

Clearinghouse Rule 07-077

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:

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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: