STATEMENT OF SCOPE

DEPARTMENT OF HEALTH SERVICES

Rule: DHS 144

Relating to: Immunization of Students

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 department proposes to update ch. DHS 144 to ensure consistency with definitions from the Centers for Disease Control and Prevention (CDC) and to update statewide immunization program requirements to reduce the incidence of vaccine-preventable disease and outbreaks.

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:

The department is required to 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. Minimum immunization requirements for entry into Wisconsin schools and day care centers are established in ch. DHS 144. The department proposes to make the following revisions to the rule chapter:

- 1. Varicella (chicken pox) and meningococcal disease are identified by the department as vaccine-preventable diseases. However, a substantial outbreak of these diseases is not currently defined in ch. DHS 144. The department proposes to amend the definition of a "substantial outbreak" to include Varicella (chicken pox) and meningococcal disease, and to ensure consistency with CDC recommendations.
- 2. In recent years, mumps outbreaks have occurred in highly-vaccinated populations and in high-transmission settings, including elementary, middle, and high schools, colleges, and camps. A substantial outbreak of mumps is currently defined as an incidence of the disease exceeding 2% of the unvaccinated population. In 2012, the CDC revised the *Manual for the Surveillance of Vaccine-Preventable Diseases*, to define a substantial outbreak of mumps as three or more cases linked by time and place. The department proposes to amend the definition of a "substantial outbreak" of mumps to be consistent with the CDC *Manual for the Surveillance of Vaccine-Preventable Diseases*.
- 3. The department is proposing to move the current recommendation for Tdap from 6th grade to 7th grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6th grade). This will reduce the number of children who enter 6th grade and are not vaccinated with Tdap, as some clinicians choose to wait until they are 11 years of age to vaccinate.
- 4. *Neisseria meningitidis* is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The meningococcal vaccine is recommended by the Wisconsin Chapter of the American Academy of Pediatrics and the Wisconsin Academy of Family Physicians to reduce the incidence of bacterial meningitis and sepsis. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be administered at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap. The department proposes to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade. This provision will ease the burden on

families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are administered at the same visit and the same grade level.

- 5. Under the current rule, a parent or adult student may report a history of varicella disease as an acceptable exception to varicella vaccination. Recent studies have demonstrated that there is a high incidence of unvaccinated children who report a positive history of varicella that are not immune. The department proposes to allow the exception only when a history of varicella disease has been reported by a health care provider.
- 6. Chapter DHS 144 currently includes provisions relating to the 2008-2009 phase-in of Tdap and Varicella Vaccine coverage. The department proposes to eliminate these provisions because phase-ins are completed.
- 7. Curently, schools must only report compliance with program requirements and key indicators of vaccine-preventable disease and outbreaks to local health departments. The department proposes to add the state as a recipient of these reports which would be congruent with the current day care reporting requirements. This will improve the availability and of important information and improve the department's reporting to the legislature, under s. 252.04 (11), Stats..
- 8. Chapter DHS 144 has not been substantially revised since 1981. The department proposes to update, correct, or clarify any outdated provisions in order to reflect current definitions, standards, and best practices.

There are no reasonable alternative to the proposed rulemaking. The department is required by s. 252.04 (1), Stats., to maintain a statewide immunization program.

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

DHS Chapter 144 is promulgated under the authority of ss. 252.04 (1) and (10), and 227.11 (2) (a), Stats...

Section 252.04 (1), Stats., reads: 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.

<u>Section 252.04 (10)</u>, <u>Stats.</u>, <u>reads</u>: The department shall, by rule, prescribe the mechanisms for implementing and monitoring compliance with this section. The department shall prescribe, by rule, the form that any person immunizing a student shall provide to the student under sub. (1).

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.

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 1,040 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 affect persons and groups.

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

Schools, school-aged children and parents, school boards, and public and private health care providers.

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:

There are no existing or proposed federal regulations that address the activities to be regulated by the rules.

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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