

**10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MAINE CENTER FOR DISEASE CONTROL AND PREVENTION**

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

**A joint rule with**

**10-144 THE MAINE VACCINE BOARD**

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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 MRSA §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 establish by rule 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 in this rule, 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 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 1<sup>st</sup> through June 30<sup>th</sup> of each year

## II. Annual Uniform Vaccine List

A. No later than January 1<sup>st</sup> of each year, the Board shall determine a base list of childhood vaccines to be made available by the Program during the program year commencing the following July 1<sup>st</sup>.

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)
  - b. Pedvax HIB ® (Merck)
6. HPV Vaccines (Human Papillomavirus)
  - a. Gardasil ® (Merck)
7. Pneumococcal Vaccines
  - a. Prevnar 13 ® (Wyeth)
  - b. Pneumovax ® (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 Live Attenuated Inactivated Virus, nasal spray presentation

B. Uniform Vaccine Lists in Subsequent Years

1. The Board shall annually review the authorized list of uniform childhood vaccines and determine whether to add or remove vaccines from the list based upon the criteria established in section II(B).
2. Any revisions of the authorized list of uniform childhood vaccines shall be adopted by the Board by rulemaking in accordance with the requirements of the Maine Administrative Procedure Act established in Title 5, Chapter 375, Subchapter 2.

IV. Interim modifications to Uniform Vaccine List

- A. 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).
- 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.

- C. 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).
  - D. 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.

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STATUTORY AUTHORITY: 22 MRSA § 1066

EFFECTIVE DATE: July 15, 2011