

Testimony

North Dakota Administrative Code

Legislative Management's Administrative Rules Committee

Wednesday, December 15, 2010

North Dakota Department of Health

Chapter 33-06-01

33-06-01-01 Reportable Conditions

1. These rule changes did not result from statutory changes.
2. These rule changes did not result from any federal statute or regulation.
3. A hearing notice was published in 52 daily or weekly newspapers in the state from Feb. 11 through Feb. 17, 2010. A public hearing was held March 25, 2010. Oral and written comments were received through April 8, 2010. The State Health Council adopted the proposed changes on Aug. 19, 2010.
4. The Department of Health received only one comment from the Senior Epidemiologist with the North Dakota Department of Health's Division of Disease Control, who asked to include organisms with reduced susceptibility to carbapenem. We did include this in the rule change. Her March 25, 2010, testimony is attached.
5. Approximate costs for public notice:

a. Newspaper publication of hearing notice	\$ 1416.00
b. Attorney General's fee	\$ 500.00
c. Division Director (10 hours @ \$ 30.00)	\$ 300.00
d. Surveillance epidemiologist (2 hours @ \$ 20.65)	\$ 41.30
e. Secretary (8 hours @ \$ 12.00)	\$ 96.00
	\$ 2353.65
6. The intent of the proposed rule change is to make changes to the reportable conditions list that will address improvements and further

clarify reporting requirements and update language for disease surveillance. The following is a summary of the proposed changes.

Item number 6, cancer: Changes are being made to update and clarify which cancers should be reported. Changes will make reporting requirements more consistent with national standards.

Item number 12, coccidioidomycosis: This condition is being added because of its potential use as a biological weapon.

Item 16, E. coli, shiga toxin producing: This is an update to the terminology used for toxin producing E. coli that can cause diarrhea and kidney and blood disorders.

Item 24, HIV Rapid Screens (positive only): This item is added to clarify that rapid HIV screenings tests that are positive need to be reported.

Item 45, Pregnancy in persons infected with hepatitis B, HIV or syphilis: This change is to provide clarity and definition to what conditions need to be reported in pregnant women. Group B strep is being eliminated from the list of conditions as reportable during pregnancy because the severe cases involving infections in babies are reported through a different reportable condition (invasive streptococcal infections). By eliminating this condition as reportable, the burden of reporting will be reduced for health-care providers.

Item 62 and item 63: These have been updated to include all tick transmitted diseases. A tick survey is ongoing.

Item 72, Vibriosis: This item includes cholera and other infections. Vibriosis is becoming a more common foodborne cause of illness.

7. A regulatory analysis was not required.
8. A regulatory analysis and economic impact statement of impact on small businesses was prepared and is attached.
9. A constitutional takings assessment was not prepared.
10. These rules were not adopted as emergency rules.

Testimony
North Dakota Administrative Code 33-06
Proposed Rule Changes
North Dakota Department of Health
March 25, 2010; 1 p.m.

Good afternoon, my name is Tracy Miller, and I am the senior epidemiologist for the Division of Disease Control with the North Dakota Department of Health. I am here today to provide information that may be helpful as you deliberate changes to North Dakota Administrative Code 33-06, Reportable Conditions.

The North Dakota Department of Health agrees with the proposed changes and suggests one further addition of the reportable disease list. We recommend the inclusion of infections or colonization with *Klebsiella pneumoniae* carbapenemase producing organisms or carbapenem –resistant organisms be made reportable with isolates of these organisms being forwarded to the Division of Laboratory Services with the North Dakota Department of Health.

The reason for this recommendation is two-fold. First, the continuing emergence of antibiotic resistance is increasing the difficulty and limiting options that physicians have when treating infections. Second, little is known about the epidemiology of antibiotic resistance in North Dakota, and this change will allow the department to collect data regarding the incidence of these events.

I would be happy to answer any questions that you may have.

Small Entity Regulatory Analysis for Proposed Changes to Administrative Code 33-06-01 –
Conditions Designated as Reportable

1. Was establishment of less stringent compliance or reporting requirements for small entities considered?

Yes. Current requirements allow for small entities to report diseases and outbreaks by a variety of methods including completing and mailing or faxing disease reports to the Department of Health, mailing, faxing or emailing laboratory reports to the Health Department, completing an on-line, web-based reporting form, sending electronic laboratory reports or by telephoning reports to the Health Department.

2. Was establishment of less stringent schedules or deadlines for compliance or reporting requirements considered for small entities?

No, these requirements have been in place for many years. and in recent years the need for timely disease reporting has increased to be able to respond to disease outbreaks sooner.

3. Was consolidation or simplification of compliance or reporting requirements for small entities considered?

Yes, although disease reporting has been required for many years, simplification can occur through electronic reporting mechanisms using laboratory information systems. These systems have the potential to send information on reportable diseases with minimum human involvement. The implementation of electronic reporting will depend on the entities' laboratory information system's capabilities.

4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rule?

As is currently the case, disease reporting performance requirements are the same for all required reporting entities.

5. Was exemption of small entities from all or any part of the requirements in the proposed rule considered?

NDCC 23-07-02 defines which entities need to report, the statute does not provide for an exception.

Small Entity Economic Impact Statement for Changes to Administrative Code 33-06-01 –
Conditions Designated as Reportable.

1. Which small entities are subject to the proposed rule?

Those individuals and institutions that are required to report reportable conditions are defined in NDCC 23-07-02 and include healthcare providers and others.

2. What are the administrative and other costs required for compliance with the proposed rule?

There is no expected increase in the administrative costs required to comply with the proposed rule. The entities that have been required to report before will still be required to report with the new rule in place.

The proposed changes to the rule will not significantly impact those entities that are already required to report reportable conditions. The proposed newly reportable conditions are, for the most part, low prevalence conditions or are likely to be rare events and it is anticipated that they will not significantly increase the reporting requirements for any entity.

3. What is the probable cost and benefit to private persons and consumers who are affected by the proposed rule?

The probable costs are not expected to change for the proposed rule. The benefits to the consumer is the increased understanding of the epidemiology of these diseases in North Dakota and the potential early warning of laboratory events that may result in the release of bioterrorism agents into the environment.

4. What is the probable effect of the proposed rule on state revenues?

There would be no effect on state revenues.

5. Is there any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule?

This is the traditional approach to reportable conditions in the United States. Reportable conditions are the cornerstone for public health surveillance. Various different reporting mechanisms are possible, however only one potentially can save time and money on behalf of the required reporters, that is electronic laboratory based reporting (ELR). ELR, in theory would make reporting an ongoing and automatic process using HL7 messaging capabilities.