

Report From Agency

ADMINISTRATIVE RULES REPORT TO LEGISLATURE CLEARINGHOUSE RULE 07-077

By the Department of Health and Family Services relating to Ch. HFS 144, Immunization of Students

Basis and Purpose of Proposed Rule

Statutory Authority:

- Section 227.11 (2), Stats., authorizes state agencies to promulgate rules that are necessary to operate their programs.
- Sections 252.04 (1) and (2), Stats., authorize the Department to carry out a statewide immunization program to eliminate several named vaccine-preventable diseases and other diseases that the Department specifies by rule.
- Section 252.04 (10), Stats., authorizes the Department to prescribe by rule the mechanisms for implementing and monitoring compliance with immunization requirements and the form immunization providers are to use to document immunization data.
- Section 48.735, Stats., permits the Department, after notice to a day care center licensee, to suspend, revoke or refuse to continue a day care center license in any case in which the department finds that there has been a substantial failure to comply with the requirements of s. 252.04, Stats.
- Chapter HFS 146 establishes a list of vaccine-preventable diseases for the purpose of purchasing and distributing vaccines without charge under s. 252.04 (8), Stats., with federal or state funds if funds are available for that purpose.

Purpose:

Under section 252.04 (1), Stats., the Department is responsible for carrying 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. To achieve this goal, any student admitted to a day care center, or a nursery, elementary, middle, junior or senior high school is required to present written evidence of having completed the immunizations for each vaccine required for the student's grade. The immunization requirement is waived if the student's parent, guardian or legal custodian submits a written statement to the school or day care center objecting to the immunization for reasons of health, religion or personal conviction. The most recent additions to the list of diseases against which students are to be immunized are hepatitis B (1997) and varicella (chickenpox) (2001). During the past six years, a new vaccine [pneumococcal conjugate vaccine (PCV)] and a new formulation of an existing vaccine [tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap)] have been licensed, a change in the number of doses of a licensed vaccine (varicella vaccine) has been recommended, and the phase-in periods for hepatitis B and varicella vaccine requirements have ended. Therefore, the Department proposes to:

1. Add pneumococcal infection to the list of diseases in ch. HFS 144 against which students in day care centers are to be immunized because PCV has been shown to be highly effective in reducing diseases caused by pneumococcus, e.g., pneumonia, bacteremia, sinusitis and acute otitis media (middle ear infection), among children less than 5 years of age. The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) recommended this vaccine for all children 2-23 months of age, and for children 24-59 months of age who attend day care centers, in 2000.
2. Add Tdap to ch. HFS 144 Table 144.03-A because this vaccine can be given to adolescents. Immunizing older students will prevent pertussis outbreaks in schools and will indirectly protect infants too young to be fully immunized. From 1986 through 2004, Wisconsin had the fifth highest incidence of pertussis in the nation. The ACIP recommended this vaccine for all children at 11-12 years of age in 2005.
3. Add a second dose of varicella vaccine to ch. HFS 144 Table 144.03-A because two doses of the vaccine have

been shown to be more effective than one dose in preventing breakthrough cases. In 2005, the ACIP provisionally recommended two doses of varicella vaccine for all children 1 through 12 years of age and the passage of middle school and high school varicella vaccine requirements.

4. Remove hepatitis B and varicella vaccine coverage phase-in language because these phase-in time periods have passed and the language is no longer necessary.

In addition, the Department proposes the following to update ch. HFS 144:

5. Add language stating that the Department may temporarily suspend a vaccine requirement if the Department determines that there is a shortage of the vaccine because a student could not possibly obtain a required vaccine in such circumstances.
6. Revise the definition of “written evidence of immunization” to include electronic records because immunization registries used by many providers store immunization data that are accessible to schools electronically.
7. Change the language regarding release of immunization information between vaccine providers and schools or day care centers, and among providers, from discretionary to mandatory to create a clear requirement for disclosure.

The intended goals of the proposed rulemaking are to:

- Prevent pneumococcal infections, pertussis infections and break-through varicella infections among students;
- Update the rules by deleting obsolete sections and adding clarifying language; and
- Create a clear requirement for disclosure of immunization information.

Responses to Legislative Council Rules Clearinghouse Recommendations

Comment 2: In s. HFS 144.04 (3) (b) and (3m) (b), the word “through” should be replaced by the word “to.” [See ss.227.27 (1) and 990.001 (14), Stats.]

Response: To describe the phase-in of grades for immunization requirements, the Department has consistently used the word “through” rather than the word “to.” [See HSS 144.03 (3), Register, January 1989, No. 397; HFS 144.03 (3) (b), Register, June 1997, No. 498; HFS 144.03 (3m), Register, December, 2003, No. 576]. The use of the word “through” leaves no doubt that the last grade mentioned is included in the requirement.

Comment 5: The agency should review the provisions relating to disclosure of student immunization information to determine whether they are consistent with the statutes governing privacy of patient records in s. 146.82, Stats. [See s. 146.82 (2) (a) 12, Stats.]

Response: The authority of information flow in the immunization system is s. 252.04 (1), Stats., which authorizes the Department to operate a statewide immunization program, and s. 252.04(10), Stats., which allows the Department to create rules prescribing implementation of the system. Those statutes supersede s. 146.82, Stats., just as the communicable disease reporting that occurs pursuant to ch. 252, Stats., supersedes s. 146.82, Stats.

Final Regulatory Flexibility Analysis

Day care centers are organized as small businesses [about 95% of the 2,485 group (9 or more children) day care centers in the state are small businesses, as are all of the 3,122 family (4-8 children) day care centers]. Day care centers will experience some increase in workload in tracking compliance with the requirement for PCV, reporting compliance to the Department, and in referring noncompliant students to the district attorney or corporation counsel for enforcement action. It is not known how much workload will increase or its impact, if any, on costs. However, since 85% of children in Wisconsin have already received PCV, the vast majority of day care center students will be compliant with the requirement when it takes effect and will not require warning letters from day care centers or enforcement action by district attorneys. Additionally, the tracking and reporting burden on day care centers will be mitigated by requiring fewer than the maximum number of doses of PCV. Day care centers for many years have been checking for compliance with required immunizations for school entry. They are part of the system for protecting children against diseases that are preventable through

administration of approved vaccines.

Day care centers are the only small businesses that the proposed rules will affect. Pursuant to the foregoing analysis, the Department believes that these rules will not have a significant economic impact on day care centers.

Changes to the Analysis or Fiscal Estimate

Analysis

No changes were made to the analysis.

Fiscal Estimate

No changes were made to the fiscal estimate.

Public Hearing Summary

Public hearings were held October 15, 2007 in Waukesha; October 16, 2007 in Wausau; October 18, 2007 in Madison. There were 4 attendees, total, at the public hearings. Several written comments were received during the public comment period.

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, the position taken by the commenter and whether or not the individual provided written or oral comments.

Name and Address	Position Taken (Support or Opposed)	Action (Oral or Written)
1. Thomas R. Saterstrom 10941 Ewing Ave. So. Bloomington, MN 55431	None given	Observed only
2. Casey Schumann 1 W. Wilson St. Madison, WI 53701	None given	Observed only
3. Sandy Breitborde 1 W. Wilson St., Rm 318 Madison, WI 53701	None given	Observed only
4. James H. Conway, MD Associate Professor of Pediatrics 600 Highland Ave. H4/450 CSC Madison, WI 53792	Support	Oral
5. A. Judy Smolarek, Co-President Wisconsin Association of Local Health Departments and Boards 702 Eisenhower Dr., Suite A Kimberly, WI 54136	Support	Written
B. Dennis Wedde, Co-President Wisconsin Association of Local Health Departments and Boards 702 Eisenhower Dr., Suite A Kimberly, WI 54136	Support	Written

	Name and Address	Position Taken (Support or Opposed)	Action (Oral or Written)
	C. Mark Huber, President Wisconsin Public Health Association 702 Eisenhower Dr., Suite A Kimberly, WI 54136	Support	Written
6.	Shannon Duffy Peterson 21494 Sherwood Ave. Sleepy Eye, MN 56085	Support	Written
7.	William L. Trager, MD Sheboygan, WI 53083	Support	Written
8.	Donna & Jeff Kutter 4320 122 nd St. Pleasant Prairie, WI 53158	Support	Written
9.	"A Group of Moms" A. Frankie Milley 17060 Cypress Circle Connor, TX 77302	Support	Written
	B. Linda Williams 321 Burch Rd. No further address available	Support	Written
	C. Dawn Thibodeaux	Support	Written
	D. Sonya Fischer ?Mississippi	Support	Written
	E. Linda ?Washington	Support	Written
	F. Renee Robertson ?Kentucky	Support	Written
10.	Dee Dee and Bob Werner S95 W32805 Hickorywood Trail Mukwonago, WI 53149	Support	Written
11.	Jason Friedlander, MD Children's Hospital and Health System	Support	Written
12.	Sheryn Abraham, MD Kenosha Area Pediatrician	Support	Written
13.	Dane County Immunization Coalition Board of Directors 2705 E. Washington Ave Madison, WI 53704	Support	Written
14.	George Idarraga, MD Aurora	Support	Written
15.	Kathleen G. Sprangers, RN, President Northeast Wisconsin Immunization Coalition PO Box 2863 Appleton, WI 54912-2863	Support	Written

Name and Address		Position Taken (Support or Opposed)	Action (Oral or Written)
16.	David Waters, MD 16 th Street Community Health Center Milwaukee, WI	Support	Written
17.	Sherry Workman, Executive Director/CEO National Association of Child Care Professionals PO Box 90723 Austin, TX 78709-0723	Support	Written

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	<p style="text-align: right;">4</p> <p>The speaker, a member of the Wisconsin Council on Immunization Practices (WCIP) and representing the Wisconsin Academy of Pediatrics, states strong support for the proposed changes because of the importance of immunizations in preventing disease and the fact that schools are likely settings for disease transmission. The immunization schedule has been expanded and the rules need to be updated to include new vaccines, formulations and recommendations. Additionally, school requirements equalize poor access to health care and effectively disseminate information to parents. The provision that allows the Department to suspend requirements if vaccine is unavailable is also needed. The requirements are phased-in gradually over time so as not to be a burden to schools, providers or parents.</p>	No response necessary
General	<p style="text-align: right;">5 A, B, C</p> <p>The writers, representing the Wisconsin Public Health Association and the Wisconsin Association of Local Health Departments and Boards, state that the proposed changes, are both sensible and necessary. The modifications strike an excellent balance between the protection of public health and the cost and obligation placed on school districts.</p>	No response necessary
Table 144.03-A, specifically, the PCV and Var requirements	<p style="text-align: right;">6</p> <p>The writer's 5 ½ year-old daughter died in 2001 of overwhelming sepsis caused by streptococcal pneumonia, congenital asplenia and hemorrhagic adrenal glands, having suffered a severe varicella infection several months earlier. She asks that this ruling to require chickenpox and pneumococcal vaccinations be passed.</p>	No response necessary

Rule Provision	Public Comment	Department Response
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">7</p> <p>The writer states that “from a medical standpoint, this vaccine for day care is a great thing. It has certainly reduced the incidence of serious pneumococcal infections.”</p>	No response necessary
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">8</p> <p>The writers’ 17 year-old son died from meningitis in 2007. They state, “Please...add the pneumococcal meningitis vaccine to the list of required childhood immunizations.”</p>	Meningitis can be caused by several agents. The PCV requirement is intended to prevent a spectrum of diseases, including meningitis, caused by Streptococcus pneumoniae (pneumococcus). Some of the people about whom commenters 8, 9 and 10 write had meningitis caused by a different agent, often Neisseria meningitidis (meningococcus), which would not have been prevented by PCV. Section 252.09 (1) (a), Stats. requires colleges and universities to annually inform students of the risks associated with meningococcal disease and the effectiveness of prevention through vaccination.
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">9 A, B, C, D, E, F</p> <p>The writers support the addition of “pneumococcal meningitis vaccine” to the list of required immunizations. They are related in some way to people who have died or been seriously injured by meningitis and share their personal stories in their letters.</p>	See response to #8.
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">10</p> <p>The writers’ 20 year-old daughter died of meningitis in 2004. “Please help us protect the children of Wisconsin and add pneumococcal vaccine to the required list of children’s vaccines.”</p>	See response to #8.
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">11</p> <p>The writer, a physician, supports the addition of PCV vaccine to the list of vaccines needed to attend day care.</p>	No response necessary
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">12</p> <p>The writer, a pediatrician, supports the proposed change to the Wisconsin Childhood Immunization Requirement that adds PCV vaccine to the list of vaccines required to attend day care and states this would ensure improved vaccine compliance.</p>	No response necessary
General	<p style="text-align: right;">13</p> <p>The Dane County Immunization Coalition Board of Directors supports the addition of</p>	No response necessary

Rule Provision	Public Comment	Department Response
	requirements for PCV, Tdap and second dose varicella to the rule. “Vaccinating children is a safe, cost-effective way to prevent illness and save lives.”	
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">14</p> <p>The writer, a physician, supports the proposed changes to the Wisconsin immunization childhood requirement which adds PCV to the list of vaccines needed to attend day care. “Young children who attend daycare are at peak risk for pneumococcal infections and I believe that the vaccine is an effective prudent way to protect them.”</p>	No response necessary
General	<p style="text-align: right;">15</p> <p>On behalf of the Northeast Wisconsin Immunization Coalition (NEWIC), the writer expresses support for the proposed amendments, stating that “Immunization requirements help improve compliance and are a very cost-effective way to keep individuals and communities healthy from vaccine-preventable diseases.” NEWIC is a multidisciplinary organization with members from Outagamie, Brown, Marinette, Door, Fond du Lac, Waupaca, Calumet, Winnebago, Manitowoc and Oconto counties.</p>	No response necessary
General	<p style="text-align: right;">16</p> <p>The writer, a pediatrician and member of the WCIP, supports all the proposed changes and improvements for vaccine administration updating HFS 144.</p>	No response necessary
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">17</p> <p>The writer, the Executive Director of the National Association of Child Care Professionals, supports the proposed rule requiring PCV for children attending Wisconsin childcare facilities. “Immunizing children is a necessity, not a burden.”</p>	No response necessary