MAINE STATE LEGISLATURE

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STATE OF MAINE 125TH LEGISLATURE FIRST REGULAR SESSION

First Report of the MAINE VACCINE BOARD

July 2011

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EXECUTIVE SUMMARY

This is the first annual report of the Maine Vaccine Board. In 2009, the Maine Vaccine Board was established by the second session of the 124th Maine Legislature in accordance with Public Law, Chapter 595.¹ The Board was given the authority and an outline of a mechanism to fund the purchasing of lifesaving childhood vaccines as established by rule and in accordance with the Universal Childhood Immunization Program each year. The Board is charged with (i) determining the costs of purchasing and administering the vaccines and (ii) assessing the costs equitably among payers for health care provided to Maine residents. By legislative directive, the Board is expected to meet at least four times per year and to report annually to the Legislature.

The Board consists of ten members; three representatives of health insurance carriers, three representatives of providers in the state as nominated by statewide associations of providers, a representative of employers that self-insure for health coverage, a representative of the pharmaceutical manufacturing industry, and two non voting ex officio members; the DHHS Commissioner (or designee) and the State Treasurer (or designee). At the core of this initiative is the desire to reduce the incidence of vaccine preventable diseases and to increase the safe use of vaccines for children in Maine.

By statute, the Universal Childhood Immunization Program will provide universal immunization coverage to Maine children. This mission will be fulfilled by purchasing and making available to health care providers vaccines for childhood immunizations as recommended by the United States Center For Disease Control's Advisory Committee on Immunization Practices (ACIP) as approved by the United States Food and Drug Administration and available under contract with the United States Department of Health and Human Services, Center for Disease Control and Prevention.

The legislation creating the Universal Childhood Immunization Program went into effect on August 2, 2010. The Board was initially convened on November 2, 2010 and since that date has met thirteen times. All Board meetings are accessible to the public. Both oral and written comments are welcome.

Upon finalizing membership, the Board moved forward quickly to negotiate the terms and conditions of a service agent contract, initiate emergency rule making, and confirm the list of vaccines to be included in the program. As of the date of this filing, an emergency rule is in place to establish the list of vaccines that will be made available by the Universal childhood Immunization Program pursuant to 22 MRSA § 1066 §(3)(E). This list of vaccines will provide the basis necessary for the Board to

¹ Codified as 22 MRSA, § 1066

² CML Administrators, LLC proposal (November, 2010)

assess and set rates in accordance with 22 MRSA § 1066 § 5. The routine technical rule making process is currently underway.

In order complete its work for the upcoming year, the Maine Vaccine Board plans to continue to meet monthly, with the exception of July, through the end of 2011. Future Board meetings are expected to address the following:

- Complete the process of routine technical rule making thus confirming the list of vaccines to be provided by the Universal Childhood Immunization Program;
- Provide regular and "robust" communication to stakeholders;
- Review insurance assessment results;
- No later than January 1st of each year, confirm a base list of childhood vaccines that are to be made available by the program;
- Set rates, approve and monitor budget;
- Develop a set of metrics that can be used to monitor the overall program impact.

The Board will submit findings, recommendations, and updates in it's next annual report, due January 1, 2012, to the Joint Standing Committee of the legislature having jurisdiction over health and human services matters.

The Board is in the process of completing setup of its initial website at www.MEvaccine.org and is scheduled to go live on that site this month. It is the intent of the Boar that its website will maintain readily-accessible and regularly-updated information on the Maine Vaccine Board and its operations. Hence future reports are expected to be considerably shorter in length.

HISTORY AND DESCRIPTION OF THE MAINE VACCINE BOARD

Up until 2009, funding for childhood vaccines in Maine was primarily through federal sources, with additional contributions from Maine health plans. Federal funds for vaccines are distributed through the Vaccines for Children program (VFC) and Title 317 funds. Since 1997, Maine provided ACIP recommended vaccines universally to all Maine children free of charge using these combined federal funds. Starting in 2007, the number of vaccines provided universally was reduced. In 2009, due to increasing costs of fully vaccinating a child (from about \$60 per child in 1980 to over \$1,600 per child in 2006) and level or decreased federal funding. Maine has had to limit vaccine access to VFC eligible children (MaineCare insured, uninsured, underinsured and Native American) only. Over the same period of time that Maine has experienced decreased access to recommended childhood vaccines, childhood immunization rates in Maine dropped and are now below the national average. This drop in childhood immunization rates translates directly to increased health risk for Maine children and, ultimately, to higher health care costs overall. The addition of State funds for childhood immunization has begun to address this issue, and the creation of the Universal Childhood Immunization Program in the 124th Legislature (2009 P.L. ch 595) will return Maine to a universal access state for childhood vaccines.

A truly public-private partnership, 2009 Public Law 595 - An Act to Establish the Universal Childhood Immunization Program - will save health plans and premium payers on the costs of immunization while increasing the numbers of children protected from vaccine preventable disease. All payers, from large health plans to small self insured groups and individual families will realize the benefits of discounted vaccine purchase and increased access. This important public health legislation means that children in Maine won't face the barrier of gaining access to life-saving pediatric vaccines. Maine parents won't have to worry about whether or not to vaccinate out of concern for out-of-pocket costs and Maine health care providers can spend more time on patient care and less on administrative accounting for dual vaccine supplies. With the implementation of this law, Maine Center for Disease Control and Prevention will be able to reduce vaccine wastage through the administrative simplification offered through a singular universal approach to childhood vaccine. Healthcare providers and families will be afforded a greater choice of vaccines for all children, regardless of insurance status, meaning fewer total sticks and greater on-time immunization rates. This law provides a renewed collaborative effort in forming our state's approach to childhood vaccination so that Maine can again lead the nation in our childhood immunization rates.

UNIVERSAL VACCINE NATIONAL CONTEXT

Currently, the six states providing universal access to children include New Hampshire, New Mexico, Rhode Island, Vermont, Washington, and Wyoming. Of

these six, four states shared information in response to a recent request by MCDC for comparison information.

The Maine CDC Immunization Program, like Rhode Island, Washington and Wyoming, offers universal childhood vaccine coverage from birth to 18 years of age. The State of Vermont's Immunization Program (i.e., which has had universal childhood vaccine coverage for over 30 years) provides comprehensive (birth to death) coverage.

Like Maine, the States of Washington and Wyoming Immunization Programs have established "Vaccine Boards". The Vaccine Board for Wyoming decides and selects which vaccines may be ordered by providers; however, the Vaccine Board for Washington until recently had relied upon the Immunization Program to select which vaccines providers may order. Commencing June 1, 2011, the Vaccine Committee of the Washington Vaccine Association has taken over determination of the method for vaccine selection and is taking steps to open that to provider choice among approved vaccines.

Historically, the State Immunization Programs of Wyoming, Vermont, and Washington relied on both state and federal funds for universal immunization coverage. However, like Maine's CDC Immunization program, the Vermont and Washington State Immunization Programs are changing to an "insurance contribution" model to support universal immunization coverage. That change, in Washington, became effective May 1, 2010.

THE VACCINE BOARD

The Maine Vaccine Board was created by the $124^{\rm th}$ Legislature through the enactment of Public Law 595. The law creating the Board took effect on August 2, 2010, and the Board subsequently held their first meeting on November 2, 2010. Additional in-person and telephone conference meetings were held on 11/17/10, 11/24/10, 12/09/10, 12/13/10, 12/14/10, 12/15/10, 1/13/11, 2/07/11, 3/1/11, 4/5/11, 5/3/11, and 6/7/11.

The Board consists of ten members; three representatives of health insurance carriers, three representatives of providers in the state as nominated by statewide associations of providers, a representative of employers who self-insure for health coverage, a representative of the pharmaceutical manufacturing industry, and two non voting ex officio members; the DHHS Commissioner (or designee) and the State Treasurer (or designee). At a November 17, 2010 Board meeting, Peter M. Gore was unanimously elected Board president. Peter Smith, MCDC Manager for the Division of Infectious Disease, will serve as the DHHS Commissioner's designee and ex officio Board member. With the exception of the pharmaceutical manufacturing industry representative, who serves a one-year term, the term of all other Board appointees is three years.

SUMMARY OF VACCINE BOARD PROGRESS

Board Priorities and Timeline

The Board assumes rulemaking authority (according to 22 MRSA § 1055 subsection 11) for selecting the list of vaccines expected to be covered through the Universal Childhood Vaccine Program. Members discussed the need to initially move forward with emergency rule making with the routine technical rule making process to follow. It was noted that annual adjustments to the vaccine list will require additional rule changes.³

Contracting Authority

Given the Board's contracting authority, it is not subject to approval by the Division of Purchases and, given the limited time within which an assessment must be in place, the Board determined that it would move forward with seeking a service agent as supported through the sole source contracting process. Three potential agents were discussed and the decision made to invite each to provide proposal presentations to the Board.

Selecting the Vaccine List

The Maine CDC representative confirmed that the Board will be able to acquire the same vaccines for VFC Children provided they remain within allotted doses by population/age and coverage rates. A sub committee was formed to develop a draft list of vaccines. The Vaccine Subcommittee, comprised of three physician Board members and the DHHS Commissioner's designee, reviewed the vaccine list and the rationale for vaccine selection. The Board was also provided with an overview of the vaccine forecasting and ordering process by Dr. Smith from the Maine Center for Disease Control, Division of Infectious Disease.

As required by statute, the following criteria were used in proposing the list of vaccines:

- 1. Vaccines recommended by the Advisory Committee on Immunization Practices of the US Department of HHS, Centers for Disease Control and Prevention;
- 2. Vaccines recommended by the Maine Department of Health and Human Services based upon the Department's review of Advisory Committee recommendations;
- 3. Specific vaccine choices based upon both clinical and cost benefit analyses. (22 MRSA § 1066 Subsection 11)

³ The legislature set January 1, 2011 as the start date for the assessment in statute therefore justifying emergency rules on these grounds. The Board has under consideration alternative approaches which may make possible an open and informed process for determining available vaccines without incurring the expense and administrative burden of rulemaking each year.

The vaccine list will be in the rule, along with estimates of population/age cohorts, estimates of current and expected immunization rates, and projections of vaccine wastage.

Service Agent

CML Administrators, LLC, of Concord, NH was selected as the vendor and administrative home of the Vaccine board and, through CML, Fred L. Potter, its managing member, was named the initial executive director. This entity will supply all management, accounting, collection, disbursement and recordkeeping services to the Board, manage any third-party support providers such as outside legal and audit services, and coordinate all supportive investment, banking, and insurance services.

Emergency Rules/Basis Statement

The emergency rules basis statement was accepted by the Board at the December 13, 2010 meeting.⁴ Emergency and routine technical rules, pursuant to 5 M.R.S.A., set forth the list of vaccines that will be available by the Universal Childhood Immunization Program. This list will provide a basis for Board calculation and assessment. Emergency rules were officially put in place on February 24, 2011.

Communication Plan

Previously acknowledging the need for a communication, CML emphasized the need for draft communication materials to be sent to insurers soon. CML Administrators assumed responsibility for creating Web design options for Board consideration. Immediate concerns regarding communication included the need to engage health systems who have close provider working relationships, to communicate with all medical groups, to recruit physicians to participate in the vaccine program, and to instill consistency across all messaging. A communication sub-group from the Board was formed and charged with preparing communications for Board consideration.

Projected Budget

The Board reviewed the projected \$9.4M budget⁵ for non-VFC kids, based on provider and product estimates, experience with other states, population estimates, and "best practice" coverage. With adjustments, the net vaccine budget was calculated at \$9,702,095.⁶ This includes an 8% allowance for administrative costs for the first year, a number below the statutory allowance of 10%.

⁴ Emergency rule, jointly proposed by DHHS MCDC & The Maine Vaccine Board

⁵ Vaccine Cost & Population Estimates, Allowances, and Planning Assumptions - Budget

⁶ Approved revised budget

The Board voted to accept the Maine CDC budget recommendation⁷ as presented at the prior Board meeting, noting a vaccine cost of \$9.7 million dollars and a preliminary assessment of \$6.98 per covered life per month.

AGENDA FOR FUTURE WORK

In accordance with the authorizing legislation, the Board holds regular public meetings during the upcoming year. In order to meet its obligation, the Board anticipates holding up to ten meetings between March 1, 2011 and January 15, 2012.

Board members have identified the following areas to be addressed at future Board meetings:

- Finalize technical routine rule making
- Implement a Communication Plan
- Monitor the budget and make necessary adjustments
- Commence assessment collections and remittances to the State Treasurer to support universal vaccine purchase for children
- Monitor compliance with the service agent agreement
- Monitor program impact

The Board will submit additional findings and recommendations in each annual report to the joint standing committee of the legislature having jurisdiction over health and human services matters.

⁷ Final approved budget