

The Governor approved this Statement of Scope on August 10, 2017

STATEMENT OF SCOPE
DEPARTMENT OF HEALTH SERVICES

Rule No.: DHS 146

Relating to: Vaccine-preventable diseases

Rule Type: Permanent

Type of Statement of Scope:

Original

1. Finding/nature of emergency (Emergency Rule only):

Not Applicable

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rulemaking is to update the Wisconsin Immunization Program's list of vaccine-preventable diseases, used by the department to purchase and distribute vaccines to school districts and local health departments.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

In s. 252.04 (1), Stats., the Wisconsin State Legislature directs the department to carry out a statewide immunization program to eliminate or protect against certain vaccine-preventable diseases and other diseases that the department specifies by rule. The department is required to provide vaccines for these diseases without charge, upon request of a school district or a local health department, and based upon the availability of federal and state funds. The department proposes to update the Wisconsin Immunization Program's list of vaccine-preventable diseases, used by the department to purchase and distribute vaccines to school districts and local health departments.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

Subsections 250.04 (1) and (8) Stats., read:

(1) The department shall carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus. Any person who immunizes an individual under this section shall maintain records identifying the manufacturer and lot number of the vaccine used, the date of immunization and the name and title of the person who immunized the individual. These records shall be available to the individual or, if the individual is a minor, to his or her parent, guardian or legal custodian upon request.

(8) The department shall provide the vaccines without charge, if federal or state funds are available for the vaccines, upon request of a school district or a local health department. The department shall provide the necessary professional consultant services to carry out an immunization program, under the requirements of sub. (9), in the jurisdiction of the requesting local health department. Persons immunized may not be charged for vaccines furnished by the department.

Paragraph 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.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule :

The department estimates that it will take approximately 320 hours to develop the proposed rule changes. This includes the time required for research and analysis, coordinating an advisory committee, rule drafting, preparing any related documents, holding a public hearing, and communicating with affected persons and groups.

6. List with description of all entities that may be affected by the proposed rule :

Entities that may be affected by the proposed rule include:

- Local health departments and school districts that receive vaccines from the department;
- Tribal health centers and public and private health care providers that distribute the vaccines;
- Individuals to whom the vaccines are administered; and
- The general public that benefits from greater protection from vaccine-preventable diseases.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule :

The Department receives funds for the Wisconsin Immunization Program to purchase vaccines through Section 13631 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) and Section 317 (j) of the Federal Public Health Service Act.

8. Anticipated economic impact of implementing the rule :

The proposed rule is anticipated to have little to no economic impact if promulgated.

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