

10-144

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAINE CENTER FOR DISEASE CONTROL AND PREVENTION

A joint rule with

95-659

THE MAINE VACCINE BOARD

Chapter 248: LIST OF VACCINES TO BE PROVIDED BY THE UNIVERSAL CHILDHOOD IMMUNIZATION PROGRAM

Summary: This rule is issued jointly between the Department of Health and Human Services and the Maine Vaccine Board, to implement the provisions of P.L. 2009, c. 595, An Act to Establish the Universal Childhood Immunization Program (22 M.R.S.A. §1066). It lists the vaccines to be provided by the Universal Childhood Immunization Program.

By statute, the Department of Health and Human Services and the Maine Vaccine Board are required to determine a list of vaccines to be provided by the Universal Childhood Immunization Program each year. In determining this list, the Board has considered: (1) vaccines recommended by the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, Centers for Disease Control and Prevention (“Advisory Committee”) that are available under contract with the United States Department of Health and Human Services, Centers for Disease Control and Prevention; (2) recommendations of the Department, based on the Department’s review of the advisory committee recommendations; and (3) clinical and cost-benefit analyses.

The vaccine list along with estimates of population/age cohorts, estimates of current and expected immunization rates, and projections of vaccine wastage will form the basis of the Board’s determination of the total cost of the fund in the succeeding program year.

I. Definitions

- A. “Advisory Committee” means the Advisory Committee on Immunization Practices (ACIP) of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.
- B. “Board” means the Maine Vaccine Board.
- C. “Department” means the Maine Department of Health and Human Services.
- D. “Program” means the Universal Childhood Immunization Program
- E. “Program Year” means July 1st through June 30th of each year

II. Annual Uniform Vaccine List

- A. The Board shall annually determine the list of childhood vaccines to be made available by the Program during the program year commencing the following July 1st.
- B. In determining the list of vaccines, the Board shall consider the following:
 1. the recommendations of the Advisory Committee relating to vaccines which are available to the Program under contract with the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention;
 2. the recommendations of the Department, based upon the Department's review of the Advisory Committee recommendations; and
 3. clinical and cost-benefit analysis relating to potential vaccines to be included on the list of pediatric vaccines.

III. Authorized List of Uniform Childhood Vaccines

- A. **2011 Base Year.** For the program year commencing on July 1, 2011, the following childhood vaccines shall be available under the Program:
 1. **DTaP Vaccines (Diphtheria, Tetanus, acellular Pertussis)**
 - a. Tripedia ® (Sanofi Pasteur)
 - b. Daptacel ® (Sanofi Pasteur)
 - c. Infanrix ® (GSK)
 2. **Hepatitis A Vaccines**
 - a. Vaqta ® (Merck)
 - b. Havrix ® (GSK)
 3. **Hepatitis B Vaccines**
 - a. Engerix B ® (GSK)
 - b. Recombivax ® (Merck)
 4. **Polio Vaccine**
 - a. IPOL ® (Sanofi Pasteur)
 5. **Hib Vaccines (Haemophilus influenzae type b)**
 - a. ActHIB ® (Sanofi Pasteur)

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- b. Pedvax HIB ® (Merck)
 6. **HPV Vaccines** (Human Papillomavirus)
 - a. Gardasil ® (Merck)
 7. **Pneumococcal Vaccines**
 - a. Prevnar 13 ® (Wyeth)
 - b. Pneumovax 23 (Merck)
 8. **Meningococcal Conjugate Vaccines**
 - a. Menactra ® (Sanofi Pasteur)
 - b. Menveo ® (Novartis)
 9. **Measles, Mumps and Rubella Vaccine**
 - a. MMRII ® (Merck)
 10. **Rotavirus Vaccines**
 - a. Rotarix ® (GSK)
 - b. RotaTeq ® (Merck)
 11. **TDAP Vaccines** (Tetanus Toxoid, Reduced Diphtheria Toxoid and acellular Pertussis – adolescent formulation)
 - a. Boostrix ® (GSK)
 - b. Adacel ® (Sanofi Pasteur)
 12. **Varicella Vaccine**
 - a. Varivax ® (Merck)
 13. **Combination Vaccines**
 - a. Kinrix ® (GSK)
 - b. Pediarix ® (GSK)
 - c. Pentacel ® (Sanofi Pasteur)
 - d. ProQuad ® (Merck)

14. Influenza Vaccines

- a. At least one preservative free, single dose vial presentation
- b. At least one multidose vial presentation
- c. At least one Influenza vaccine live Intranasal presentation

B. Uniform Vaccine Lists in Subsequent Years

1. The Board shall annually review new vaccines and vaccines not on the authorized list and determine the feasibility of either adding or removing vaccines to or from the authorized uniform list in accordance with the criteria established in section II(B).
2. In the event the Board whether as a result of the above annual review or for any other reason determined appropriate by the Board, determines that revision of the authorized list of uniform vaccines is warranted, it may revise the uniform vaccine list by appropriate Board vote after conducting a public hearing in accordance with 5 M.R.S.A. §8052(2), provided any revision of the list of uniform vaccines be consistent with the criteria established in 22 M.R.S.A. §1066(3)(E) and Section 2(B) of these Rules.
3. Any revision of the uniform childhood vaccine list is contingent upon the availability of adequate funding through the assessment mechanism established by 22 M.R.S.A. §1066(5).
4. The Authorized List of Uniform Childhood Vaccines shall be published on the Maine Vaccine Board Website at: <http://www.mevaccine.org/mevaccine.nsf/pages/for-providers.html>
5. In the event that the ACIP modifies existing product recommendations or adds a new vaccine product to the Vaccines for Children program, the Board shall meet within 90 days of the ACIP decision and determine if modifications to the authorized list of uniform vaccines is warranted.

IV. Interim Modifications to Uniform Vaccine List

The Board shall periodically review new vaccines and vaccines not on the authorized list and determine the feasibility of either adding or removing vaccines to or from the authorized uniform list in accordance with the criteria established in section II(B).

In the event the Board determines that revision of the authorized list of uniform vaccines is necessary to protect public health prior to revision of the authorized list through rulemaking, it may revise the authorized list on an interim basis, not to exceed 18 months, in accordance with the procedure established by subsection IV(C), provided that any interim revisions be included in the next scheduled Board rulemaking regarding uniform childhood vaccines.

The board may revise on an interim basis the authorized uniform list of childhood vaccines after conducting a public hearing in accordance with the requirements of 5°M.R.S.A. §8052(2).

Any revision of the uniform childhood vaccine list is contingent upon the availability of adequate funding through the assessment mechanism established by 22 M.R.S.A. §1066(5).

V. Determining the total vaccine cost for the program §1066(5)(A)(1)

- A. The Department will estimate the total vaccine cost for the succeeding year based on age-cohort population estimates, the ACIP vaccination schedule, the list of vaccines determined by the board and projected immunization rates.
- B. The Department will provide the Board with a projected vaccine cost for the succeeding year to be included in the assessment.
- C. The Department will review vaccine usage projections and actual usage throughout the year to assure that the program remains within budget. The Department will provide quarterly reports to the board on vaccine usage and budget projections.
- D. The Department will promptly notify the Board in the event of a vaccine shortage or other disruption of the vaccine supply that will affect the vaccine budget.

VI. Appeals

- A. General Provisions. A party aggrieved by a Board decision or action has recourse to administrative review in accordance with the provisions of the Maine Administrative Procedure Act, 5 M.R.S.A. Chapter 375, Subchapter IV.
- B. Procedure for Securing Administrative Review.
 - 1. A person aggrieved by a Board decision or action may request administrative review by filing a written request for administrative review with the Maine Vaccine Board, c/o Maine Center for Disease Control and Prevention, Division of Infectious Disease Control, Department of Health and Human Services, 11 State House Station, Augusta, ME 04333-0011.
 - 2. A written request for administrative review shall identify the decision or action under challenge, and the issue or issues which form the basis for review. .
 - 3. The written request for administrative review must be filed with the Board no later than thirty days after the Board decision or action which is the subject of the appeal.
 - 4. Upon the timely filing of a request for administrative review, the Board shall determine whether or not the decision or action under challenge is appropriate for administrative review and notify the appellant in writing in timely fashion.
 - 5. In the event the Board determines a request for administrative review is appropriate, it shall promptly schedule an administrative review hearing.
 - 6. Any administrative hearing shall be conducted in accordance with the requirements of the Maine Administrative Procedure Act, 5 M.R.S.A. Chapter 375, Subchapter IV.
 - 7. In the event a request for administrative review is granted, the Board shall designate an Administrative Hearing Officer, who shall provide appropriate notice of the hearing date, conduct the administrative review hearing, and issue a written decision upon the close of evidence, all in accordance with the relevant provisions of the Maine Administrative

Procedure Act. The Maine Vaccine Board decision after administrative review shall be considered final agency action.

C. Judicial Review

1. A party aggrieved by final agency action of the Maine Vaccine Board has recourse to judicial review in accordance with 5 M.R.S.A. §§ 11001-11008 and Rule 80C of the Maine Rules of Civil Procedure.

STATUTORY AUTHORITY: 22 M.R.S.A. §1066

EFFECTIVE DATE:

February 24, 2011 – filing 2011-58 (EMERGENCY) (filed under 10-144, Department of Health and Human Services)

July 15, 2011 – filing 2011-210

January 25, 2012 – relocated to 95-659, Maine Vaccine Board)

EFFECTIVE DATE: November 2nd, 2013