May 10, 2018

Legislative Reference Library
645 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, Minnesota 55155

Re: In The Matter of the Proposed Rules of the Department of Health Governing Communicable Disease Reporting; Revisor's ID Number 4465

Dear Librarian:

The Minnesota Department of Health intends to adopt rules governing communicable disease reporting. We plan to publish a Notice of Intent to Adopt Rules without a Public Hearing in the May 14, 2018, 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

Enclosure: Statement of Need and Reasonableness

STATEMENT OF NEED AND REASONABLENESS (SONAR)

COMMUNICABLE DISEASE REPORTING RULES

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

Note: A glossary of terms can be found in Attachment A.

April 26, 2018

Minnesota Department of Health
Infectious Disease Epidemiology, Prevention and Control
P.O. Box 64975, St. Paul, MN 55164-0975
651-201-5414 | 1-877-676-5414
www.health.state.mn.us

STATEMENT OF NEED AND REASONABLENESS (SONAR)

COMMUNICABLE DISEASE REPORTING RULES

I. INTRODUCTION

The Minnesota Department of Health (MDH) is proposing amendments to the current Communicable Disease Reporting Rules (the rules). These rules, Minnesota Rules, chapter 4605, are the backbone of MDH's ability to monitor and control communicable[1] diseases in Minnesota. 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] 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 essential epidemiological practice for monitoring the spread of disease to establish patterns of how diseases spread. Disease surveillance's main role is to predict, observe, and minimize the harm caused by outbreaks, epidemics, and pandemics. It also increases knowledge about which factors contribute to such circumstances.

MDH revised the current rules comprehensively in 2016. This proposal, based on recent experience using the rules, is limited to updating the requirements for submitting clinical materials. We propose to allow MDH to adjust the mandatory clinical materials that providers must collect and submit in real time to fit the individual circumstances of the health situation it is dealing with as they are occurring. For example, MDH no longer needs to routinely receive all influenza clinical materials due to reliable testing capability at local clinical laboratories. However, MDH needs to retain the ability to broadly obtain specimens if there is a unique or novel influenza event so that MDH can help monitor the event and respond. Reducing the submission requirements for laboratories lessens both the laboratories and MDH's burden and saves time and money.

MDH needs more flexible rules for clinical laboratory testing to eliminate unnecessary steps for all parties. This flexibility will allow the reporting laboratories to respond to emerging diseases more efficiently and effectively, using current clinical practice standards. Updating the rules to incorporate current laboratory practices will ensure a strong future public health system. These changes are thus critical for MDH's continued ability to conduct the surveillance[3] and disease investigation that allow it to both identify outbreaks, and respond promptly to new and emerging communicable diseases—all of which keep Minnesotans both medically and economically healthy.

MDH began working on these rule revisions in January 2017. The agency published a Request for Comments in the State Register on August 28, 2017, with a closing date of October 30, 2017. 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. It is defined in Minnesota Rules 4605.7000, Subp. 3.

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

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 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 submit clinical materials for diseases on the communicable disease reporting rules list (Minn. Rules 4607.7040). The proposed amendments do not change who is required to report but rather affect what those entities must submit as circumstances change what materials MDH needs to collect. These revisions 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;
- Coroners and medical examiners required to report disease and submit clinical materials;
- The general public and all visitors to the state who either acquire a reportable disease or condition or have contact with a person who has a reportable disease or condition;
- MDH Public Health Laboratory that receives clinical materials; and

- Local public health agencies.

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

   - Those who are mandated to submit clinical materials per the rules
   - Minnesota Department of Health

3. Classes of Persons Who Will Benefit from the Proposed Rule

   - Those mandated to submit clinical materials to MDH. This change, when applicable, will reduce the burden on those who must submit clinical materials to MDH because they will be sending in fewer materials.

   - Minnesota Residents and Visitors: Every person who lives in or visits the state of Minnesota benefits from the improved reporting the proposed amendments allow. This change will ensure that those entities submitting clinical materials need only send what is necessary for prevention and communicable-disease control, saving time, money, and effort. Individual patients will not experience a specific change in treatment.

   - Insurance Payors/Entities: This may reduce costs for insurance companies and the state from fewer laboratory tests being performed. MDH will request only the necessary amount of clinical materials needed for prevention and control of the disease. In addition, improved surveillance may help control outbreaks and yield cost savings to insurance companies.

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

   MDH's probable costs for implementing the proposed rule amendments will be minimal. Existing agency staff will be able to handle the outreach needed to educate and communicate with affected entities when circumstances require modifying clinical material submission. To the extent possible, MDH will incorporate these educational materials into MDH's regular communication channels. At the same time, however, the MDH PHL should save money because they will be collecting and processing less clinical materials and conducting fewer tests.

2. Probable costs to any other agency of implementation and enforcement

   No other state agency or local public health agencies will have costs. Only MDH receives the disease reports and clinical materials.

3. Anticipated effect on state revenues

   The proposed rule amendments will not affect state revenues.

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 reducing clinical materials collection to only those that are necessary and useful for disease prevention and control. Furthermore, this change results in a more efficient and prudent use of resources (This factor is also discussed in the performance-based standard section and in the Rule-by-Rule Analysis.)

1. Less costly methods

MDH kept cost in mind when drafting this proposed amendment. And as noted above, this change will result in a better use of state and private resources and save money by reducing costs incurred under the existing rules. Allowing MDH to adjust the clinical material submissions to only those needed, reduces these requirement to the bare minimum that MDH needs to carry out communicable disease surveillance, timely investigation, and control. 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[4] (helps MDH link cases to a common source of infection) and antimicrobial susceptibility (helps MDH monitor antibiotic-resistant pathogens). Without the tools necessary for disease investigation and control, costs and threats to public health would rise substantially, including increased illness and unnecessary death. Thus reducing these requirements further is simply impossible. 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 those persons and entities that submit clinical materials and persons whose clinical materials are submitted. Mandated reporters and those mandated to submit clinical materials did not voice any significant concerns during the Request for Comments period.

Persons whose clinical material is submitted could view the proposed amendments as intrusive because it requires submitting an individual's clinical materials. Submission is, however, already required by law for many reportable diseases. The 2015 rule changes, which were broader and more intrusive than these proposed changes, did not prompt controversy. MDH did not hear any concerns during the 2015 Request for Comments period and did not in 2017 either.

In summary, we know of no method for adjusting the requirements for submitting clinical materials other than what we have proposed in these revisions. MDH monitors disease and collects clinical materials for certain disease to contain its spread and limit illness or death in real time. MDH simply must have clinical materials to ensure an accurate diagnosis. MDH can make recommendations to seek medical attention, obtain prophylaxis (use of drug therapy to prevent disease), or take appropriate infection control precautions.

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 clinical materials 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.

Our proposed rule revisions simply give MDH the flexibility to adjust the clinical submission requirements to match what the entities must submit to MDH during specific public-health situations. Regulated parties benefit from the lessening burden of responding. The only other solution that exists is the status quo, which adheres to a single standard of clinical-materials submissions, no matter what specific circumstances, such as intensity of the influenza season, might require. Our experience is that being limited to a single standard for a situation that changes over time does not account for fluctuating needs and, consequently, causes reporting entities unnecessary costs. Managing the materials under a standard that does not fit also costs MDH time and money to handle the unneeded clinical materials. Therefore, MDH rejected the status quo.

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

Those who submit clinical materials to MDH will not incur additional costs. This amendment actually lowers the number of clinical materials that must be submitted and should lower the workload and costs for both the public and private sector involved in this endeavor.

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

- Mandated Submitters: Under regulatory analysis factor A, MDH listed the categories of affected parties. MDH does not anticipate that hospitals and medical laboratories will bear any additional costs
- 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 and will be for educational and promotional materials. 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

Not adopting this amendment will result in continued unnecessary costs because submitters will be submitting superfluous clinical materials. Significant potential costs for not going forward with the proposed rule amendment would be the unnecessary clinical-materials submission. For example, under the current rule, all pertussis clinical materials must be submitted and yet not all are needed. This leads to more costs and unnecessary administrative work for both MDH PHL and submitters.

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. Only necessary clinical materials and health information would be submitted.

Mandated submitters: The discussion under factor A reflects how mandated submitters 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.

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.

Every state in the United States requires mandated reporters to report communicable diseases and most require submission of clinical materials for select diseases. In fact, all states have had some form of reporting since 1901.[5] Such reporting and testing is at the heart of communicable disease control. Nationally, there is a list of notifiable (reportable) diseases but the federal government has no similar requirement to submit clinical materials.[6][7] There are no federal regulations regarding communicable disease submission of clinical materials. 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.

---

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

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

[7] The Centers for Disease Control and Prevention (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.

No federal regulations on communicable disease reporting conflict with Minnesota's Communicable Disease Reporting rule. Reporting, and submission of clinical materials is a state function. 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 and mandating submission of isolates and clinical materials. 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.

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.

This 2018 rule revision follows very quickly after the 2016 comprehensive revision. MDH seeks to change only the requirements for collecting and submitting clinical materials so that the agency can tailor those requirements as public-health-response need flows and ebbs. This change would give MDH the ability to administer its initial requirements that all mandated parties submit such materials at the beginning of the event, and then reduce those requirements as the need lessens. Thus the flexibility that MDH is building in these amendments will allow the parties to perform their duties based on real need. This improves the present all-or-nothing system that currently exists. For these reasons, MDH asserts that it has met its requirements for establishing performance-based standards and maximum flexibility.

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 April 24, 2018 by Administrative Law Judge Eric L. Lipman.

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 Notice of Intent to Adopt Without a Hearing, and the SONAR on MDH's communicable disease rule website at http://www.health.state.mn.us/divs/idepc/dtopics/reportable/newrule/index.html. The website also includes a link to subscribe to email alerts for the proposed revisions to the rules.

3. Providing via email a copy of the Notice of Intent to Adopt Without a Hearing, the proposed rules, and a Web link to the MDH proposed rules website, directly or through MDH subscribers services, such as GovDelivery to various individuals, groups, and organizations. MDH will also request, when possible, that these

organizations post the information on their website and send it out to their listserv. The list includes:

- 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 Nurses Association
  - Physician assistant groups
  - Minnesota Chapter of the National Association of Pediatric Nurses and Practitioners
- 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

4. Publishing information such as the notice of intent to adopt without a hearing, 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 via email a copy of the proposed rules and SONAR to the Executive Budget Officer on January 24, 2018, 2018.

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).

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.

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, and
3. A clinical microbiologist.

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.

PART 4605.7000 DEFINITIONS.

This proposed definition provides 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 13. Submitter. This amendment adds the definition "submitter" to the rule. Submitter means a health care provider or laboratory that collects and submits clinical materials to the Minnesota Department of Health under Minnesota Rules, chapter 4605.

This subpart is reasonable and necessary and corresponds to the new section, 4605.7031, Clinical Materials Submission Modification.

PART 4605.7041 CLINICAL MATERIALS SUBMISSION MODIFICATION

Minnesota rule 4605.7030 requires certain individuals and entities to report a case, suspected case, carrier, or death from any of the diseases listed part 4605.7040 or a pregnancy under part 4605.7044. (*See* attachment C for list of diseases.)

Minnesota rules 4605.7040 not only lists the diseases that mandated reporters must report but also whether or not they must submit clinical materials. For example, gonorrhea is a reportable disease, but does not require submission of clinical materials, while pertussis is reportable and requires submitting clinical materials.

This amendment permits the commissioner of health to modify clinical material submission requirements under certain circumstances. These circumstances are:

> (1) Laboratory testing methods or capabilities are not sufficient or adequate to determine the presence of the pathogen of concern; or
>
> (2) Surveillance needs have changed; or
>
> (3) Evolving pathogen knowledge indicates that either the pathogen is no longer a concern or advances in diagnostic testing provide the necessary information to public health.

The amendment also requires the commissioner to issue an order and notify submitters that he or she is suspending the normal submission requirements under 4604.7040 and lists what information the order must contain. The order must identify the circumstance listed above that warrants the change and specific directions for the new submission requirements.

The current rule requires submitters to send all clinical materials for the disease listed in 4605.7040 without any flexibility to ensure that surveillance remains focused on the appropriate public health issue. At the same time, we need not want impose an undue burden on laboratories and providers by requiring information or materials that we do not need.

For example, the current rule requires submission of all clinical materials for unusual case incidence, critical illness, or laboratory-confirmed cases of influenza. MDH, however, does not need all these clinical materials every influenza season. It would be more efficient, effective, and a prudent use of resources if MDH based its clinical material submission needs on surveillance and epidemiological factors. Examples of these factors are disease incidence, disease severity, seasonal trends, laboratory capacity, and evaluating net gains from increased information. This list is not exhaustive. These changes would allow MDH to request clinical materials based on these factors instead of requiring submitters to submit all materials all the time. This change is thus necessary to lessen unnecessary burdens and reasonable to collect materials in a timely manner. Giving the commissioner the discretion to use this flexibility under very specific, limited circumstances described below is both necessary and reasonable because the discretion respects the need for both MDH and the regulated entities to conserve their respective resources of both time and money. The amended rule confines the commissioner's discretion to the very limited criteria described in the rule, and the commissioner must justify each use in an order. Thus the discretion is not unbridled.

Laboratory Testing Methods or Capabilities Are Not Sufficient or Adequate to Determine the Presence of the Pathogen of Concern

The following is an example of inadequate laboratory testing methods. Enteric *Escherichia coli (E. coli)* infection is a reportable disease that requires submitting clinical materials. *E. coli* are bacteria that normally live in the intestines of people and animals. Most *E. coli* are harmless and actually are an important part of a healthy human intestinal tract. However, some strains of *E. coli* can cause illness, either diarrhea or illness, outside of the intestinal tract. The types of *E. coli* that can cause diarrhea can be transmitted through contaminated water or food, or through contact with animals or persons. Enteropathogenic *E. coli* (EPEC), which is a reportable pathogen under Minnesota Rules 4605.7040, is one of these harmful categories of *E. coli.*

There is currently one culture-independent diagnostic test available to clinical laboratories to diagnose EPEC. Before that test entered the market in 2014, clinical laboratories could not test for EPEC. After an outside laboratory finds EPEC through diagnostic testing, the laboratory sends the materials and results to the MDH Public Health Laboratory (PHL). The MDH PHL then tests the sample further to confirm the presence of EPEC. In MDH's efforts to confirm that EPEC is present, we found that only 57% of samples that test positive for EPEC at outside laboratories are confirmed as having EPEC. Among those confirmed EPEC samples, 4% have typical EPEC (a well-established cause of disease). The other 96% of confirmed EPEC samples have atypical EPEC, some of which cause disease and some of which do not. In general, the epidemiology community thinks that currently unidentified or unknown factors exist that enable some atypical EPEC to cause disease. MDH cannot confirm the presence of EPEC in 43% of samples that test positive for EPEC at outside laboratories. We do not know why there is this discrepancy; possibly the outside laboratory's test was a false positive, or that MDH PHL's confirmatory test is not as sensitive as the test used at the outside laboratory. (A sensitive test means that there are few false negative results, and thus fewer cases of disease are missed.)

In sum, the outside clinical laboratory test identifies a mix of EPEC known to cause illness (known pathogens), and EPEC that do not cause illness at all. The problem is that the outside clinical laboratory test cannot differentiate which type of EPEC it detected, disease-causing or not disease-causing. Even though MDH PHL can further differentiate the type of EPEC detected through their laboratory test, we do not know at present if our confirmation methods are sufficiently sensitive. Furthermore, under the current state of knowledge, we do not know what makes some atypical EPEC cause illness and others not. No test currently available provides further discrimination of these atypical EPEC.

The current rule requires reporters to submit all clinical materials for EPEC. Because of the issues described above, having the flexibility to suspend this requirement while better confirmatory tests are being developed would be prudent. MDH would universally still require submission of clinical materials if evidence suggests an outbreak is taking place. Most positive EPEC tests, however, are not associated with a suspect outbreak. Consequently, MDH needs the flexibility to require submission of clinical specimens for these positive tests only when the benefits to public health exceeds the burden of those submissions for submitters or MDH. Once more is known about the clinical significance of EPECs identified by clinical laboratories, MDH would resume the universal requirement of submitting clinical materials for all EPEC to confirm and further characterize pathogens to better prevent and control disease.

Changing Surveillance Needs

The following is an example of "changing surveillance needs" circumstance. When influenza season is at its peak, there can be hundreds of laboratory-confirmed samples submitted to the MDH PHL weekly for testing. Not only does the MDH PHL not have capacity to test all the materials, but they are all not needed after influenza activity reaches a high level during the season.[8] Allowing submitters to submit only those materials that MDH needs for surveillance and disease prevention and control eases the burden on the submitters, as well as both MDH and the clinical laboratory. MDH will have sufficient data for recommendations for public health interventions and prevention based on epidemiological trends determined through sampling clinical material submissions. In the summer, however, MDH sees very few cases of influenza, so MDH needs submitters to submit all laboratory-confirmed cases for surveillance and epidemiological purposes. Depending on the epidemiology and number of cases during a season, the number of submissions needed will vary.

Pertussis disease is another example of changing surveillance needs. The number of pertussis cases fluctuates from year to year. For example, in 2012, there were over 4,000 possible, suspect, and confirmed cases in Minnesota, while in 2015 there were 700. In 2016, there were 586 cases, and as of September 22, 2017, there were 1,247 cases. MDH does not need all materials, all the time, on every case. Instead, MDH needs only certain materials during certain situations, which is similar to some of the influenza surveillance needs. MDH only needs to receive clinical materials that are necessary to prevent and control disease.

---

[8] Influenza season (when MDH sees the highest activity) lasts from November to May but influenza can circulate outside those months.

Evolving pathogen knowledge

MDH also needs flexibility when we have learned enough about an evolving pathogen to know that the pathogen either is no longer a concern or can be monitored using more efficient testing strategies. For example, clinical laboratory testing has advanced so that many laboratories can now subtype multiple influenza strains, [1] work that historically MDH-PHL has performed. Subtypes provide information about the classification of an influenza virus, information needed to understand disease trends and appropriate public health responses. Influenza has two main types (influenza A and influenza B). Each type has subtypes, such as A(H1N1), A(H3), B(Yamagata), and B(Victoria). MDH-PHL continues to play an important role in two ways. It monitors different subtypes and it looks for novel strains. But increasingly, clinical laboratories can subtype influenza themselves, meaning that MDH-PHL does not need to subtype all specimens. MDH-PHL must, however, continue to receive a subset of samples to verify results. Also, MDH must continue doing surveillance for novel influenza strains to respond accordingly. This modified approach will save MDH time and money by not repeating testing that other laboratories have already done. Therefore, MDH can allocate its resources more efficiently to meet our needs for disease prevention and control.

MDH received no comments or questions during the Request for Comment Period.

These changes are reasonable and necessary to ensure that MDH receives only the clinical materials necessary for public health purposes to prevent and control disease. Moreover, these changes allow a more prudent use of both private and public resources and create a more efficient system for submitting clinical materials without risking the public's health.

VII. CONCLUSION

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

April 26, 2018
[Date]

Jan K. Malcolm
Commissioner
Minnesota Department of Health

Attachments

Attachment A: Glossary of Terms

case. A person or deceased person infected with a particular infectious agent or having a particular disease diagnosed by a health care practitioner.

carrier. A person or deceased person identified as harboring a specific infectious agent and who serves as a potential source of infection.

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.

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

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.

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

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

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

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.

pathogen. An organism that can produce disease.

PCR Polymerase Chain Reaction is a fast technique used to reproduce (amplify) selected sections of DNA or RNA for analysis.

sensitive. A highly sensitive test means that there are few false negative results, and thus fewer cases of disease are missed.

subtype. Refers to the subgroup an organism belongs to.

subtyping. To classify according to subtype.

suspected case. A person or deceased person having a condition or illness in which the signs and symptoms resemble those of a recognized disease

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.

.

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
   - Community Health Services Administrators and Public Health Nursing Directors
   - State Community Health Services Advisory Committee (SCHSAC)
   - Minnesota Council of Health Plans
   - Minnesota AIDS Project

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

Minn. R. Ch. 4605.7040 DISEASE AND REPORTS; CLINICAL MATERIALS SUBMISSIONS.

Cases, suspected cases, carriers, and deaths due to the following diseases and infectious agents shall be reported. When submission of clinical materials is required under this part, submissions shall be made to the Minnesota Department of Health, Public Health Laboratory.

A. Diseases reportable immediately by telephone to the commissioner:
(1) anthrax (Bacillus anthracis). Submit clinical materials;
(2) botulism (Clostridium botulinum);
(3) brucellosis (Brucella spp.). Submit clinical materials;
(4) cholera (Vibrio cholerae). Submit clinical materials;
(5) diphtheria (Corynebacterium diphtheriae). Submit clinical materials;
(6) free-living amebic infection (including at least: Acanthamoeba spp., Naegleria fowleri, Balamuthia spp., Sappinia spp). Submit clinical materials;
(7) hemolytic uremic syndrome. Submit clinical materials;
(8) measles (rubeola). Submit clinical materials;
(9) meningococcal disease (Neisseria meningitidis) (all invasive disease). Submit clinical materials;
(10) Middle East Respiratory Syndrome (MERS). Submit clinical materials;
(11) orthopox virus. Submit clinical materials;
(12) plague (Yersinia pestis). Submit clinical materials;
(13) poliomyelitis. Submit clinical materials;
(14) Q fever (Coxiella burnetii). Submit clinical materials;
(15) rabies (animal and human cases and suspected cases);
(16) rubella and congenital rubella syndrome. Submit clinical materials;
(17) severe acute respiratory syndrome (SARS). Submit clinical materials;
(18) smallpox (variola). Submit clinical materials;
(19) tularemia (Francisella tularensis). Submit clinical materials; and
(20) viral hemorrhagic fever (including but not limited to Ebola virus disease and Lassa fever). Submit clinical materials.
B. Diseases reportable within one working day:
(1) amebiasis (Entamoeba histolytica/dispar);
(2) anaplasmosis (Anaplasma phagocytophilum);
(3) arboviral disease, including, but not limited to, La Crosse encephalitis, eastern equine encephalitis, western equine encephalitis, St. Louis encephalitis, West Nile virus disease, Powassan virus disease, and Jamestown Canyon virus disease;
(4) babesiosis (Babesia spp.);
(5) blastomycosis (Blastomyces dermatitidis);
(6) campylobacteriosis (Campylobacter spp.). Submit clinical materials;
(7) carbapenem-resistant Enterobacteriaceae (CRE). Submit clinical materials;
(8) cat scratch disease (infection caused by Bartonella species);
(9) chancroid (Haemophilus ducreyi);
(10) Chikungunya virus disease;

(11) Chlamydia trachomatis infections;
(12) coccidioidomycosis;
(13) Cronobacter sakazakii in infants under one year of age. Submit clinical materials;
(14) cryptosporidiosis (Cryptosporidium spp.). Submit clinical materials;
(15) cyclosporiasis (Cyclospora spp.). Submit clinical materials;
(16) dengue virus infection;
(17) Diphyllobothrium latum infection;
(18) ehrlichiosis (Ehrlichia spp.);
(19) encephalitis (caused by viral agents);
(20) enteric Escherichia coli infection (E. coli O157:H7, other Shiga toxin-producing (enterohemorrhagic) E. coli, enteropathogenic E. coli, enteroinvasive E. coli, enteroaggregative E. coli, enterotoxigenic E. coli, or other pathogenic E. coli). Submit clinical materials;
(21) giardiasis (Giardia intestinalis);
(22) gonorrhea (Neisseria gonorrhoeae infections);
(23) Haemophilus influenzae disease (all invasive disease). Submit clinical materials;
(24) hantavirus infection;
(25) hepatitis (all primary viral types including A, B, C, D, and E);
(26) histoplasmosis (Histoplasma capsulatum);
(27) human immunodeficiency virus (HIV) infection, including acquired immunodeficiency syndrome (AIDS);
(28) influenza (unusual case incidence, critical illness, or laboratory confirmed cases). Submit clinical materials;
(29) Kawasaki disease;
(30) Kingella spp. (invasive only). Submit clinical materials;
(31) legionellosis (Legionella spp.). Submit clinical materials;
(32) leprosy (Hansen's disease) (Mycobacterium leprae);
(33) leptospirosis (Leptospira interrogans);
(34) listeriosis (Listeria monocytogenes). Submit clinical materials;
(35) Lyme disease (Borrelia burgdorferi and other Borrelia spp.);
(36) malaria (Plasmodium spp.);
(37) meningitis (caused by viral agents);
(38) mumps. Submit clinical materials;
(39) neonatal sepsis (bacteria isolated from a sterile site, excluding coagulase-negative Staphylococcus) less than seven days after birth. Submit clinical materials;
(40) pertussis (Bordetella pertussis). Submit clinical materials;
(41) psittacosis (Chlamydophila psittaci);
(42) retrovirus infections;
(43) salmonellosis, including typhoid (Salmonella spp.). Submit clinical materials;
(44) shigellosis (Shigella spp.). Submit clinical materials;
(45) Spotted fever rickettsiosis (Rickettsia spp. infections, including Rocky Mountain spotted fever);

(46) Staphylococcus aureus (only vancomycin-intermediate Staphylococcus aureus (VISA), vancomycin-resistant Staphylococcus aureus (VRSA), and death or critical illness due to community-associated Staphylococcus aureus in a previously healthy individual). Submit clinical materials;
(47) streptococcal disease (all invasive disease caused by Groups A and B streptococci and S. pneumoniae [including urine antigen laboratory-confirmed pneumonia]). Except for urine, submit clinical materials;
(48) syphilis (Treponema pallidum);
(49) tetanus (Clostridium tetani);
(50) toxic shock syndrome. Submit clinical materials;
(51) toxoplasmosis (Toxoplasma gondii);
(52) transmissible spongiform encephalopathy;
(53) trichinosis (Trichinella spiralis);
(54) tuberculosis (Mycobacterium tuberculosis complex) (pulmonary or extrapulmonary sites of disease, including clinically diagnosed disease). Latent tuberculosis infection is not reportable. Submit clinical materials;
(55) typhus (Rickettsia spp.);
(56) varicella (chickenpox). Submit clinical materials;
§(57) Vibrio spp. Submit clinical materials;
(58) yellow fever;
(59) yersiniosis, enteric (Yersinia spp.). Submit clinical materials;
(60) zika virus disease; and
(61) zoster (shingles) (all cases <18 years old; other unusual case incidence or complications regardless of age). Submit clinical materials.

ATTACHMENT C: REPORTABLE DISEASES
SONAR: COMMUNICABLE DISEASE REPORTING RULE