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**** 07hr_CRule_07-077_SC-PHSILTCP_pt01**

WISCONSIN STATE
LEGISLATURE ...
PUBLIC HEARING
COMMITTEE RECORDS

2007-08

(session year)

Senate

(Assembly, Senate or Joint)

Committee on
Public Health, Senior
Issues, Long Term
Care and Privacy

(SC-PHSILTCP)

(FORM UPDATED: 07/02/2010)

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**INFORMATION COLLECTED BY
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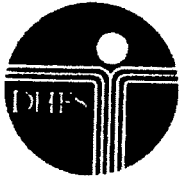
Name:

➤ Clearinghouse Rules ... CRule
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State of Wisconsin
Department of Health and Family Services

Jim Doyle, Governor
Kevin R. Hayden, Secretary

November 27, 2007

The Honorable Fred Risser, President
Wisconsin State Senate
State Capitol, Room 220 South
Madison, WI 53702

The Honorable Michael Huebsch, Speaker
Wisconsin State Assembly
State Capitol, Room 211 West
Madison, WI 53702

Re: Clearinghouse Rule 07-077
HFS 144, relating to student immunizations

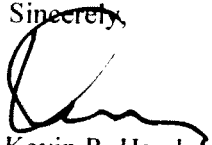
Gentlemen:

In accordance with the provisions of s. 227.19 (2), Stats., you are hereby notified that the above-mentioned rules are in final draft form. This notice and the report required by s. 227.19 (3), Stats., are submitted herewith in triplicate.

The rules were submitted to the Legislative Council for review under s. 227.15, Stats. A copy of the Council's report is also enclosed.

If you have any questions about the rules, please contact Marjorie Hurie at 608- 264-9892.

Sincerely,



Kevin R. Hayden
Secretary

cc Gary Poulson, Assistant Revisor of Statutes
Senator Robert Jauch, JCRAR
Representative Daniel LeMahieu, JCRAR
Marjorie Hurie, DHFS-DPH
Katie Plona, DHFS Secretary's Office

**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
	C. Mark Huber, President Wisconsin Public Health Association 702 Eisenhower Dr., Suite A Kimberly, WI 54136	Support	Written

	Name and Address	Position Taken (Support or Opposed)	Action (Oral or 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
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	Support	Written

Name and Address	Position Taken (Support or Opposed)	Action (Oral or Written)
Austin, TX 78709-0723		

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 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 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 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
Table 144.03-A, specifically, the PCV requirement	<p 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,	<p align="right">8</p>	Meningitis can be caused by

Rule Provision	Public Comment	Department Response
specifically, the PCV requirement	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."	several agents. The PCV requirement is intended to prevent a spectrum of diseases, including meningitis, caused by <i>Streptococcus pneumoniae</i> (pneumococcus). Some of the people about whom commenters 8, 9 and 10 write had meningitis caused by a different agent, often <i>Neisseria meningitidis</i> (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: center;">9 A, B, C, D, E, F</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.	See response to #8.
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">10</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."	See response to #8.
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">11</p> The writer, a physician, supports the addition of PCV vaccine to the list of vaccines needed to attend day care.	No response necessary
Table 144.03-A, specifically, the PCV requirement	<p style="text-align: right;">12</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.	No response necessary
General	<p style="text-align: right;">13</p> The Dane County Immunization Coalition Board of Directors supports the addition of 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."	No response necessary
Table 144.03-A, specifically, the PCV	<p style="text-align: right;">14</p> The writer, a physician, supports the	No response necessary

Rule Provision	Public Comment	Department Response
requirement	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."	
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





**WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE**

Ronald Sklansky
Clearinghouse Director

Terry C. Anderson
Legislative Council Director

Richard Sweet
Clearinghouse Assistant Director

Laura D. Rose
Legislative Council Deputy Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE 07-077

AN ORDER to amend HFS 144.01 (1), 144.02 (3) and (14), and 144.03 (10) (a) and (b); to repeal and recreate HFS 144.03 (2) (title) and (a) and Table 144.03-A, 144.02 (2) (f), and 144.03 (3) and (3m); and to create HFS 144.02 (6m), 144.03 (2) (h) and (i), and 144.09 (1) (d), relating to the statewide immunization program and affecting small businesses.

Submitted by **DEPARTMENT OF HEALTH AND FAMILY SERVICES**

08-10-2007 RECEIVED BY LEGISLATIVE COUNCIL.

08-28-2007 REPORT SENT TO AGENCY.

RS:RW

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]

Comment Attached YES NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES NO



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sklansky
Clearinghouse Director

Richard Sweet
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Laura D. Rose
Legislative Council Deputy Director

CLEARINGHOUSE RULE 07-077

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated January 2005.]

2. Form, Style and Placement in Administrative Code

In s. HFS 144.03 (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.]

5. Clarity, Grammar, Punctuation and Use of Plain Language

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.]



**PROPOSED ORDER OF
DEPARTMENT OF HEALTH AND FAMILY SERVICES
TO ADOPT RULES**

The Wisconsin Department of Health and Family Services proposes to amend HFS 144.01 (1), 144.02 (3) and (14), 144.03 (10) (a) and (b); to repeal and recreate HFS 144.03 (2) (title) and (a) and Table 144.03-A, 144.02 (2) (f), 144.03 (3) and (3m); and to create HFS 144.02 (6m), 144.03 (2) (h) and (i), 144.09 (1) (d), and affecting small businesses.

SUMMARY OF PROPOSED RULE

Statute interpreted: Sections 252.04 (1) to (7) and (10), Stats.

Statutory authority: Sections 227.11 (2), 252.04 (1), (2), and (10), Stats.

Explanation of agency authority:

Section 227.11 (2), Stats., authorizes state agencies to promulgate rules that are necessary to operate their programs. Sections 252.04 (1) (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.

Related statute or rule:

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.

Plain language analysis:

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 amend ch. HFS 144, rules governing immunization of students, to accomplish the following:

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.

An alternative to regulatory action is promotion of these vaccine recommendations to parents and immunization providers. Allowing time to elapse between licensure of a vaccine and enacting a school requirement has traditionally allowed market forces to increase the number of immunized children. However, coverage achieved through voluntary compliance with vaccine recommendations is always lower than that achieved through regulation. Before states enacted school vaccine requirements, outbreaks of vaccine-preventable diseases continued long after vaccine licensure because vaccine coverage was suboptimal. For example, although an effective measles vaccine was licensed in 1967, measles outbreaks involving thousands of Wisconsin children continued to occur until a school requirement was set in place in 1980.

Summary of, and comparison with, existing or proposed federal regulations:

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

Comparison with rules in adjacent states:**Illinois:**

77 Illinois Administrative Code Section 695.10 requires students entering a child care facility or a school to present proof of immunity against diphtheria, pertussis, tetanus, poliomyelitis, measles, rubella, mumps, Haemophilus influenzae type B (Hib), hepatitis B and varicella. The rules do not require pneumococcal conjugate vaccine (PCV), tetanus, diphtheria and acellular pertussis (Tdap) vaccine for 6th graders, or a second dose of varicella vaccine for students 1-12 years of age. However, at the time these rules were last revised in 2002, Tdap vaccine had not been licensed and a second dose of varicella vaccine for 1-12 year olds had not been recommended. Lastly, the rule does not mention electronic records, suspend a vaccine requirement due to a vaccine shortage or require release of immunization information between providers and schools.

Iowa:

Iowa Administrative Code 641 Chapter 7.4 (1) requires diphtheria, pertussis, tetanus, poliomyelitis, measles, rubella, varicella and Hib for students enrolling in a licensed child care center and diphtheria, pertussis, tetanus, poliomyelitis, measles, rubella, varicella and hepatitis B for students in an elementary or secondary school. Ch. 7.6 (1) states that a valid certificate of immunization may be a computer-generated copy from an immunization registry. Ch. 7.12 (1) and 7.12 (2) state that release of immunization information between vaccine providers and schools or day care centers, and among providers, is required. The rules do not require Tdap vaccine for 6th graders, or a second dose of varicella vaccine for students 1-12 years of age. However, a requirement for PCV was passed by the Iowa legislature in the spring of 2007 and will go into effect in January 2009.

Michigan:

Michigan Administrative Code 325.176 Rule 6 (2) – 6 (6) requires diphtheria, pertussis, tetanus, poliomyelitis, Hib, measles, mumps, rubella, hepatitis B, varicella and PCV for students in day care centers. Rule 6 (9) requires diphtheria, tetanus, poliovirus, measles, mumps, rubella, hepatitis B and varicella for students 7 through 18 years of age who are entering school or in the 6th grade. Rule 6 (17) states that a specific vaccine requirement may be suspended temporarily at the request of the department director if the vaccine supply is inadequate. Rule 325.163 (5) requires that immunization information be submitted on a form prescribed by the department except for a report that is submitted by electronic transmission or on electronic media. These rules were last revised in 2006. Michigan Compiled Law (MCL) 333.9206 (3) requires health care providers to report to the department each immunization they administer unless the parent objects in writing. Requirements for Tdap vaccine and a second dose of varicella vaccine for students who were previously required to have only one dose are pending in the Michigan legislature. Passage is expected in the fall of 2007 with the requirements anticipated to go into effect in January 2009.

Minnesota:

Minnesota Statute 121A.15 subdivision 1 requires diphtheria, pertussis, tetanus, poliomyelitis, measles, rubella, mumps, Hib and hepatitis B vaccine for students in child care facilities and schools. This statute was last revised in 2006. Minnesota Rule Chapter 4604.0900 requires varicella vaccine for children enrolled in a child care facility, kindergarten or seventh grade. Since the rule requires documentation of receipt of varicella vaccine consistent with medically acceptable standards, the rule would not need to be revised to require 2 doses of vaccine for students 1 through 12 years of age. Minnesota Rule Chapter 4604.1000 requires PCV for children enrolled in

child care facilities. The requirements for varicella vaccine and PCV went into effect in 2004. Minnesota Rule Chapter 4604.0700 requires the commissioner of health to suspend an immunization requirement if the commissioner determines that suspension is necessary to address a vaccine shortage or other emergency situation statewide or in a portion of the state. Minnesota statute 144.3351 states that providers, group purchasers, schools, child care facilities, boards of health, community action agencies and the commissioner of health may exchange immunization data with each other. There is no requirement for Tdap vaccine for 6th graders in these statutes or rules.

The table below compares the important elements in the Department’s proposed rulemaking with current immunization rules and statutes in Illinois, Iowa, Michigan and Minnesota:

Comparison with Neighboring States						
State	PCV required	Tdap for 6 th graders required	2 nd dose Varicella for 5-12 yr. olds required	Electronic records	Health authority able to suspend vaccine requirement	Release of imm. info between vaccine providers and schools OK
Illinois	No	No	No	No	No	No
Iowa	Yes	No	No	Yes	No	Yes - mandatory
Michigan	Yes	Pending in legislature	Pending in legislature	Yes	Yes	Yes - mandatory
Minnesota	Yes	No	No	No	Yes	Yes - discretionary

Summary of factual data and analytical methodologies:

This proposed rulemaking adds immunization requirements for students in day care centers and schools, necessitating the purchase of vaccine by public and private insurers. Sources of funds for vaccine purchase for children 18 years of age and younger include the federal Vaccines for Children Program (VFC), which covers children who are eligible for Medical Assistance, have no insurance, are Native American or Alaska Native, or are underinsured and receive care from a federally qualified health center or a rural health center; section 317 of the Public Health Service Act funds, which are used to purchase vaccine for children who receive their immunizations from local health departments; and private health insurance. VFC funds are sum sufficient. Federal 317 funds may not meet actual needs but have been sufficient to cover the vaccine costs associated with the Department’s implementation of previous vaccine requirements.

- The estimate of the percentage of Wisconsin children who are privately insured is based on data from the Wisconsin Health Insurance Coverage section of the 2005 Wisconsin Family Health Survey.
- The number health and medical insurance carriers in Wisconsin (North American Industry Classification Code 524114), as well as summary data on the annual payroll and number of paid employees, was reported in the 2002 Economic Census – Wisconsin Geographic Series.
- Information on the small business status per s. 227.114 (1), Stats., of Wisconsin health insurers was obtained from the Office of the Commissioner of Insurance (Julie Walsh, Attorney, 264-8101).

Adding the requirement for PCV will also increase by one the number of immunizations day care center staff must review to determine whether a child meets the requirements of the rule.

- The number of family and group day care centers in Wisconsin in 2006 was reported in the Department's Division of Children and Family Services, Bureau of Regulation and Licensing's Statewide Capacity Statistics Report (http://www.dhfs.state.wi.us/rl_dcfs/SummaryReports/Attachments/c.pdf): Because the Bureau does not gather data on day care center staffing, the percent of day care centers that fit the small business definition in s. 227.114 (1), Stats., is based on the percentage of group day care centers with capacity for less than 150 children. It is assumed that day care centers with capacity for less than 150 children employ fewer than 25 staff, according to Ann Carmody, Day Care Licensing, 267-9761.
- The 2005 National Immunization Survey shows that 85% of Wisconsin children aged 19 to 35 months had received 3 doses of PCV.

Analysis and supporting documents used to determine effect on small business:

Approximately 60% of children in Wisconsin have private health insurance. There are 122 direct health and medical insurance carriers in Wisconsin with a total of 23,000 paid employees. The only health care insurers in Wisconsin that meet the definition of a small business in s. 227.114 (1), Stats., are limited scope health plans that, for example, only offer dental or vision coverage. Health care insurers that offer comprehensive coverage for pediatric health care, including immunizations, do not meet the definition of a small business.

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.

Effect on small business:

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.

Agency contact person:

Marjorie Hurie, RN, MS
 Program Consultant
 Immunization Program
 PO Box 2659
 Madison, WI 53701
 608-264-9892

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The deadline for submitting comments and the notice of public hearing will be posted on the Wisconsin Administrative Rules Website at <http://adminrules.wisconsin.gov> after the hearing is scheduled.

TEXT OF PROPOSED RULE

SECTION 1. HFS 144.01 (1) is amended to read:

HFS 144.01(1) PURPOSE AND AUTHORITY. The purpose of immunization is to prevent disease and suffering and any permanent disability resulting from the disease. These rules implement s. 252.04, Stats., which as public policy seeks to identify and immunize those students who are still susceptible to measles, mumps, rubella, polio, hepatitis B, varicella, diphtheria, tetanus and pertussis upon admission to an elementary, middle, junior or senior high school or a day care center, or *Haemophilus influenzae b* and pneumococcal infection upon admission to a day care center, in order to prevent transmission of these diseases.

SECTION 2. HFS 144.02 (3) and (14) are amended to read:

HFS 144.02 (3) "DTP/DTaP/DT/Td/Tdap" means any combination of diphtheria, tetanus, and pertussis vaccine; diphtheria, tetanus and acellular pertussis vaccine; pediatric type diphtheria and tetanus vaccine; ~~or adult type tetanus and diphtheria vaccine; or tetanus, reduced diphtheria and acellular pertussis vaccine.~~

(14) "Written evidence of immunization" means a paper or an electronic record of at least the month and year that each required dose of vaccine was administered or the results of a laboratory test indicating immunity to the disease. Students who have not previously attended a Wisconsin school ~~and who enter after the 1980-81 school year~~ must provide the month, day and year for each required dose of vaccine.

SECTION 3. HFS 144.02 (6m) is created to read:

HFS 144.02 (6m) "PCV" means pneumococcal conjugate vaccine.

SECTION 4. HFS 144.03 (2) (title) and (a) and Table 144.03-A are repealed and recreated to read:

HFS 144.03 (2) (title) REQUIREMENTS FOR THE 2008-09 SCHOOL YEAR AND FOR SCHOOL YEARS FOLLOWING THE 2008-09 SCHOOL YEAR. (a) Table HFS 144.03-A as qualified by pars. (b) to (g) lists the number of doses of each required vaccine that each student in the 2008-09 school year and following school years shall have received since birth for the age or grade of the student. These comprise the minimum basic and booster immunizations required under s. 252.04 (2), Stats. They do not, however, represent all the recommended immunizations for those individuals who begin immunizations in infancy and follow currently accepted immunization schedules.

**TABLE HFS 144.03-A
Required Immunizations for the 2008-09 School Year and
the Following School Years**

Age/Grade	Required Immunizations (Number of Doses)					
5 months through 15 months	2 DTP/DTaP/DT		2 Polio		2 Hep B	2 Hib 2 PCV ⁵
16 months through 23 months	3 DTP/DTaP/DT		2 Polio	1 MMR	2 Hep B	3 Hib ⁴ 3 PCV ⁵
2 years through 4 years	4 DTP/DTaP/DT		3 Polio	1 MMR	1 Var	3 Hep B 3 Hib ⁴ 3 PCV ⁵
Kindergarten through grade 5	4 DTP/DTaP/DT/Td ¹		4 Polio	2 MMR	2 Var ³	3 Hep B
Grade 6 through grade 8	4 DTP/DTaP/DT/Td	1 Tdap ²	4 Polio	2 MMR	2 Var ³	3 Hep B
Grade 9 through grade 12	4 DTP/DTaP/DT/Td	1 Tdap ²	4 Polio	2 MMR	2 Var ³	3 Hep B

1. For kindergarten only, at least one dose to be received after 4 years of age unless medically contraindicated. A dose received 4 days or less before the fourth birthday is acceptable.
2. A single dose, booster immunization against tetanus, diphtheria and pertussis is required on entrance to grades 6, 9 and 12, beginning with the 2008-09 school year. See sub. (3) for phase-in of other grades.
3. Two doses of Var vaccine are required on entrance to grades K, 6 and 12, beginning with the 2008-09 school year. See sub. (3m) for phase-in of other grades.
4. At least one dose to be received after 12 months of age unless medically contraindicated. A dose received 4 days or less before the first birthday is acceptable
5. Required on entrance to a day care center, beginning with the 2008-09 school year.

SECTION 5. HFS 144.03 (2) (f) is repealed and recreated to read:

HFS 144.03(2) (f) Exceptions may be made in requirements for Var vaccine. Students who have a reliable history of varicella disease are not required to receive Var vaccine. A parent of a minor student or an adult student may indicate a reliable history of varicella by signing a statement that the student has had varicella disease.

SECTION 6. HFS 144.03 (2) (h) and (i) are created to read:

HFS 144.03 (2) (h) Exceptions may be made in requirements for PCV. Students who begin the PCV series at 12 to 23 months of age are only required to receive 2 doses at least 2 months apart. Students who receive their first dose of PCV at 24 months of age or after are not required to obtain additional doses. A dose received 4 days or less before 24 months of age is acceptable.

(i) Exceptions may be made in requirements for Tdap vaccine. Students who received a dose of tetanus or diphtheria containing vaccine within 5 years of entering a grade for which Tdap is required are not required to receive Tdap vaccine.

SECTION 7. HFS 144.03 (3) and (3m) are repealed and recreated to read:

HFS 144.03 (3) Tdap VACCINE COVERAGE PHASE-IN. (a) Beginning with the 2008-09 school year, students entering grades 6, 9 and 12 shall have received Tdap vaccine in addition to the other required vaccines listed in Table HFS 144.03-A as qualified by sub. (2) (b) to (i).

(b) For the 2009-10 school year, the requirements for Tdap vaccine listed in par. (a) that apply to students in grades 6, 9 and 12 shall apply to students in grades 6, 7, 9, 10 and 12; and to students in grades 6 through 12 in 2010-11 and thereafter.

(3m) VAR VACCINE COVERAGE PHASE-IN. (a) Beginning with the 2008-09 school year, students entering grades K, 6 and 12 shall have received two doses of Var vaccine in addition to the other required vaccines listed in Table HFS 144.03-A as qualified by sub. (2) (b) to (i).

(b) For the 2009-10 school year, the requirements for two doses of Var vaccine listed in par. (a) that apply to students in grades K, 6 and 12 shall apply to students in grades K, 1, 6, 7 and 12; to students in grades K through 2, 6 through 8 and 12 in 2010-11; to students in grades K through 3, 6 through 9 and 12 in 2011-12; to students in grades K through 4, 6 through 10 and 12 in 2012-13; and to students in grades K through 12 in 2013-14 and thereafter.

SECTION 8. HFS 144.03 (10) (a) and (b) are amended to read:

HFS 144.03 (10) (a) *Between vaccine providers and schools or day care centers.* Vaccine providers ~~may~~shall disclose a student's immunization information, including the student's name, date of birth and gender and the day, month, year and name of vaccine administered, to a school or day care center upon written or verbal request from the school or day care center. Written or verbal permission from a student or parent is not required to release this information to a school or day care center.

(b) *Among vaccine providers.* Immunization information, including the student's name, date of birth and gender and the day, month, year and name of vaccine administered, ~~may~~shall be provided by one vaccine provider to another without written or verbal permission from the student or the parent.

SECTION 9. HFS 144.09 (1) (d) is created to read:

HFS 144.09 (1) (d) The department may temporarily suspend an immunization requirement if the department determines that the supply of a necessary vaccine is inadequate.

EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health and Family Services

Dated:

Kevin R. Hayden, Department Secretary

SEAL:



ADMINISTRATIVE RULES – FISCAL ESTIMATE

1. Fiscal Estimate Version

Original Updated Corrected

2. Administrative Rule Chapter Title and Number

HFS 144, Immunization of Students

3. Subject

To revise ch. HFS 144, relating to pneumococcal conjugate vaccine; tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine; and second dose varicella vaccine requirements for students.

4. State Fiscal Effect:

No Fiscal Effect

Indeterminate

Increase Existing Revenues

Decrease Existing Revenues

Increase Costs

Yes No

May be possible to absorb within agency's budget.

Decrease Costs

5. Fund Sources Affected:

GPR FED PRO PRS SEG SEG-S

6. Affected Ch. 20, Stats. Appropriations:

7. Local Government Fiscal Effect:

No Fiscal Effect

Indeterminate

Increase Revenues

Decrease Revenues

Increase Costs

Decrease Costs

8. Local Government Units Affected:

Towns Villages Cities Counties School Districts WTCS Districts Others:

9. Private Sector Fiscal Effect (small businesses only):

No Fiscal Effect

Indeterminate

Increase Revenues

Decrease Revenues

Yes No May have significant economic impact on a substantial number of small businesses

Increase Costs

Yes No

May have significant economic impact on a substantial number of small businesses

Decrease Costs

10. Types of Small Businesses Affected:

Day care centers

11. Fiscal Analysis Summary

This rulemaking requires pneumococcal conjugate vaccine (PCV), a new formulation of diphtheria, tetanus and pertussis (whooping cough) vaccine (Tdap), and a second dose of varicella (chickenpox) vaccine for students. The vaccines the Department provides upon request and without charge to local health departments and private health care providers is purchased by the Department with a line of credit provided by the federal government's Centers for Disease Control and Prevention (CDC) or with GPR funds under s. 20.43(1)(cm), Stats. Section 20.43(1)(cm), Stats., authorizes the Department to expend an amount that is equal to the difference between the statutory limit of a \$9,000,000 sum sufficient appropriation and the amount of funding the Department receives for the federal Vaccines for Children Program (VFC) and Section 317 of the Public Health Service Act. VFC funds are sum sufficient. Federal 317 funds are not guaranteed to meet actual need but have been sufficient to cover the vaccine costs associated with the Department's implementation of previous vaccine requirements. The total estimated cost for vaccine to implement the proposed requirements in the 2008-09 school year is \$22

million; the possible annual cost to the state, in the unlikely event that no 317 funds are available, is \$3.6 million. The following assumptions were used to estimate costs:

- PCV: The vaccine costs \$73.70 in the private sector and \$57.59 in the public sector; 85% of children have already received PCV vaccine; 50% of children are enrolled in a day care center; 5% of students' parents will elect to waive the requirement. Thus, of a total annual cohort of 359,000 0-4 year olds, 25,500 students will require vaccine. Private providers will pay 59% of the vaccine cost (\$1.6 million); the federal VFC Program will pay 21% of the vaccine cost (\$434,000); and federal 317 funds or GPR funds will pay 19% of the vaccine costs (\$392,000).
- Tdap Vaccine: The vaccine costs \$36.84 in the private sector and \$30.75 in the public sector; 20% of the cohort of 6th, 9th and 12th grade students has already been vaccinated; 5% of the students' parents will elect to waive the requirement. Thus, of a total annual cohort of 228,000 students, 182,000 will require vaccine. Private providers will pay 59% of the vaccine cost (\$3.8 million), the federal VFC Program will pay 21% of the vaccine cost (\$1.1 million, and federal 317 funds or GPR funds will pay 19% of the vaccine costs (\$1 million).
- Second Dose Varicella Vaccine: The vaccine costs \$71.11 in the private sector and \$56.90 in the public sector; 3% of the cohort of kindergarteners, 6th and 12th grade students has already had chickenpox; 5% of the students' parents will elect to waive the requirement. Thus, of a total annual cohort of 223,000 students, 205,000 will require vaccine. Private providers will pay 59% of the vaccine costs (\$8.6 million); the federal VFC Program will pay 21% of the vaccine costs (\$2.5 million); and federal 317 funds or GPR funds will pay 19% of the vaccine costs (\$2.2 million).

The rule changes will not affect the expenditures or revenues of local county and city health departments. Local health departments are responsible under s. HFS 144.08 for making available the required immunizations but only insofar as free vaccines are available from the Department. Local health departments are to administer the vaccines without charging for the vaccines but they may charge, and some do charge, for the costs of administration.

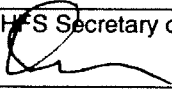
The rule changes may increase costs for schools and for district attorney or corporation counsel offices. Schools, including day care centers, will experience some increase in workload tracking compliance with the new requirements, reporting compliance to the Department and referring noncompliant students to the district attorney or corporation counsel for enforcement action. It is not know 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 or enforcement action. Additionally, the tracking and reporting burden on day care centers has been mitigated by requiring fewer than the maximum possible number of doses of PCV. Day care centers for many years have been checking for compliance with required immunizations for school entry. This is part of the system for protecting children against diseases that are preventable through administration of approved vaccines.

This rulemaking also removes outdated language, adds clarifying language and permits the Department to suspend a vaccine requirement in the event of a vaccine shortage. These changes carry no fiscal effect. Vaccine shortages are impossible to predict and any savings that resulted from the suspension of a requirement would be spent when the requirement resumed.

12. Long-Range Fiscal Implications

The vaccination requirement phase-in period will take 3 years for Tdap and 6 years for the second dose of varicella, beginning in the 2008-09 school year. The phase-in strategy for both vaccines initiates requirements at 3 grade levels and advances requirements by 2 grade levels annually. Advancing requirements has little effect on costs, since most students will have received the required vaccines in the year they were required. The estimate of how many students will need vaccine in the succeeding years of the requirements is based on the average domestic net migration to Wisconsin, which was considerably less than 1% in 2004. The total estimated costs for vaccine to implement these proposed requirements in the school years following the 2008-09 school year, (and the possible but unlikely annual cost to the state), are as follows: 2009-10: \$22 million (\$3.6 million); 2010-11: \$22 million (\$3.6 million); 2011-12: \$18 million (\$3 million); 2012-13: \$18 million (\$3 million); 2013-14: \$18

million (\$3 million). After the phase-in period is complete, the total ongoing vaccine costs of these requirements (and the the possible but unlikely annual cost to the state) will be \$8.9 million (\$1.2 million).

13. Name - Prepared by Marjorie Hurie	Telephone Number 608-264-9892	Date 06/20/07
14. Name - OSF Analyst Reviewer Ellen Hadidian/Donna Moore	Telephone Number 608-266-8155	Date 8/8/07
Signature - DHS Secretary or Designee 	Telephone Number 266-0667	Date 8-10-07