Report From Agency

DEPARTMENT OF HEALTH SERVICES **STATE OF WISCONSIN**
Office of Legal Counsel
F-02113 (05/2017)

RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 17-014

Ch. DHS 145 relating to Control of Communicable Diseases

Basis and Purpose of Proposed Rule
Statutory basis of proposed rule:

Section 252.02 (1) and (4), Stats., reads:
(1) The department may establish systems of disease surveillance and inspection to ascertain the presence of any communicable disease. Any agent of the department may, with a special inspection warrant issued under s. 66.0119, enter any building, vessel or conveyance to inspect the same and remove therefrom any person affected by a communicable disease. For this purpose, the agent may require the person in charge of the vessel or conveyance, other than a railway car, to stop the same at any place and may require the conductor of any railway train to stop the train at any station or upon any sidetrack, for such time as may be necessary.
(4) The department may promulgate and enforce rules or issue orders for guarding against the introduction of any communicable disease into the state, for the control and suppression of communicable diseases, for the quarantine and disinfection of persons, localities and things infected or suspected of being infected by a communicable disease and for the sanitary care of jails, state prisons, mental health institutions, schools, hotels and public buildings and connected premises. Any rule or order may be made applicable to the whole or any specified part of the state, or to any vessel or other conveyance. The department may issue orders for any city, village or county by service upon the local health officer. Rules that are promulgated and orders that are issued under this subsection supersede conflicting or less stringent local regulations, orders or ordinances.

Section 252.07 (11), Stats., reads: The department may promulgate any rules necessary for the administration and enforcement of this section, including, if necessary to prevent or control the transmission of mycobacterium tuberculosis, rules that require screening of members of specific groups that are at risk for contracting or transmitting mycobacterium tuberculosis.

Section 254.51 (3), Stats., reads: The department shall promulgate rules that establish measures for prevention, surveillance and control of human disease that is associated with animal-borne and vector-borne disease transmission.

Section 227.11 (2) (a) , Stats., reads: Rule-making authority is expressly conferred on an agency as follows:
(a) Each agency may promulgate rules interpreting the provisions of any statute enforced or administered by the agency, if the agency considers it necessary to effectuate the purpose of the statute, but a rule is not valid if the rule exceeds the bounds of correct interpretation. All of the following apply to the promulgation of a rule interpreting the provisions of a statute enforced or administered by an agency:

1. A statutory or nonstatutory provision containing a statement or declaration of legislative intent, purpose, findings, or policy does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

2. A statutory provision describing the agency's general powers or duties does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

3. A statutory provision containing a specific standard, requirement, or threshold does not confer on the agency the authority to promulgate, enforce, or administer a rule that contains a standard, requirement, or threshold that is more restrictive than the standard, requirement, or threshold contained in the statutory provision.

Purpose of proposed rule:

Chapter DHS 145 establishes a surveillance system for the purpose of controlling the incidence and spread of

communicable diseases. This surveillance system consists of timely and effective communicable disease reporting by local health departments, laboratories, health care facilities, schools, day care centers, and others (reporters); methods of intervention to prevent transmission of communicable diseases; means of investigation; and prevention and control of outbreaks by local health officers and the department.

Since 2008, when the list of communicable diseases was last revised, a number of communicable diseases and conditions, including Ebola, valley fever, and dengue, have been determined by the state epidemiologist to be reportable, or have been recommended as reportable at the national level by the Council of State and Territorial Epidemiologists (CSTE). These communicable diseases are not currently listed in ch. DHS 145. The outdated list therefore makes it difficult for reporters to determine whether to report a disease or condition, and adds to the failure of not reporting diseases not specifically listed.

The department proposes to revise the list to include communicable diseases and conditions declared notifiable by the state epidemiologist, and/or CSTE. The CSTE encourages states to establish parallel reporting requirements and typically places under surveillance novel pathogens, or those with severe manifestations, whose transmission is amenable to control by public health measures. The department also proposes to remove any disease or condition from the list that may no longer be reportable.

The department also proposes to incorporate updated standards by reference, including for methods of communicable disease control, laboratory testing, and treatment. Chapter DHS 145 includes numerous literature citations to standards the department incorporated by reference that are now outdated, and may lead to implementation of inaccurate and possibly harmful recommendations for disease control and prevention. It also obligates the department and local health departments to maintain access to outdated materials to meet public health accreditation requirements.

There are no reasonable alternatives to rulemaking. Without proposed revisions to ch. DHS 145, disease reporters may fail to report communicable diseases that threaten public health, national communicable disease data may not reflect diseases occurring in Wisconsin, public health surveillance and response to those diseases may be diminished, and the rule would remain outdated.

Department Response to Legislative Council Rules Clearinghouse Recommendations

The department accepts the recommendations made by the Legislative Council Rules Clearinghouse and has modified the proposed rule where suggested.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s).

The proposed rules will not have an economic impact on small businesses.

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives.

NA

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule.

NA

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule.

NA

The reason for including or not including in the proposed rule any of the following methods for reducing the rule's impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule's impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules

NA

Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis

Analysis

No changes were made to the rule's analysis.

Fiscal Estimate/Economic Impact Analysis

No changes were made to the rule's analysis.

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and through the Department's Administrative Rules Website on January 23, 2017. A public hearing was held on May 15, 2017, in Madison, Wisconsin. Two persons attended the hearing. Public comments on the proposed rule were accepted until May 22, 2017

List of Public Hearing Attendees and Commenters

The following is a complete list of the persons who attended the public hearing or submitted comments on the proposed rule during the public comment period, the position taken by the commenter and whether or not the individual provided written or oral comments.

Commenter	**Name and Address**	**Position Taken** (Support or Opposed)	**Method of Commenting** (Oral or Written)
1.	Dan Carpenter Government Affairs and Communications Associate Hoven Consulting WI Public Health Association and WI Association of Local Health Departments and Boards 44 E. Mifflin St. Ste 600 Madison, WI 53703	See Summary of Public Comments	Oral and Written
2.	Andrew Brenton Assistant General Counsel Wisconsin Hospital Association 5510 Research Park Dr. Fitchburg, WI 53711	See Summary of Public Comments	Public hearing observer; Written comments provided separately
3.	Bethany Gardner nursing student 516 Goldenrod Circle West Bend, WI 53095	See Summary of Public Comments	Written
4.	Angela Tonozzi Director, Infection Prevention Aurora Health Care 647 W. Virginia St. Milwaukee, WI 53204	See Summary of Public Comments	Written

Summary of Public Comments and Department Responses

The number(s) following each comment corresponds to the number assigned to the individual listed in the Public Hearing Attendees and Commenters section of this document.

Rule Provision	Public Comment	Department Response
General	Support revision of DHS 145 as proposed. 1	No change. The department accepts WALHDAB and WPHA's support for the proposed rule revisions.
General	Expressed concern about lack of state funding to combat communicable diseases at local level. No changes recommended to rule. 1	No change. Additional comments relating to state funding of communicable disease programming cannot be addressed by the department in ch. DHS 145. These comments are documented in this report for consideration by the Wisconsin State Legislature.
DHS 145.07(4)	Request language change to timing of ophthalmia neonatorum prophylaxis from one hour to two hours. 3	No change. The requested change is outside the current statement of scope.
DHS 145.07(4)	Add requirement for ophthalmia neonatorum prophylaxis monitoring system. 3	No change. The requested addition is outside the current statement of scope.
DHS 145 Appendix A, General	Request for disease-specific reporting criteria. 4	No change. Disease-specific reporting criteria are provided in department publications outside of statute.
DHS 145 Appendix A, Category II	Clarity as to why Zika appears twice in Category II. 4	No change. Both Zika disease and infection (regardless of clinical disease) are reportable. Zika virus is included as an Arboviral disease; and Zika infection is listed separately.
DHS 145 Appendix A, Key 2	Questions about disease-specific follow-up form requirement details. 4	Partially accepted. For each disease or condition that includes key 2, the instructions for completing the disease-specific form are provided in department publications. Guidance can be found on DHS' website (index found at https://www.dhs.wisconsin.gov/disease/index.htm), in the "For Health Professionals" section of each reportable disease. Per discussion with Commenter, Key 2 was revised to specify that public health agencies (not health care providers or other disease reporters) are responsible for completing the required follow-up forms.
DHS 145 Appendix A, Key 6	Request to declare that state and local health departments, not health care facility, coordinate follow-up. 4	No change. Key 6 is a recommendation for coordination between local and state health departments. There is no implicit responsibility for health care facility coordination.

DHS 145 Appendix A, General	Any diseases and conditions added to DHS 145 Appendix A should not exceed DHS's statutory authority to promulgate rules. In the absence of statutory authority for DHS to promulgate a rule requiring health care providers to report environmental and occupational health-related conditions and toxicological conditions to public health agencies, WHA recommends that these conditions not be added to DHS 145 Appendix A. 2	DHS has statutory authority to conduct environmental and occupational disease surveillance under s. 254.02(5)(a), Stats., which states that the chief medical officer for environmental and occupational health "shall establish a system for assessment, collection and surveillance of disease outcome and toxic exposure data." Addition of the proposed environmental and occupational conditions to the Communicable Diseases and Other Notifiable Conditions list in Appendix A meets this statutory requirement.
DHS 145 Appendix A, General	The public benefit of adding any disease or condition to DHS 145 Appendix A should outweigh the cost for and burden on the provider community. WHA recommends that environmental and occupational health-related conditions and toxicological conditions not be added to DHS 145 Appendix A. 2	The proposed environmental and occupational diseases are an important cause of morbidity and mortality within Wisconsin, but they are uncommon compared to some infectious diseases that are currently reportable. Accordingly, the anticipated reporting burden on healthcare providers will be low. Gathering additional information on these diseases is needed to inform public health interventions. Both silicosis and carbon monoxide poisoning are nationally notifiable diseases.
DHS 145 Appendix A, General	Any diseases and conditions added to DHS 145 Appendix A should be based on national standards or otherwise be easily and uniformly identifiable. WHA recommends that no disease or condition should be added unless it is associated with an ICD-10 code. 2	Partially accepted: DHS agrees that reportable conditions should be defined as clearly as possible. DHS therefore removed "Other non-infectious environmental and occupational lung diseases" from the list of proposed reportable conditions. Each remaining disease identified in Appendix A has Wisconsin case reporting and public health follow-up guidelines publicly available in the "For Health Professionals" section of each DHS disease-specific website (disease index: https://www.dhs.wisconsin.gov/disease/index.htm). Reporters of notifiable conditions, including hospitals, are given flexibility in DHS 145.04(1)(a) as to how they identify persons with notifiable diseases and conditions. Though not required in public health reporting, ICD-10-CM codes are available, with variable specificity, for all established reportable conditions of public health importance. Emerging diseases, such as Zika virus infection, may initially require reporting before a highly specific ICD-10 code is developed and implemented by the World Health Organization. A less specific yet related code is often used in the interim.

DHS 145 Appendix A, General	To the greatest extent practicable, the proposed rule should provide flexibility to health care providers to meet the reporting requirements. WHA recommends that DHS finalize the proposed addition of "or the local health officer's designee", with a further clarification that DHS automatically qualifies as a designee of local health officers, even in the absence of an affirmative action by a local health officer to formally designate DHS as such. 2	No change. Wisconsin is a home-rule state and s. 252.03, Stats., describes the duties of local health officers. Section 252.05 (1), Stats., indicates that health care providers must "…report the appearance of the communicable disease or the death to the local health officer. The local health officer shall report this information to the department or shall direct the person reporting to report to the department. Any person directed to report shall submit this information to the department." It is common practice for reports of notifiable conditions to be sent by providers directly to DHS. However, DHS is often unaware of whether it is receiving a duplicate report from a provider, or a primary report at the direction of a local health officer. Though the department recognizes the difficulty in identifying whether each local health officer has designated DHS to directly receive specific disease reports, the department cannot declare itself as the default designee. Section 252.05 (1) requires that reports be communicated to the local health officer.
DHS 145, Appendix A, Category II list	WHA agrees that a requirement to report a disease with such incidence as "influenza-associated hospitalization" should be explicitly listed in DHS 145 Appendix A so that health care providers can better know what DHS expects them to report. 2	No change. The department accepts WHA's support for explicitly listing those diseases and conditions that the State Epidemiologist declares through emergency memo to be reportable, such as Mandatory reporting of Influenza-associated Hospitalizations, declared November 23, 2010.

Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

Documents/Information	Included in Report	Attached	Not Applicable
Final proposed rule -- Rule Summary and Rule Text		X	
Department response to Rules Clearinghouse recommendations	X		
Final Regulatory Flexibility Analysis	X		
Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis	X		
Public Hearing Summary	X		
List of Public Hearing Attendees and Commenters	X		
Summary of Public Comments and Department Responses	X		
Fiscal Estimate/Economic Impact Analysis		X	
Revised Fiscal Estimate/Economic Impact Analysis			X
Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response			X
Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing			X
DOA report under s. 227.137 (6), Stats., on rules with economic impact of $20 MM or more			X
Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule			X