

Clearinghouse Rule 18-064

PROPOSED ORDER OF DEPARTMENT OF HEALTH SERVICES TO ADOPT PERMANENT RULES

The Wisconsin Department of Health Services (the “department”) proposes an order to amend s. DHS 146.04 (2) (Note), and repeal and recreate s. DHS 146.03 and (Note), relating to Vaccine-Preventable Diseases.

RULE SUMMARY

Statutes interpreted

Section 252.04, Stats.

Statutory authority

Sections 252.04 and 227.11 (2) (a), Stats.

Explanation of agency authority

In s. 252.04 (1), Stats., the Legislature directs the department to carry out a statewide immunization program to eliminate or protect against certain vaccine-preventable diseases and other diseases that the department specifies by rule.

Related statute or rule

Chapters DHS 144 and 145, and Chapter 250, Stats.

Plain language analysis

The department is charged with carrying out a statewide immunization program. Essential to this charge of protecting individuals from vaccine preventable diseases is the ability to purchase vaccines, should federal or state funds be available. These vaccines are then made available, free of charge, to eligible individuals through the local health departments and tribal health clinics, as well as health care providers throughout the state who participate in the Vaccines for Children (“VFC”) Program. The proposed rule updates the list of vaccines which the Division of Public Health may make available.

No reasonable alternatives exist to the rulemaking. Without proposed revisions to Chapter DHS 146, the vaccines provided to Wisconsin local health departments and tribes, and VFC providers will be outdated and not in accordance with the latest national recommendations from the Advisory Committee on Immunization Practices, failing to reflect current, national practices in public health and clinical medicine.

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

There appears 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

States generally receive and distribute vaccines through the VFC Program and the utilization of Section 317 funds. The VFC Program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. CDC purchases vaccines and distributes them to grantees (i.e., state health departments and certain local and territorial public health agencies) which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers. Children who are eligible for VFC vaccines are entitled to receive those vaccines recommended by the Advisory Committee on Immunization Practices.

VFC program distribution authority is found here:

<https://www.cdc.gov/vaccines/programs/vfc/about/distribution.html>.

In addition to VFC authority of states to receive and distribute vaccines, Section 317 funds of the Public Health Services Act give states authority to receive and distribute vaccines.

<https://www.ncbi.nlm.nih.gov/books/NBK225583/>;

<https://www.law.cornell.edu/uscode/text/42/247b>.

Illinois, Iowa, Michigan, and Minnesota do not have the same equivalent to Chapter DHS 146 administrative rule purchasing authority. However, there are similar provisions in the states that are relevant to the authority of those states to purchase vaccines.

Illinois:

General state departments within Illinois do contain certain state healthcare purchasing functions, which would include vaccine purchasing. [15 Ill. Comp. Stat. Ann. 16/15](#).

Iowa:

The Iowa Department of Public Health is authorized to purchase vaccines to prepare for or to control a public health disaster. "The department may purchase and distribute antitoxins, serums, vaccines, immunizing agents, antibiotics, and other pharmaceutical agents or medical supplies as deemed advisable in the interest of preparing for or controlling a public health disaster." [Iowa Code Ann. § 135.142\(1\)](#).

Also, Iowa's Executive Council may approve requests from the Department of Public Health to authorize payments regarding the purchase of vaccines. "The executive council shall receive requests from the Iowa department of public health relative to the purchase, storing, and distribution of vaccines and medication for prevention, prophylaxis, or treatment. Upon review and after compliance with subsection 2, the executive council may approve the request and may authorize payment of the necessary expense. The expense authorized by the executive council under this subsection shall be paid from the appropriations referred to in subsection 1." [Iowa Code Ann. § 7D.29\(3\)](#).

Michigan:

The Michigan Department of Health and Human Services can purchase pharmaceutical products and provide to local health departments at no cost. "The department may develop, produce, purchase, and receive by gift pharmaceutical, biologic, and diagnostic products and by-products for human, veterinary, or agricultural use. . . . The department shall provide and distribute these products and by-products at no cost upon request of local health departments, hospitals, or

physicians for use within this state if considered necessary by the department to protect the public health.” [Mich. Comp. Laws Ann. § 333.9111](#).

Minnesota:

The Minnesota Department of Health has authority to purchase vaccines generally through the Commissioner of Health. “The commissioner of health, in preparation for and in carrying out the duties of sections 144.05, 144.4197, and 144.4198, may purchase, store, and distribute antituberculosis drugs, biologics, vaccines, antitoxins, serums, immunizing agents, antibiotics, antivirals, antidotes, other pharmaceutical agents, and medical supplies to treat and prevent communicable disease.” [Minn. Stat. Ann. § 151.37](#).

Summary of factual data and analytical methodologies

The department relied on the following sources to draft the proposed rule:

- A. Pickering LK, ed. *Red Book: 2015 Report of the Committee on Infectious Diseases*. 30th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2015.
- B. Heymann DL, ed. *Control of Communicable Diseases Manual*. 20th ed. Washington, DC: American Public Health Association, 2015.
- C. Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015.
- D. Centers for Disease Control and Prevention. Manual for the Surveillance of Vaccine-Preventable Diseases Measles website: <https://www.cdc.gov/vaccines/pubs/surv-manual/index.html>.

The department formed an Advisory Committee consisting of representatives from the Wisconsin Department of Public Instruction, Wisconsin Chapter of the American Academy of Pediatrics, Wisconsin Department of Health Services Medicaid Program, Wisconsin Association of Local Health Departments and Boards, Wisconsin Academy of Family Physicians, Wisconsin Association of School Nurses, Wisconsin Medical Society, and Pharmacy Society of Wisconsin. Proposed rule revision language was drafted based on the recommendations of this committee.

Analysis and supporting documents used to determine effect on small business

None, the proposed rule only affects the department, pending an economic impact analysis.

Effect on small business

Revisions to ch. DHS 146 are expected to have no impact on small businesses, pending an economic impact analysis.

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Statement on quality of agency data

The data sources referenced and used to draft the rules and analyses are accurate, reliable, and objective and are discussed in the “Summary of factual data and analytical methodologies.”

Place where comments are to be submitted and deadline for submission

Comments on the proposed rules may be submitted by accessing the department’s rules site, at <https://www.dhs.wisconsin.gov/rules/permanent.htm>. Once a public hearing has been scheduled, additional commenting will be enabled through the Wisconsin State Legislature’s site, at <http://docs.legis.wisconsin.gov/code>. The notice of public hearing and the deadline for submitting comments will be published both to the department’s rules site, and in the Administrative Register, at <https://docs.legis.wisconsin.gov/code/register>.

RULE TEXT

SECTION 1. DHS 146.03 and (Note) are repealed and recreated to read:

DHS 146.03 **Vaccine-preventable diseases.** All of the following are vaccine-preventable diseases for purposes of the statewide immunization program under s. 252.04 (1), Stats., including for purposes of purchasing and distributing vaccines without charge under s. 252.04 (8), Stats.:

- 1) Diphtheria.
- 2) *Haemophilus influenzae type b*.
- 3) Hepatitis A.
- 4) Hepatitis B.
- 5) Human Papilloma Virus.
- 6) Influenza.
- 7) Measles.
- 8) Meningitis.
- 9) Mumps.
- 10) Pertussis (whooping cough).
- 11) Pneumococcal.
- 12) Poliomyelitis.
- 13) Rabies.
- 14) Rotavirus.
- 15) Rubella (German measles).
- 16) Tetanus.
- 17) Varicella (chickenpox).
- 18) Zoster (shingles).

Note: This is not the list of diseases for which immunizations are required as a condition of admission to an elementary, middle, junior high or senior high school or a childcare center. See ch. DHS 144 for those requirements.

SECTION 2. DHS 146.04 (2) (Note) is amended to read:

Note: Contact the Wisconsin Immunization Program at 608-267-9959 for vaccine requests. A request for vaccines should be sent to Immunization Program, Division of Health, P.O. Box 309, Madison, WI 53707-0309.

SECTION 3. 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.