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Department of Public Health
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January 1, 2016

William F. Welch
Senate Clerk
State House Room 335
Boston, MA 02133

Steven T. James
House Clerk
State House Room 145
Boston, MA 02133

Dear Messrs. Welch and James:

Pursuant to Massachusetts General Law Chapter 111 Section 24N, please find enclosed a report from the Department of Public Health entitled "Vaccine Purchase Trust Fund Fiscal Years 2015 and 2016."

Sincerely,

Monica Bharel, MD, MPH
Commissioner of Public Health

Charles D. Baker
Governor

Karyn Polito
Lieutenant Governor

Marylou Sudders
Secretary

Monica Bharel, MD, MPH
Commissioner

Vaccine Purchase Trust Fund

Fiscal Years 2015 and 2016

January 1, 2016

Massachusetts Department of Public Health

Legislative Mandate

The following report is hereby issued pursuant to **Massachusetts General Law Chapter 111 Section 24N** as follows:

Section 24N. (a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:--

"Children", individuals less than 19 years of age.

"Estimated vaccine cost", the estimated cost over the course of a fiscal year for the purchase, storage and distribution of vaccines for all children in the commonwealth.

"Payments subject to surcharge", as defined in section 64 of chapter 118E.

"Routine childhood immunizations", immunizations for children until their nineteenth birthday including: (i) the immunizations recommended by the federal Vaccines for Children Program, and (ii) any immunizations recommended by the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention.

"Surcharge payors", those entities defined as surcharge payors pursuant to section 64 of chapter 118E, who made payments subject to surcharge in the amount of $1,000,000 or more during the most recent period for which data is available on July 1 of the current fiscal year.

"Total non-federal program cost", the estimated annual cost of vaccines needed for routine childhood immunizations for children covered by surcharge payors in the commonwealth less the amount of federal revenue available to the commonwealth for purchase, storage, distribution and administration of the vaccines.

(b) There shall be established in the commonwealth a separate trust fund to be known as the Vaccine Purchase Trust Fund to support a universal purchase system for routine childhood immunizations in the commonwealth. The fund shall be expended to cover the costs to purchase, store and distribute vaccines for routine childhood immunizations and to administer the fund and the immunization registry, established pursuant to section 24M. The fund shall consist of all monies paid to the commonwealth under subsection (d) and any interest earnings on such monies. The fund shall be maintained by the commissioner of public health or a designee. The monies shall be expended under the direction of the department of public health, without prior appropriation, solely to cover total non-federal program costs; provided, however, that the amount to be expended for storing and distributing vaccines for routine childhood immunizations, if such costs are not covered by federal contribution, and for the costs of administering the immunization registry, shall not exceed 10 per cent of the total amount of the fund expended for the purchase of vaccines needed for routine childhood immunizations for all children in the commonwealth. The department may incur expenses and the comptroller may certify for payment amounts in anticipation of the most recent estimate of expected receipts, as certified by the secretary of administration and finance; provided, however, that no expenditure shall be made from the fund which shall cause the fund to be in deficit at the close of a fiscal

year. Any balance in the fund at the close of a fiscal year shall be available for expenditure in subsequent fiscal years and shall not be transferred to any other fund or revert to the General Fund. The commissioner of public health or a designee shall annually report the amount of funds collected and any expenditures made from the fund to the clerks of the house of representatives and senate to be forwarded on to the house and senate committees on ways and means, the house and senate chairs of the joint committee on public health and the house and senate chairs of the joint committee on health care financing.

(c) There shall be a vaccine program advisory council consisting of the commissioner of public health or a designee, who shall serve as chair; the medical director of the universal immunization program of the department of public health established under section 24I; the executive director for the center for health information and analysis or a designee; the executive director of the commonwealth health insurance connector authority or a designee; 1 person to be appointed by the director of Medicaid, who shall be a representative of managed care organizations contracting with MassHealth; 3 persons to be appointed by the commissioner of insurance, each of whom shall be a representative of 1 of the 3 health insurance companies having the most insured lives in the commonwealth; and 7 persons to be appointed by the commissioner of public health, 1 of whom shall be a representative of an employer that self-insures for health coverage who shall be appointed from lists of nominees submitted by statewide associations of employers, 1 of whom shall be a member of the Massachusetts Medical Society, 1 of whom shall be a member of the Massachusetts chapter of the American Academy of Pediatrics, 1 of whom shall be a member of the Massachusetts Academy of Family Physicians, and 3 of whom shall be physicians licensed to practice in the commonwealth and who shall have expertise in the area of childhood vaccines. The council shall recommend the types of vaccines to be purchased based on a list of routine childhood immunizations and shall take into account provider preference, cost, availability and other factors as determined by the council. The council shall recommend the amount of funding needed each fiscal year by calculating the total non-federal program cost. The council shall make recommendations to the commissioner on whether the commissioner may authorize provider choice of more than 1 comparable brand or type for a routine childhood immunization vaccine. In its recommendations, the council shall examine the feasibility, costs and benefits of authorizing provider choice, provide a schedule of the cost of each comparable brand or type of a vaccine recommended for provider choice and demonstrate that the estimated vaccine cost of authorizing provider choice would not be substantially greater than the estimated vaccine cost of purchasing a single brand or type of a vaccine. The commissioner of public health shall determine the final vaccines to be purchased.

(d) Under regulations adopted by the commissioner of public health, each surcharge payor in the commonwealth shall pay to the commissioner of public health, for deposit in the Vaccine Purchase Trust Fund, a routine childhood immunizations surcharge assessed by the commissioner. By January 1 of each year, the commissioner of public health shall determine the total amount of the surcharge for the current fiscal year by determining the final amount required to be included in the Vaccine Purchase Trust Fund for the current fiscal year to cover the estimated costs to purchase, store and distribute vaccines for routine childhood immunizations and to administer the fund and the immunization registry, established pursuant to section 24M. The amount shall exclude any costs anticipated to be covered by federal contribution, shall take into consideration the limitations on expenditures described in subsection (b) and shall take into

account any anticipated surplus or deficit in the trust fund. Any increase in the surcharge amount for the prior fiscal year shall not increase more than the percentage set as the health care cost growth benchmark, established under section 9 of chapter 6D, unless the commissioner of public health submits a detailed report to the clerks of the house of representatives and senate who shall forward the report to the house and senate committees on ways and means, the house and senate chairs of the joint committee on public health and the house and senate chairs of the joint committee on health care financing explaining the need for the increase. If the reason for the increase is due to the purchase of new vaccines and the authorization of provider choice for certain vaccines, as recommended by the vaccine program advisory council, the report shall include an analysis of cost savings generated by use of the state vaccine purchasing discount.

The commissioner shall annually provide surcharge payors notice of the assessment amount for the trust fund year not later than 15 days prior to the due date of the first scheduled surcharge payment or March 1, whichever is earlier. Surcharge payors shall pay the surcharge on a schedule determined by regulation; provided, however, that the schedule shall ensure sufficient funds for the trust fund to fulfill the purposes described in subsection (b). Each surcharge payor shall pay a portion of the total amount of the surcharge proportional to their payments subject to surcharge during the most recent period for which data is available, as further defined in regulation.

(e) The department of public health may adopt rules and regulations as necessary to implement the universal purchase and distribution system under this chapter and other applicable state and federal laws. The rules and regulations shall establish the system by which vaccines are distributed for children in the commonwealth.

(f) Every surcharge payor, to the extent not preempted by federal law, shall provide benefits for: (i) routine childhood immunizations for residents of the commonwealth; and (ii) immunizations for residents of the commonwealth who are 19 years of age and older according to the most recent schedules recommended by the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention. These benefits shall be exempt from any copayment, coinsurance, deductible or dollar limit provisions in the health insurance policy or contract.

Executive Summary

Chapter 28 of the Acts of 2014 established the Vaccine Purchase Trust Fund. The Fund is financed through an assessment charged to Massachusetts health insurance carriers for the cost of state-supplied pediatric vaccines. The Department purchases vaccines at a reduced price under federally negotiated manufacturer contracts and oversees the ordering and inventory of vaccines, their allocation to providers, and their administration. It also maintains the Massachusetts Immunization Information System (MIIS), the Massachusetts vaccine registry. The financing structure provided by the Trust supports vaccine access for children and adolescents in the Commonwealth.

In state FY15 Fund expenditures did not exceed collected revenues. While $59M was anticipated to be spent in FY15, a total of $71M was collected into the Fund, generating just under $12M in revenues to be credited to FY16. Actual expenditures on vaccines and MIIS maintenance were just under $53M leaving an additional $6M to be carried forward into fiscal year 16 (see Tables 1 & 2). The Department has fully planned for FY16 expenditures with a moderate (+1.05%) increase to the percentage of the Health Safety Net surcharge on payors pursuant to c. 118E s. 64-69 (see Tables 3 & 4). This increase allows for one vaccine (against human papilloma virus) and one booster dose of a vaccine (against meningococcal disease) to be added to the formulations supplied by the DPH Immunization Program, allowing Massachusetts again to offer all federally recommended pediatric vaccines (universal status). These additions to the Program's state-supplied vaccines were recommended by a consensus of the Massachusetts Vaccine Program Advisory Council and approved by the Commissioner of Public Health.

This added assessment and associated expenditures are needed in order to fully protect the Commonwealth's children and adolescents against preventable infectious disease as recommended by the Centers for Disease Control and Prevention (CDC). Cost savings of state purchase of these vaccines under federally negotiated contracts with manufacturers is estimated to be 22% below cost for HPV vaccine and 33% below cost for MCV4 vaccine.

Introduction

Chapter 28 of the Acts of 2014 the Vaccine Purchase Trust Fund is a public-private collaboration that greatly improves child health while saving money for the Commonwealth. This financing system is comprised of an assessment charged to Massachusetts insurers and health plans for the cost of state-supplied childhood vaccines which are purchased at a reduced price the state receives under the federal contract. The Vaccine Purchase Trust Fund is a stable financing framework enabling Massachusetts to guarantee that all children 0-18 years of age receive every vaccine recommended by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), which sets national standards for immunizations. The Fund helps to guarantee that Massachusetts maintains one of the highest childhood vaccination rates in the country and returns to universal pediatric vaccine access status for the first time since 2007.

Report

For over 100 years, the Department has distributed all of the routinely recommended childhood vaccine, free of charge to health care providers in the state. This universal distribution has allowed children to be vaccinated by their own provider in their medical home.

Starting in 2007, Massachusetts was no longer a universal vaccine distribution state. Several factors, including new vaccine introductions, revised dosing schedules, and increasing vaccine costs challenged the ability of annual state appropriations to keep apace. For example, the booster dose of the meningococcal vaccine that extends the protection for adolescents and young adults against a potentially deadly brain infection was not universally provided due to cost. This required providers to purchase the dose themselves, charge patients for its administration, and seek reimbursement from health insurance carriers at current rates, increasing costs.

The establishment of the Vaccine Purchase Trust Fund has allowed Massachusetts to once again provide all vaccines in the universal childhood vaccine program. Effective November 1, 2015, the Department's Immunization Program made available two vaccines previously not provided with state funds. These are the human papilloma virus (HPV) vaccine and the booster dose of meningococcal conjugate four-valent (MCV4) vaccine. These additions to the Program's state-supplied vaccines were recommended by a consensus of the Massachusetts Vaccine Program Advisory Council and approved by the Commissioner of Public Health.

The HPV vaccine protects against nine strains of HPV responsible for over 80% of cervical cancers in women. Cervical cancer kills over 4,000 women annually in the US. HPV vaccine also reduces the risk of anal and oropharyngeal cancers and genital warts in men and women. The expansion of HPV vaccine availability added an additional $14.4 million to the pediatric vaccine budget, but will protect nearly 40,000 additional adolescents of both sexes each year from these forms of cancer.

The MCV4 vaccine protects against four strains of meningococcal meningitis, a serious bacterial infection of the central nervous system that can kill 10-15% of those infected. Immunity granted by the first dose at age 11-12 can wane and requires a booster dose at age 16 to be maximally

protective. The inclusion of the booster dose of MCV4 vaccine added $4.4 million to the pediatric vaccine budget, but will allow an additional 50,000 adolescents to receive this vaccine as recommended by the ACIP.

This additional vaccine is needed in order to fully protect the Commonwealth's children and adolescents against preventable infectious disease as recommended by the Centers for Disease Control and Prevention (CDC). Cost savings of state purchase of these vaccines under federally negotiated contracts with manufacturers is estimated to be 22% below retail cost for HPV vaccine and 33% below retail cost for MCV4 vaccine.

The Vaccine Purchase Fund assessment is applied to surcharge payors under c. 118E s. 66-69 as a percentage of payments made to the Health Safety Net Fund. Any collections from the previous year in excess of expenditures are credited to the subsequent year, reducing the assessment. In state FY15 Fund collections exceeded expenditures. While $59M was anticipated to be spent in FY15, a total of $71M was collected into the Fund, generating just under $12M in revenues to be credited to FY16. Actual expenditures on vaccines and MIIS maintenance were just under $53M leaving an additional $6M to be carried forward into fiscal year 16 (see Tables 1 & 2).

The Department has fully planned for FY16 expenditures with a moderate (+1.05%) increase to the percentage of the Health Safety Net surcharge on payors pursuant to c. 118E s. 64-69 (see Tables 3 & 4). This increase allows for HPV vaccine and the MCV4 booster to be added to the formulations supplied by the DPH Immunization Program, allowing Massachusetts again to offer all federally recommended pediatric vaccines (universal status). These additions to the Program's state-supplied vaccines were recommended by a consensus of the Massachusetts Vaccine Program Advisory Council and approved by the Commissioner of Public Health.

This added assessment and associated expenditures are needed in order to fully protect the Commonwealth's children and adolescents against preventable infectious disease as recommended by the Centers for Disease Control and Prevention (CDC). Cost savings of state purchase of these vaccines under federally negotiated contracts with manufacturers is estimated to be 22% below cost for HPV vaccine and 33% below cost for MCV4 vaccine.

Conclusion

The establishment of the Vaccine Purchase Trust Fund allows Massachusetts to once again provide all federally recommended pediatric vaccines through the DPH Immunization Program for all children 0-18 years of age and maintain a state-of-the-art vaccine registry. By applying surplus and carryforward funds from FY15 collections, the net increase to the assessment of health insurance carriers will be limited to 1.05% while ensuring timely and well-monitored pediatric vaccine coverage for the Commonwealth's children and adolescents.

Addendum

Table 1. Calculation of Childhood Immunization Program Assessment FY15	
FY15 Assessment Base (Q1 Health Safety Net Fund surcharge)	1,798,308,451.23
FY15Pediatric Immunization Program Assessment Revenue Requirement	59,361,684.84
FY14 Credit for Excess Prior Collections	9,208,028.92
Amount Required to be Collected by June 30, 2015	50,153,655.92
2015 Pediatric Immunization Program Assessment Percentage	**2.79%**

Table 2. Childhood Immunization Program Expenditures FY15

	FY15 Final
Total Collections FY15	71,321,604
Total Revenue Requirement FY15	59,361,685
Total Collections to be credited to FY16	11,959,919
Total Revenue Requirement FY15	59,361,685
Total Expenditures FY15	52,896,432
Total unspent to be carried forward into FY16	6,465,253

Table 3. Calculation of Childhood Program Assessment Percentage FY16			
	Original	Revised for Full Universal	Increase for Full Universal
FY16 Assessment Base (Q1 Health Safety Net Fund surcharge)	1,798,308,451	1,798,308,451	-
FY16 Pediatric Immunization Program Assessment Revenue Requirement	61,540,259	80,345,887	18,805,628
Credit for Excess FY15 Collections	(11,959,919)	(11,959,919)	-
Amount Required to be Collected by June 30, 2016	49,580,339	68,385,967	18,805,628
FY15 Pediatric Immunization Program Assessment Percentage	2.76%	3.80%	1.05%

Table 4. Vaccine Purchase Trust Fund Ceiling FY16	
Amount Required to be Collected by June 30, 2016	68,385,967
FY15 Excess Collections	11,959,919
Unspent from prior authorization (carryforward from FY15)	6,465,253
Total FY16 obligation ceiling	86,811,140