and *Sappinia* species has evolved in recent years to include risk factors other than warm recreational freshwater exposure in southern tier states and soil exposure. Recent developments include expansion of the geographic range of *N. fowleri* infection to northern and Midwestern states, including Minnesota, and the identification of nasal irrigation[29] for either medical or religious purposes as a risk factor for infection. Organ transplantation has also recently emerged as a risk factor for *Balamuthia mandrillaris* infection in organ recipients.

Surveillance Background and Justification. From 2005 to 2014, 35 *Naegleria fowleri* infections were reported in the United States. Of those cases, 31 people were infected by contaminated recreational water, three people were infected after performing nasal flushing using contaminated tap water, and one person was infected by contaminated tap water used on a backyard slip-n-slide. In Minnesota, there have been two confirmed cases—both children.

Of 90 reported U.S. cases of *B. mandillaris* infection from 1974–2012, only seven patients have survived (survival rate 8%). The mean age of *B. mandrillaris* patients was 30 years and 65 percent were male. Their exposure source to *B. mandrillaris* was unknown, but thought to be soil or water. The exact incubation period[30] is also unknown, since cases have varied from weeks to months to even years. In the recent *B. mandrillaris* outbreaks due to transplanted organs, the incubation periods ranged from 18–25 days. Cases have been located across the United States. And there is no apparent seasonality to infections. Patients with *B. mandrillaris* infection are sometimes immunosuppressed.

Of 118 reported U.S. cases of *Acanthamoeba* from 1955–2012, there have been 11 known survivors (survival rate 9%). There are no known U.S. survivors of *Acanthamoeba* spp. GAE. The mean age of *Acanthamoeba*-infected patients was 39 years, and 73 percent were male. Patients were frequently immunosuppressed. Cases have been identified across the United States. There is no apparent seasonality.

Further, submitting clinical materials is essential. Free-living amebic infections can be challenging to diagnose in a clinical laboratory; molecular detection[31] methods, however, are available at MDH and CDC. Clinical materials are necessary to do this. Due to the often rapidly-progressing nature of these illnesses, prompt identification and treatment is vital (experimental treatment for *Naegleria fowleri* infections is currently available only through consultation with CDC). The expanding geographic

[29] Nasal irrigation is a personal hygiene practice in which the nasal cavity is washed to flush out excess mucus and debris from the nose and sinuses

[30] Incubation period is the period between infection and the appearance of signs of a disease

[31] Molecular detection methods are techniques used to identify or analyze DNA or RNA for specific diseases

range that has occurred in recent years and newly emerging transmission routes underscore the necessity for immediate reporting.

This addition is reasonable and necessary because while these infections remain rare, their severe outcomes can be devastating. Additionally, they can undermine the public's confidence in recreational activities such as swimming and medical procedures such as solid organ transplantation. Prompt reporting, including submission of clinical materials, is necessary to obtain treatment, determine the source of the infection, and assess whether others may be at risk.

- **Middle East Respiratory Syndrome (MERS).** This amendment requires immediate reporting of MERS cases and suspect cases to MDH and submission of clinical materials to the MDH Public Health Laboratory (PHL).

  Disease Background. Middle Eastern Respiratory Syndrome (MERS), a viral respiratory syndrome that was first recognized in Middle Eastern countries, is caused by a coronavirus (CoV). MERS was first reported in Saudi Arabia and in Jordan in 2012 and imported cases with limited person-to-person spread have occurred in other countries, including the United States. The severe disease that MERS causes is not well understood. Not all people infected with MERS develop severe disease but an estimated 40–60 percent of people who become ill die from the disease. Symptoms of MERS-CoV include severe respiratory illness, including fever, cough, and shortness of breath. As of December 3, 2015 over 1,600 cases and nearly 600 deaths have been reported worldwide due to MERS.

  MERS-CoV is transmitted by respiratory droplets produced when an infected person coughs or sneezes. However, the precise way the virus spreads is not currently well understood. As a result, health care facilities treating cases are required to use Airborne Precautions, including respirators and rooms with specialized air pressure. Ill people have passed the disease through close contact to those caring for or living with them, generating most identified cases. For example, infected people have spread MERS-CoV to others in health care settings, such as hospitals.

  All reported cases have been linked to countries in and near the Arabian Peninsula; and cases have either lived in the Arabian Peninsula or recently traveled from the Arabian Peninsula before they became ill. Limited spread of MERS-CoV has been reported from cases outside the Arabian Peninsula usually only to caregivers (household and health care workers). However, in the summer of 2015 a large outbreak of MERS occurred in South Korea. One hundred eighty-six cases and 33 deaths were linked to one imported "super spreader"[32] MERS case in South Korea.

  In general, the virus does not appear to pass easily from person to person unless there is close contact, such as providing care to an infected patient without appropriate precautions. This has been seen among family members, patients, and health care

[32] Super spreaders are individuals who are more likely to infect others than most people with the disease.

workers. The majority of cases have resulted from human-to-human transmission in health care settings and are often due to cases not being identified and isolated quickly.

Surveillance Background and Justification. MERS-CoV presents a considerable threat to the public's health. MERS has a high case fatality rate and is spread through the respiratory route. Additionally, understanding of MERS-CoV is limited; we do not know who or why certain cases are super spreaders and how best to mitigate disease transmission of super spreaders. Additionally, MERS CoV is a new virus that could change genetic properties over time, which might result in more efficient person-to-person transmission.

There are no current treatments for MERS-CoV infection. Treatments used to date are supportive only.[33] There is also no current vaccine to prevent MERS CoV infection. Control of MERS CoV relies on rapidly identifying cases who are then isolated to prevent transmission. In addition, these cases' contacts are monitored and quickly isolated if symptoms occur.

Further, submitting clinical materials is essential. Laboratory testing is critical because MERS has symptoms that are similar to many other respiratory illnesses such as influenza. Although many medical laboratories in Minnesota may perform diagnostic tests to evaluate the causes of community-associated pneumonia, the MDH PHL, in collaboration with the CDC, is the only laboratory in the state that performs MERS-specific testing for MERS-CoV. MDH PHL tests through polymerase chain reaction (PCR), which identifies genetic segments of the virus. CDC can conduct additional tests, including serology, to identify MERS-CoV. CDC testing is coordinated through state health departments. Without this testing, distinguishing MERS from these other diseases may be difficult, if not impossible. It is also important that clinical laboratories that lack sufficient biosafety safeguards do not conduct viral isolation, which is essential to diagnosis, to avoid putting lab personnel at risk.

The recent emergence of MERS in Saudi Arabia in 2012, its subsequent importation into and spread to other countries, including Canada and the United States, its severe clinical manifestations, and the method of transmission (which is not completely understood), make its inclusion necessary as a reportable disease. To ensure effective disease control, making MERS reportable immediately is reasonable and necessary. As stated above, no specific treatment for MERS exists, so identifying cases and their contacts early, coupled with rapidly instituted infection control measures are critical for controlling the disease's spread.

[33] Supportive care means medical and other interventions that attempt to support and make comfortable; these interventions, however, do not cure or treat the virus.

- **Viral hemorrhagic fever (including Ebola virus disease and Lassa fever).** This amendment requires immediate reporting of all viral hemorrhagic fevers, such as the diseases Ebola and Lassa fever. The amendment also requires submitting clinical materials to the MDH PHL

  Disease Background. Viral hemorrhagic fevers (VHFs) are a group of illnesses caused by several distinct families of viruses including Arenaviridae, Bunyaviridae, Filoviridae, Flaviviridae, and Paramyxoviridae. Each virus has a specific animal or arthropod[34] reservoir. Humans are not the natural reservoir; infections to humans are accidental and occur rarely. Once infected, humans can transmit to other persons. There generally is no treatment or cure for VHFs. The infecting virus determines whether multiple body systems are affected, including the vascular system's ability to clot, thus the name "hemorrhagic fever." Case fatality rates vary by agent; for Ebola in prior outbreaks 30–90 percent of cases died.

  Once a human is infected, Ebola virus is spread by direct contact with blood or other body fluids (such as: vomit, diarrhea, urine, breast milk, sweat, semen) of an infected person. The virus can also spread through objects (such as syringes) or surfaces contaminated by body fluids of an infected person. It is easily spread in health care settings without proper infection control procedures. Since its discovery in 1976, there have been over 25 documented outbreaks in Central Africa. The 2014–2015 Ebola outbreak in West Africa had more cases and deaths than all other previous outbreaks combined. Two cases occurred in the United States in travelers from West Africa.

  Lassa fever is endemic in West Africa. Its reservoir is the African rat. It is spread from aerosol or direct contact with excreta[35] from infected rats.

  Surveillance Background and Justification. Diseases such as Ebola and Lassa fever present a considerable threat to the public's health. Ebola virus disease currently has a high fatality rate, on average about 50 percent. Between November 2014 and December 2015, MDH monitored over 985 people who traveled to Minnesota from countries that had Ebola cases. (Monitoring means an MDH or local health department staff person spoke to a traveler about his or her temperature and symptoms at least once a day.)

  Immediate reporting is necessary because of these diseases' very high fatality rates and their person-to-person infection transmission, often in health care settings. Thus, immediate notification enables MDH to make sure two things take place: clinical consulting for the patient's benefit and infection control guidance to protect health care workers in the health care setting. VHFs are rare diseases in humans that have

[34] An invertebrate animal of the large phylum Arthropoda, such as an insect, spider, or crustacean

[35] Waste matter discharged from the body, especially feces and urine

been imported into the United States in rare situations. Some infections are considered to be potential bioterrorism agents.

Submitting clinical materials is necessary because only the MDH PHL or the CDC have the facilities to confirm this infection.

This change is reasonable and necessary because these infections are rare and deadly. Moreover, the 2014–2015 Ebola epidemic demonstrated that these diseases can be imported easily into the United States. Identifying these cases and their contacts early, coupled with rapidly instituting infection control measures, is critical for controlling spread of the disease.

Newly Reportable Diseases: Report within one working day

- **Arboviral Diseases—Powassan virus disease and Jamestown Canyon virus disease**. Currently only five endemic[36] arboviral diseases are listed as reportable conditions in Minnesota. They are: "La Crosse encephalitis, Eastern equine encephalitis, Western equine encephalitis, St. Louis encephalitis, and West Nile virus disease." This amendment adds two more: Powassan virus disease and Jamestown Canyon virus disease.

  Arboviruses (arthropod-borne viruses) are transmitted to people by mosquitoes, ticks, or other blood-feeding arthropods.[37] In nature, these viruses cycle between mosquitoes, the vectors, and birds or small mammals, the reservoirs. Some infected birds or mammals develop high virus levels in their bloodstream; and mosquitoes become infected by biting these infected animals. These infected mosquitoes then infect other animals when they feed again. These cycles often involve several different species of mosquitoes, birds, and mammals. Vectors and reservoirs are likely to vary by region. Historically, the primary arboviral diseases found in Minnesota have been La Crosse encephalitis, Western equine encephalitis (WEE), and more recently, West Nile virus (WNV).

  Although the number of new cases (incidence) of arboviral disease varies from year to year, and some diseases like Western equine encephalitis are extremely rare and confined to limited geographic ranges, others (like West Nile virus) are established throughout Minnesota and cause some disease in humans every year. Among the factors that influence disease incidence are the presence and abundance of mosquitoes and the effect of weather, including temperature and precipitation, on both vectors and viruses.

  Surveillance Background and Justification. The Minnesota Department of Health does routine surveillance for all of Minnesota's endemic arboviruses, and the MDH

[36] A disease that occurs frequently in a given group, such as people living in a particular location

[37] Includes insects, mites, spiders, and ticks.

PHL tests for these viruses. Arboviral diseases' symptoms are often very similar to each other, requiring lab testing to differentiate between these clinically similar viruses. This testing allows MDH to accurately identify and monitor the viruses, including new and emerging diseases, circulating throughout the state.

As the arrival and spread of West Nile virus in the United States demonstrated in the early 2000s, new viruses can arrive and circulate in new areas, quickly becoming established and requiring changes to existing surveillance, monitoring and control systems. In recent years, both Powassan virus and Jamestown Canyon virus (JCV) have been identified in Minnesota residents. JCV was first identified in mosquitoes and deer in Minnesota in the 1980s. The first human case occurred in 2013 in Minnesota. Since then, MDH has identified six additional cases of the virus. Patients have been between 11 to 62 years of age, and disease symptoms ranged from fever to more severe illness, including acute flaccid paralysis[38] and encephalitis. Jamestown Canyon virus is a California group virus related to La Crosse transmitted by *Aedes* genus mosquitoes, and the maintenance cycle in nature is thought to include deer and other large mammals. Much remains unknown about the range of symptoms in people with Jamestown Canyon virus, but it is likely similar to other arboviruses. The virus is likely widespread in Minnesota, but diagnostic tests for this virus are not widely available.

Powassan virus (POW) is a tick-borne virus that includes a strain (lineage II or "deer tick virus") that the blacklegged tick (deer tick) transmits. The virus can cause encephalitis or meningitis, and approximately half of those patients experience long-term complications. Approximately 10–15 percent of cases are fatal. Since 2008, 22 cases (1 fatal) of POW disease have been reported in Minnesota residents. Most of these patients had neuroinvasive[39] disease (12 encephalitis and 8 meningitis), only two had mild illness with fever. Similar to other tick-borne diseases, the majority of patients (18, 82%) reported illness onsets between May and August. The number of patients reported with Powassan virus peaked in 2011, with 11 cases. All patients reported exposure to ticks in several north-central Minnesota counties. MDH has also identified POW virus-positive ticks at sites in six counties that have been investigated to date (Clearwater, Cass, Pine, Anoka, Morrison, and Houston). Thus, Powassan virus appears to be widely distributed in the same wooded parts of the state that are endemic to other diseases that the blacklegged tick transmits.

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[38] An abnormal condition characterized by the weakening or the loss of muscle tone

[39] Capable of infecting the nervous system

This amendment is reasonable and necessary because it allows MDH to continue to monitor the incidence of these new and emerging arboviral diseases, which will help the Department prevent and control their spread.

- **Chikungunya virus disease**. This amendment requires reporting of chikungunya virus disease.

  Disease Background. Chikungunya virus is transmitted to humans when infected mosquitoes bite them. A mother can also transmit the virus to her baby at birth, but it is rare. And theoretically, the virus could spread through blood transfusion but to date there are no known reports of this happening. The typical period between infection and the appearance of disease[40] ranges from three to seven days, and although a person might not show symptoms of disease (asymptomatic), the majority of people (72-97%) develop symptoms. Characteristic symptoms are fever and joint pain. Other symptoms, including rash, headache, fatigue, digestive complaints, and conjunctivitis, may occur. Acute symptoms normally go away within seven to ten days, although a proportion of patients may continue to experience persistent joint pain for months to years after infection. Chikungunya is rarely fatal, although complications, particularly in young children, the elderly, and those with underlying medical conditions can occur.

  Surveillance Background and Justification. Before 2013, chikungunya virus outbreaks had been identified in countries in Africa, Asia, Europe, and the Indian and Pacific Oceans, but was rarely reported in U.S. travelers. In late 2013, health officials identified the first local transmission of chikungunya virus in the Americas on the Caribbean island of St. Martin. The virus quickly spread to other countries and territories in the region. The outbreak continued in 2014 and nearly 3,000 U.S. travelers were infected, and transmission was reported in Florida, Puerto Rico, and the U.S. Virgin Islands. Local transmission of the virus has been identified in 45 countries or territories in the Americas, resulting in more than 1.7 million suspected cases. In 2014, Minnesota reported 28 cases of chikungunya virus. Beginning in 2015, the disease was added to the list of nationally notifiable diseases.[41]

  Adding the chikungunya virus to the list is reasonable and necessary to monitor instances of this disease. At present, all Minnesotans' reported cases have been travel-associated, but routine surveillance will allow us to rapidly detect any locally acquired cases, resulting in better prevention and control measures.

- **Lyme disease—other Borrelia spp**. Currently, Lyme disease caused by *Borrelia burgdorferi* is reportable. This amendment requires reporting of other *Borrelia* spp. infections in addition to *Borrelia burgdorferi*.

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[40] This is called the "incubation period."

[41] The CDC collaborates with the Council of State and Territorial Epidemiologists (CSTE) to determine which conditions reported to local, state, and territorial public health departments are nationally notifiable. http://wwwn.cdc.gov/nndss/data-collection.html

Disease Background. Borrelia is a type of bacteria transmitted primarily by ticks. Of the 36 known species of *Borrelia,* 12 are known to cause Lyme disease or borreliosis. In the United States, the Lyme disease's primary cause is *Borrelia burgdorferi,* while in Europe *Borrelia afzelii* and *Borrelia garinii* are the primary disease agents. In recent years, new species of Borrelia have also been identified.

Surveillance Background and Justification. Lyme disease is the most commonly reported vector-borne disease in the United States. In 2014, it was the fifth most common nationally notifiable disease. Incidence of the disease is not evenly distributed across the country. The majority of cases are reported from the northeastern states and the upper Midwest, including Minnesota and Wisconsin.

Outside of the northeastern United States, Minnesota routinely has some of the highest case counts for Lyme disease. MDH has conducted statewide surveillance for this disease since the 1980s. Not only has the number of reported cases continued to rise during this time, but MDH has also documented a geographic spread of the disease to the north and west of the traditional risk areas in central and east central Minnesota. In recent years newly identified species of Borrelia such as B. *miyamotoi* and a novel species of *Borrelia (B. mayonii, proposed)*[42] have been found in ticks in Minnesota.

In addition, the state has identified cases of these newly identified *Borrelia* species in Minnesota residents. Although symptoms and treatments are similar in patients with these novel species and Lyme disease caused by *Borrelia burgdorferi*, we still have a lot to learn about the epidemiology of *Borrelia* in Minnesota. MDH is currently participating in collaborative projects with both the Centers for Disease Control and Prevention (CDC) and researchers at the Mayo Clinic Laboratories to look for these and other emerging tick-borne pathogens affecting Minnesotans.

This change is reasonable and necessary because it allows MDH to continue to maintain and improve its vector-borne surveillance by accurately monitoring the specific tick-borne pathogens known to circulate in Minnesota resulting in better Lyme disease prevention and control measures.

- **Zika virus disease**. This amendment requires reporting of Zika virus disease.

Disease Background. Zika virus is spread to people through mosquito bites. Mosquitoes become infected when they feed on infected people and then transmit the virus when they subsequently bite another person. The same mosquitoes that carry chikungunya virus also carry the Zika virus. A mother infected with Zika virus during her pregnancy can pass on the virus to her fetus and severe microcephaly can result. A link between Zika virus infection in pregnant women and subsequent birth defects has been documented. In addition, a link between Zika virus infection and Guillain–Barré syndrome (GBS) has also been documented, as have other severe outcomes

[42] This is the proposed name for the organism, but it hasn't been officially approved yet, but is expected to be approved.

(e.g., encephalitis). In theory, Zika virus could be spread through blood transfusion. To date, there are no known reports of this happening. There have been multiple reports of spread of the virus through sexual contact.

About one in five people infected with Zika virus become ill. The most common symptoms of Zika virus disease are fever, rash, joint pain, and conjunctivitis (red eyes). The illness is usually mild with symptoms lasting from several days to a week. Severe disease requiring hospitalization is uncommon.

Surveillance Background and Justification. Zika virus was first discovered in Uganda in 1947. From its discovery until 2007, confirmed cases of Zika virus infection from Africa and Southeast Asia were rare. However, in 2007 a major epidemic occurred in Yap Island, Micronesia. More recently, epidemics have occurred in Polynesia, Easter Island, the Cook Islands, New Caledonia, and Brazil.

In December 2015, Puerto Rico reported its first confirmed Zika virus case. In the United States, Zika has been reported in returning travelers, including two in Minnesota. With the recent outbreaks in the Pacific Islands and South America, the number of Zika cases among travelers visiting or returning to the United States will likely increase. These imported cases may result in local spread of the virus in some areas of the United States.

Based on the symptoms, Zika virus can look like many other diseases, including dengue fever, leptospirosis, malaria, spotted fever Rickettsia, Group A streptococcus, rubella, measles, and parvovirus, enterovirus, adenovirus, and alphavirus infections (e.g., chikungunya). Preliminary diagnosis is based on the patient's symptoms shown in the clinic, travel history, and possible exposure to mosquitoes. Laboratory diagnosis is generally accomplished by testing serum or plasma to detect virus, viral nucleic acid, or virus-specific immunoglobulin M and neutralizing antibodies.

Adding Zika virus is reasonable and necessary to monitor instances of this disease. At this time, all reported cases in Minnesotans have been travel-associated, but routine surveillance of this disease will allow us to rapidly detect any locally acquired cases, resulting in better prevention and control measures.

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

- **Carbapenem-resistant Enterobacteriaceae (CRE).** This amendment adds Carbapenem-resistant Enterobacteriaceae (CRE) and submission of clinical materials to the MDH Public Health Laboratory to Minn. R. 4605.4040.

  Disease Background. CRE are a family of bacteria that resist treatment by several antibiotics, limiting options for treating them. Because they are difficult to treat, poor patient outcomes and high death rates result. CRE cause a variety of infections including pneumonia; bloodstream, wound, and urinary-tract infections. Healthy people usually do not get CRE infections; the infections usually occur among patients in hospitals, nursing homes, and other health care settings. Infections most commonly occur in people who have chronic medical conditions; recent, frequent, or prolonged

stays in health care settings; invasive medical devices such as ventilators or catheters; or a history of taking antibiotics for long periods of time. In health care settings, CRE can easily spread from one patient to another on the hands of health care personnel or through contact with contaminated surfaces and patient-care equipment. These bacteria are not spread through the air. Some CRE produce an enzyme, carbapenemase, which enables the bacteria to break down antibiotics called carbapenems, a situation that makes antibiotic resistance worse. The genes that enable it to produce this enzyme can be transferred to other types of bacteria, a particularly troublesome circumstance.

Surveillance Background and Justification. Over the past few years, health care providers and the Centers for Disease Control and Prevention (CDC) have grown increasingly concerned about CRE. In 2013, the CDC released a major report on antibiotic resistance, "Antibiotic resistant threats in the United States, 2013." It identified CRE as one of three urgent public health threats requiring immediate and aggressive action. If health care officials and public health do not act quickly to control these infections, CRE 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. In August 2015, CDC published a Vital Signs report calling for continued vigilance and a more coordinated, public health-led approach to CRE prevention across the spectrum of health care settings. (CDC. Vital Signs: Carbapenem-Resistant Enterobacteriaceae. *MMWR Morb Moral Wkly Rep.* 2013;62:165-170.)

The MDH PHL first confirmed a CRE isolate in Minnesota in March 2009. As a result, the MDH PHL asked laboratories statewide to be on alert for Enterobacteriaceae with reduced susceptibility to carbapenem antibiotics and to submit isolates for further testing. In 2011, MDH initiated active, laboratory- and population-based sentinel surveillance for CRE in Hennepin and Ramsey Counties. Outside of these two counties, health care facilities and clinical laboratories have been voluntarily reporting CRE cases and sending CRE isolates to the MDH PHL to test for carbapenemase genes. In January 2016, MDH expanded CRE reporting statewide through the commissioner's authority in Minnesota Rules, 4605.7080. This rule permits the Commissioner of Health to require reporting of newly recognized or emerging diseases and syndromes suspected to be of infectious origin or previously controlled or eradicated infectious disease, if certain criteria are met. The goal of this surveillance is to monitor the problem similarly throughout the state, and enable a quick response to health care facilities when carbapenemase-producing bacteria are identified. The rationale for requiring statewide CRE reporting under Minn. Rules 4605.7080 is described further in Attachment C.

Even though CRE is already reportable through Minn. R. 4605.7080 under the commissioner's authority, adding it also in the general reporting section for all reportable diseases under Minn. R. 4605.7040 is important too. If an individual looks at Minn. R. 4605.7040 on-line to verify what is reportable and does not see CRE

because it was only added under 4605.7080, he or she might not report it. In addition, even though MDH had the authority to add CRE through 4605.7080, MDH believes it is helpful to also give the public an opportunity to deliberate and participate in the addition.

Submitting clinical materials is also essential. The MDH PHL tests isolates to determine whether they produce carbapenemase. Many Minnesota labs are unable to do this testing. MDH communicates these results back to the facility with recommendations for enhanced infection control measures, if necessary. Additional tests include a type of "fingerprinting" of the organism that can help determine whether infections occurring among different patients came from one source. This helps MDH detect outbreaks and assist facilities in investigation and infection control.

Requiring statewide CRE reporting is necessary and reasonable to protect the public's health against this urgent threat that looms both in the United States and internationally. These resistant infections 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 in Minnesota, stay up to date with changing patterns in the bacteria, and provide actionable information back to our health care facilities.

- **Streptococcal disease—including urine-antigen pneumonia.** This amendment requires reporting *Streptococcus pneumoniae* when a laboratory confirms it through a urine-antigen test. This amendment expands the current reporting of streptococcal disease by adding an additional laboratory confirmation criteria.

  Disease Background. Streptococcus pneumoniae (SP) is a bacteria that causes a wide variety of infections in adults and children. Infections from SP can be relatively mild, such as ear infections, or severe, such as blood stream infections. SP has been reportable in the seven-county metropolitan area in Minnesota since 1995 and reportable statewide since 2002 if the bacteria is identified from a body site that is considered sterile (e.g., blood, spinal fluid, bone, etc.). This is also called invasive SP. The number of new cases (incidence) of invasive SP[43] is highest among the very young and the elderly.

  Incidence of invasive SP dramatically declined among young children under five years of age after the pneumococcal conjugate vaccine was introduced. The initial vaccine for children was licensed in 2000 and contained seven SP serotypes[44]

43 Invasive SP means the germ invade parts of the body that are normally free from germs, such as the blood, cerebrospinal fluid, bones, or joints.

44 Grouping a microorganism by certain biological characteristics

(PCV7). In 2010, PCV7 was replaced by PCV13, which increased the number to 13 serotypes. In 1999, one year before license of PCV7, the incidence of SP was 111.7 cases per 100,000 population among children less than five years old. In 2014, the incidence of invasive SP among children less than five years old was 11.8 cases per 100,000 population. Studies have also found that the PCV7 and PCV13 vaccines were modestly successful in decreasing non-invasive SP infections (such as ear and sinus infections). Officials also saw declines in invasive SP among adults (age 50 and older) from vaccinating children with PCV7 and PCV13.

Surveillance Background and Justification. The federal Advisory Committee on Immunization Practices (ACIP)[45] has routinely recommended pneumococcal polysaccharide vaccine (PPSV23) for older adults (65 years and older) and adults with immunosuppressive conditions,[46] a measure that is effective primarily for preventing pneumonia from invasive infections. Since SP causes pneumonia in many older adults without an invasive infection, this is another area threat for public health. Noninvasive infection is detected when SP bacteria is identified from a body site that is not sterile (e.g., urine, skin). At present, these cases are not reported to MDH but should be because they represent a substantial disease burden. Furthermore, PCV13 vaccine has recently been recommended in adults 65 years and older, in addition to PPSV23 vaccine. Some studies have shown that pneumonia caused by SP that is not invasive may occur less often in adults vaccinated with PCV13. Expanding SP surveillance to include cases with a positive urine antigen test will improve surveillance by identifying adults with SP pneumonia who do not have a positive invasive culture. We need to evaluate the impact of the PCV13 vaccine on adults. From laboratory surveys and sentinel surveillance of urine antigen SP, we know that large hospitals will be reporting approximately 40 cases per year.

This change is reasonable and necessary to improve surveillance for SP pneumonia, allowing MDH to better understand the burden of SP pneumonia. We need to know how PCV13 vaccine works among adults 65 years and older. This important information will help prevent and control the disease.

4605.7042 VARICELLA ZOSTER DISEASE.

This technical amendment repeals an obsolete rules provision that MDH added in 2004 before case-based reporting[47] of varicella (chickenpox) existed. MDH decided not to add case-based reporting at that time based on public and Advisory Committee comments. MDH instead added reporting specified cases of varicella zoster disease as an interim measure. MDH chose to rely on

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[45] The U.S. Public Health Service's Advisory Committee on Immunization Practices. A statutorily created advisory committee that meets three times a year to make immunization recommendations for every U.S. licensed vaccines.

[46] Immunosppressive conditions occur when the body's immune response is reduced or absent often making individuals more vulnerable to disease.

[47] Case-based reporting means that every case of a disease is reportable.

sentinel surveillance until varicella zoster disease cases decreased (due to the vaccine) and therefore sentinel surveillance would no longer provide adequate epidemiological data. In 2013, the commissioner decided to require case-based reporting of varicella zoster disease. As a result, this part is obsolete and should be repealed.

VII. CONCLUSION

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

7-6-16

Ed Ehlinger, M.D., M.S.P.H.
Commissioner
Minnesota Department of Health

Attachments

Attachment A: Glossary of Terms

ACIP. The U.S. Public Health Service's Advisory Committee on Immunization Practices. A statutorily created advisory committee that meets three times a year to make immunization recommendations for every U.S. licensed vaccines.

airborne precautions. These precautions are designed to reduce the risk or eliminate the airborne transmission of infectious agents. The infectious particles are so small that they can remain suspended in the air for long periods of time and are carried on air currents.

antibody. A protein produced in the blood by the immune system that helps identify and destroy foreign germs (*e.g.*, viruses or bacteria) that attack the body. Antibodies can be produced in response to a vaccine or to a natural infection. They circulate in the blood to protect against future infections.

antigen. A protein on the surface of a virus, bacteria or cell that can stimulate the immune system to produce antibodies as a defense mechanism.

arthropod. An invertebrate animal of the large phylum *Arthropoda*, such as an insect, spider, or crustacean.

asymptomatic. Having no symptoms of illness or disease.

assay. A type of diagnostic test.

CDC. The abbreviation for the Centers for Disease Control and Prevention. A federal agency under the U.S. Department of Health and Human Services that serves as "the nation's health department."

Clinical material. Clinical materials are defined in Minnesota Rules, 4605.7000, Subp. 3, which 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

CSTE: Council of State and Territorial Epidemiologists, a national organization that recommends policies for epidemiologists working at the state level.

encephalitis. An acute inflammation (swelling up) of the brain resulting either from a viral infection or when the body's own immune system mistakenly attacks brain tissue

endemic. A disease that occurs frequently in a given group, such as people living in a particular location.

epidemic. A large outbreak (*see* outbreak) of disease. An epidemic could include many people in the same city or community, or even in an entire county. A world-wide epidemic is called a pandemic.

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

hemorrhagic. Excessive discharge of blood from the blood vessels; profuse bleeding.

immunosuppressive conditions. Any of various diseases that suppress the immune system, such as cancer.

incidence of disease. The number of new cases of a specific disease occurring during a certain period of time in the population.

incubation period. The period between infection and the appearance of signs of a disease

infectious agent. An organism that is capable of producing an infection or an infectious disease.

invasive disease. A serious, life-threatening, infection that invades body sites such as the blood, cerebrospinal fluid, bones, or joints, which are normally free from germs.

isolate. A population of identical bacteria, viruses, or other microorganisms derived and separated from a patient specimen. A pure culture of viable microorganism.

meningitis. Inflammation or infection involving the membranes surrounding the brain and spinal cord.

meningoencephalitis. An inflammation of the brain and its membranes

microcephaly. A condition that results in babies being born with abnormally small heads that cause often serious developmental issues and sometimes early death.

morbidity. Sickness.

mortality rate. The frequency or number of deaths in ratio to population.

nationally notifiable disease. The CDC collaborates with the Council of State and Territorial Epidemiologists (CSTE) to determine which disease conditions reported to local, state, and territorial public health departments are nationally notifiable.

outbreak. An unusually large number of cases of a disease occurring around the same time and place, involving people who acquired the disease from the same source or from each other.

neuroinvasive. Capable of infecting the nervous system

pathogen. An organism that can produce 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.

sentinel surveillance. 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.

serology. Examination of blood serum. In practice, the term usually refers to the diagnostic identification of antibodies in the serum

serotyping. Grouping a microorganism by certain biological characteristics.

surveillance. Disease surveillance is an epidemiological practice by which the spread of disease is monitored in order to establish patterns of progression. The main role of disease surveillance is to predict, observe, and minimize the harm caused by outbreak, epidemic, and pandemic situations, as well as increase knowledge about which factors contribute to such circumstances

vaccine-preventable diseases. Diseases that can be prevented, or their severity greatly reduced, by immunization. Diseases such as measles, mumps, rubella, polio, tetanus, smallpox, and chickenpox are vaccine-preventable.

vascular system. The vascular system, also called the circulatory system, is made up of the vessels that carry blood and lymph through the body.

vector. An organism, typically a biting insect or tick, that transmits a disease or parasite from one animal or plant to another.

vector borne disease: A disease usually transmitted by insects–eg, ticks–eg, Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, Colorado tick fever; mosquitos–eg, California-or La Crosse, St Louis, Eastern, Western encephalitides

virulence. How toxic or deadly the disease agent is.

WHO. World Health Organization.

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

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

2. Posted the Request for Comments and a copy of the draft rules on MDH's communicable disease rule website at http://www.health.state.mn.us/divs/idepc/dtopics/reportable/newrule/index.html.

3. Provided a summary of the Request for Comments and a web link to the proposed rules via e-mail, directly or through a listserv, to various individuals, groups, and organizations in Minnesota. MDH also requested that these organizations post the information on their website. The list included, but was not limited to:
   - Medical laboratories on 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 Chapter of the National Association of Pediatric Nurses and Practitioners
   - Minnesota Medical Association
   - Minnesota Academy of Pediatrics
   - Minnesota Academy of Family Physicians
   - Minnesota Nurses Association
   - Physician Assistant groups
   - Early childhood providers, including school readiness, ECFE, and screening coordinators
   - Minnesota Council of Health Plans
   - MDH Minnesota school nurses listserve
   - Childcare health consultants, childcare licensors and Childcare Resource and Referral Agencies
   - Community Health Services Administrators and Public Health Nursing Directors
   - State Community Health Services Advisory Committee
   - Minnesota AIDS Project
   - Disease Prevention and Control Leadership Team

4. Published a summary of the Request for Comments and where people could get further information in publications that reached affected parties.

Attachment C: Proposal for Conducting Statewide Surveillance for Carbapenem-resistant Enterobacteriaceae (CRE) in Minnesota under the Minnesota Communicable Disease Rule (4605.7080)

Division: Infectious Disease Epidemiology, Prevention and Control Division

Section: Cross-Cutting Epidemiology, Programs and Partnerships Section

Section Manager: Claudia Miller

Proposal Contact: Catherine Lexau (651-201-5120)

Under part 4605.7080 of the Communicable Disease Reporting Rule, the Commissioner may select new diseases/syndromes if certain criteria are met. Specifically, 4605.7080 says:

> "Subpart 1. Disease selection. The commissioner shall, by public notice, require reporting of newly recognized or emerging diseases and syndromes suspected to be of infectious origin or previously controlled or eradicated infectious diseases if:
> - the disease or syndrome can cause serious morbidity or mortality; and
> - report of the disease or syndrome is necessary to monitor, prevent, or control the disease or syndrome to protect public health."
>
> "Subp. 2. Surveillance mechanism. The commissioner shall describe a specific, planned mechanism for surveillance of the disease or syndrome including persons and entities required to report, a time frame for reporting, and protocols for the submission of test results and clinical materials from cases and suspected cases to the Minnesota Department of Health, Public Health Laboratory."

1. DISEASE SELECTION.

   The commissioner shall, by public notice, require reporting of newly recognized or emerging diseases and syndromes suspected to be of infectious origin or previously controlled or eradicated infectious diseases if:

   A. The disease or syndrome cause serious morbidity or mortality.

      Based on the following information, MDH finds that Carbapenem-resistant Enterobacteriaceae (CRE) causes serious morbidity or mortality.

      Enterobacteriaceae is a large family of Gram-negative bacteria (GNB) that can cause a wide range of infections in humans. Several species of Enterobacteriaceae (e.g., *Escherichia coli*, *Klebsiella pneumoniae*, etc.) are responsible for both community- and healthcare-associated infections (HAIs). HAIs are infections that patients get while receiving treatment for medical or surgical conditions, while community-associated infections are those acquired outside of a healthcare setting. Enterobacteriaceae are also among the most common disease causing agents identified in clinical microbiology laboratories. Over the past decade extremely drug resistant Enterobacteriaceae, called

carbapenem-resistant Enterobacteriaceae (CRE), have emerged in the United States (U.S.). Carbapenems are broad-spectrum antibiotics, often considered antibiotics of last resort for treating patients with severe or resistant GNB infections. CRE are resistant to carbapenems and most other available antibiotics, resulting in limited treatment options, poor patient outcomes (e.g., poor functional status, prolonged hospital stays, discharge to long-term care facilities, etc.), and high mortality rates – contributing to death in up to 50% of patients who develop invasive infections according to one report.[1]

Data collected through the National Healthcare Safety Network (NHSN) suggest CRE are on the rise among patients in U.S. healthcare facilities. Risk factors for CRE infection include: recent exposure to healthcare, invasive devices (e.g., urinary catheter), and/or antimicrobial therapy. Patients with a recent history of receiving healthcare in countries outside the U.S. with a high prevalence of CRE may also be at increased risk for CRE colonization/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 that are usually sterile like the bladder, the lungs, or the bloodstream. CRE-colonized or infected patients can spread the bacteria to other patients either on the hands of healthcare workers or through the environment. Identifying and isolating these patients is a critical measure to control the spread of CRE in healthcare settings.

B. Report of the disease or syndrome is necessary to monitor, prevent, or control the disease or syndrome to protect public health.

Based on the following information, MDH finds that reporting of Carbapenem-resistant Enterobacteriaceae (CRE) is necessary to monitor, prevent, and control the disease to protect the public's health.

In 2013, the Centers for Disease Control and Prevention (CDC) released its first ever report on antibiotic resistance, *Antibiotic resistant threats in the United States, 2013*. It identified CRE as one of three 'urgent' public health threats requiring immediate and aggressive action. If action to control these infections is not taken quickly, CRE 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 CRE prevention and control efforts. Public health actions outlined in the CDC report include new surveillance and prevention efforts to track CRE, prevent infections, and halt further spread of resistance. In August 2015, CDC published a Vital Signs report calling for continued vigilance and a more coordinated, public health-led approach to CRE prevention across the spectrum of healthcare settings. [2]

Unlike other antibiotic-resistant organisms (e.g., methicillin-resistant *Staphylococcus aureus)*, which represent a single species and a single resistance mechanism, CRE are complex and resistance may be due to a variety of mechanisms. CRE that produce an enzyme known as a carbapenemase are able to efficiently break down carbapenem antibiotics rendering them ineffective. In the U.S., the most prevalent and concerning carbapenemase is the *Klebsiella pneumoniae* carbapenemase (KPC). These CRE are

referred to as carbapenemase-producing CRE (CP-CRE) and include other less commonly reported carbapenemases such as oxacillinase-48 (OXA-48), the New Delhi metallo-β-lactamase (NDM) and Verona integron-encoded metallo-β-lactamase (VIM). The genes that code for many of these carbapenemases are contained on genetic elements that can be transferred between species of Enterobacteriaceae, facilitating the spread of resistance.

In early 2009, the MDH Public Health Laboratory (PHL) confirmed its first CRE isolate with KPC that a clinical laboratory had submitted. As a result, in 2009 the MDH PHL asked laboratories statewide to be on alert for Enterobacteriaceae with reduced susceptibility to carbapenem antibiotics and to submit isolates for further testing. In 2011, MDH initiated active, laboratory- and population-based sentinel surveillance for CRE in Hennepin and Ramsey Counties. Outside of these two counties, healthcare facilities and clinical laboratories have been voluntarily reporting CRE cases and sending CRE isolates to the MDH PHL for further characterization (e.g., polymerase chain reaction [PCR] testing for CP genes such as KPC). Approximately one-third of CRE reported to MDH are identified as KPC-positive. Both NDM and oxacillinase-48 (OXA-48) carbapenemases have been detected among patients in Minnesota healthcare facilities with recent travel to and receipt of medical care outside the U.S. Statewide reporting of CRE to MDH will increase awareness, allow for prompt follow-up regarding infection prevention and control recommendations, and provide data to facilitate coordination across the spectrum of healthcare.

Statewide surveillance for CRE is also critical to more completely describe the epidemiology of CRE in MN, including microbiologic characteristics (e.g., species, resistance mechanisms, etc.), patient demographics, co-morbidities, site(s) of infection, epidemiologic classification (healthcare- vs. community-associated), and patient outcomes. Most clinical laboratories in Minnesota do not have the resources or capacity to identify specific carbapenemase genes, but the MDH PHL does. Information on resistance genes is crucial to detecting outbreaks and understanding local epidemiology. Data collected through surveillance and isolate submission will be used to monitor CRE trends, estimate the incidence and prevalence of CRE statewide and by region to identify healthcare clusters or geographical areas of concern, describe resistance genes (e.g., KPC) present in MN, and drive targeted infection prevention and control measures to protect the health of Minnesotans.

Because CRE can be spread between patients on the hands of healthcare workers or via contaminated medical equipment (e.g., duodenoscopes), statewide reporting is necessary. Guidelines for preventing the spread of CRE in healthcare settings are outlined in the CDC Facility Guidance for Control of Carbapenem-resistant Enterobacteriaceae (CRE) – November 2015 Update CRE Toolkit (http://www.cdc.gov/hai/organisms/cre/cre-toolkit/index.html) and MDH Recommendations for the Management of CRE in Acute Care, Long-term Acute Care (http://www.health.state.mn.us/divs/idepc/dtopics/cre/hcp/acuterecs.html), and MDH Recommendations for the Management of CRE in Long-term Care Facilities (http://www.health.state.mn.us/divs/idepc/dtopics/cre/hcp/rec.html).

Outbreaks of CRE reported in other states and countries have often involved multiple healthcare settings, highlighting the importance of early detection and prompt implementation of enhanced infection prevention and control measures (e.g., screening cultures to identify CRE-colonized patients), as well as communication of a patient's CRE status between facilities upon transfer. Expanding surveillance beyond the existing sentinel surveillance in Hennepin and Ramsey Counties will improve awareness of CRE in Minnesota and drive targeted interventions and outbreak response activities, which are crucial for protecting the public's health against this serious threat.

2. SURVEILLANCE MECHANISM

The commissioner shall describe a specific, planned mechanism for surveillance of the disease or syndrome including persons and entities required to report, a time frame for reporting, and protocols for the submission of test results and clinical materials from cases and suspected cases to the Minnesota Department of Health, Public Health Laboratory.

A. Disease or Syndrome

CRE includes Enterobacteriaceae isolated from any body site that is resistant to any one of the following carbapenem antibiotics, imipenem, meropenem, doripenem, or ertapenem, based on current Clinical and Laboratory Standards Institutes Standards (M100) or that demonstrates production of a carbapenemase.

B. Reporting Entities

The Commissioner requires all mandated reporters to report CRE. (For a listed of mandated reporters see Minn. Rules, Chapter 4605.7030)

C. Reporting Time Frame

Providers and laboratories must report CRE cases to MDH within one working day after the test result is finalized.

D. Protocol for Submission

a. **Provider Submissions.**
Providers will report using a designated case report form and must be submitted either by direct electronic transmission, phone, or fax. The report must include, at a minimum, the following information:

1) Patient data – patient name, birthdate, gender, race, ethnicity (if available), telephone number, residential address, including street, city, county, state, and postal code
2) Culture data – specimen collection date, specimen source, isolate genus and species, antibiotic susceptibility report (medical record), carbapenemase test results (if known/reported in medical record)
3) Facility data – patient medical record number, date of report, physician name, address, and telephone number, name of hospital (including date of

admission/discharge) or other healthcare facility, and the diagnostic laboratory name.

b. **Clinical and Laboratory Submissions.**
Clinical and reference laboratories must forward CRE isolates from any body site (e.g., urine, blood, sputum, wound, etc.) along with results of antibiotic susceptibility testing and carbapenemase testing performed on the isolate to the PHL. The submission must include, at a minimum, the following information:

1) MDH isolate submission form(s) with project number
2) Results of antibiotic susceptibility testing, including automated testing instrument printouts (e.g., Vitek2, Phoenix, etc.), and/or results of other manual susceptibility testing performed (e.g. manual MicroScan, E-test, disk diffusion, etc.), including MIC value and final interpretation result
3) Results of additional testing performed on the specimen and/or isolate(s) for carbapenemase production (e.g., E-test, modified Hodge test, Carba NP, PCR, nucleic acid testing [NAAT], etc.)

Upon request from the Commissioner, each reporting facility shall provide access to additional information from all medical, pathological, and other pertinent records related to the CRE diagnosis, treatment, and follow-up for the purposes of surveillance and infection prevention and control. Epidemiologists review select patient medical records using a standardized case report form that is used to collect basic demographic information and risk factors of epidemiologic or infection prevention concern.

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Attachment D: References

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