

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
Drug Control Program
Immunization Program
Board of Registration in Pharmacy

JOINT POLICY 2015-01 and FAQs on PHARMACIST ADMINISTRATION of VACCINES

The Massachusetts Department of Public Health (MDPH or the Department), through the Drug Control Program, Immunization Program and Board of Registration in Pharmacy, is making adult vaccines more accessible by allowing administration by pharmacists. Qualified pharmacists may administer to adults 18 years of age and older certain vaccines included in the Recommended Adult Immunization Schedule approved by the U.S. Centers for Disease Control and Prevention (CDC).

Regulations of the MDPH, Drug Control Program at 105 CMR 700.004(B)(6) permit pharmacists, who have completed a duly accredited training course, to administer vaccines designated by the Department. The regulations can be viewed at https://www.sec.state.ma.us/reg_pub/pdf/100/105700.pdf.

1. Vaccines Covered by this Policy

Vaccines covered under this policy are those vaccines included in the most recent Recommended Adult Immunization Schedule – United States approved by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). The Recommended Adult Immunization Schedule is published at: <http://www.cdc.gov/vaccines/schedules/>.

2. Vaccine Recipients Covered by this Policy

Under this policy, qualified pharmacists are authorized to administer vaccines included in the CDC's Recommended Adult Immunization Schedule to adults 18 years of age and older.

3. Requirements for Vaccine Administration

- a. To administer vaccines, a prescription or standing order is required.
- b. To administer single dose emergency epinephrine, a standing order is required.
- c. Model standing orders for all vaccines included in the Recommended Schedule; emergency standing orders for the treatment of adverse events following vaccination; and *General Protocols for Vaccine Storage, Administration, Standing Orders and Mass Immunization Clinics* are available at the MDPH website <http://www.mass.gov/eohhs/gov/departments/dph/programs/id/immunization/model-standing-orders.html>
- d. Federal Law (<http://www.immunize.org/catg.d/p2027.pdf>) requires that a vaccine provider give a patient or legal representative the appropriate Vaccine Information Statement (VIS) whenever a vaccine is administered. More information about VIS can be found at <http://www.cdc.gov/vaccines/pubs/vis/vis-facts.htm>.

4. Communications

- a. A notification/record of immunization should be provided to the patient's physician.

<http://www.immunize.org/catg.d/p2023.pdf>

- b. The pharmacist may consider using the opportunity of the patient encounter to ask if the patient has been seen by the patient's primary care provider within the past year (or other appropriate time frame) and, if not, to encourage the patient to make an appointment with the primary care provider 's practice.
- c. See no. 7. on the Massachusetts Immunization Information System.

5. Reporting of Adverse Events

The National Childhood Vaccine Injury Act (NCVIA) requires healthcare providers to report to the Vaccine Adverse Event Reporting System (VAERS) (<http://vaers.hhs.gov/index>):

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine; or
- Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccination.

6. Training

- a. Pharmacists administering vaccines must attend and pass an accredited training course meeting the requirements of 105 CMR 700.004(B)(6)(c)1. These courses include, but are not necessarily limited to:
 - Pharmacy Based-Immunization Delivery (Live Training Seminar)
 - At APHA website <http://www.pharmacist.com/pharmacy-based-immunization-delivery>
- b. All such courses must, at a minimum, be accredited by the U.S. Centers for Disease Control and Prevention, the Accreditation Council for Pharmacist Education (ACPE) (www.acpe-accredit.org/), or similar health authority or professional body, and include pre-administration education and screening, vaccine storage and handling, administration of medication, record-keeping and reporting of adverse events.
- c. Information on other accredited courses is available through professional organizations, colleges and other sources.
- d. Proof of training must be kept on file in the pharmacy.
- e. Current CPR certification is recommended.

7. Participation in the Massachusetts Immunization Information System (MIIS)

In June 2010, legislation was passed requiring all licensed health care providers who administer immunizations to report vaccines administered to the immunization registry such data related to immunizations as the Department determines is necessary for disease prevention and control (M.G.L. Chapter 111, Section 24M)

www.malegislature.gov/laws/generallaws/parti/titlexvi/chapter111/section24m). MDPH is actively working on rolling out the system to pharmacies across the state to ensure they comply with the reporting requirement. IIS staff in More information about the MIIS can be found at www.mass.gov/dph/miis.

Resources:

CDC. Prevention and Control of Influenza with Vaccines: Recommendations of the ACIP, 2011. MMWR Early Release. August 18, 2011:1-6.

www.cdc.gov/mmwr/pdf/wk/mm60e0818.pdf?source=govdelivery

Model standing orders for all vaccines included in the Recommended Schedule, emergency standing orders for the treatment of adverse events following vaccination, and *General Protocols for Vaccine Storage, Administration, Standing Orders and Mass Immunization Clinics* are available at the MDPH website

<http://www.mass.gov/eohhs/gov/departments/dph/programs/id/immunization/model-standing-orders.html> Vaccine Information Statements (VIS) for all vaccines in English and other languages: www.immunize.org/vis

Instructions for Use of VISs: <http://www.cdc.gov/vaccines/hcp/vis/current-vis.html>

Resources on Proper Vaccine Storage and Handling:

www.cdc.gov/vaccines/recs/storage/default.htm

Centers for Disease Control and Prevention (CDC) website, www.cdc.gov/vaccines

MDPH Immunization Program website: the Department's website at www.mass.gov/dph/imm

MDPH Board of Registration in Pharmacy website:

www.mass.gov/eohhs/provider/licensing/occupational/pharmacy

MDPH Drug Control Program website: www.mass.gov/dph/dcp

Immunization Action Coalition: Vaccination Resources for Pharmacists

<http://www.immunize.org/pharmacists/>

JOINT POLICY 2015-01

Adopted by the Board of Registration in Pharmacy: April 3, 2012 as Joint Policy 2012-02, revised January 6, 2015 as Joint Policy 2015-01.

Effective Date: January 6, 2015

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
JOINT POLICY on PHARMACIST ADMINISTRATION of VACCINES
Frequently Asked Questions
January 2015

1. What are current vaccination rates for adults in Massachusetts?

While Massachusetts has often led the nation in childhood vaccination rates, vaccination rates for adults have lagged behind. See table below.

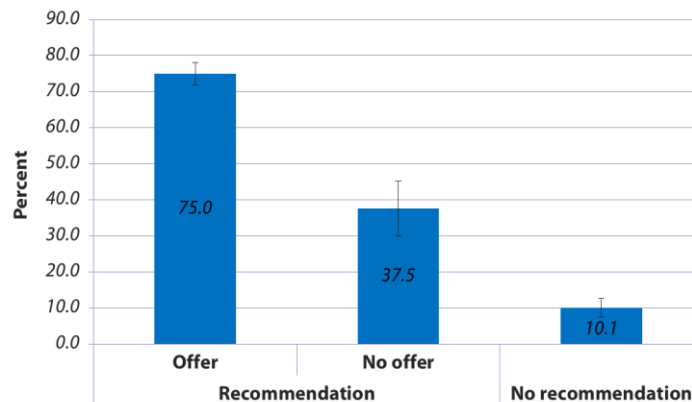
Massachusetts Adult Immunization Rates for Select Vaccines
Results from the 2010 BRFSS

Ever had Zoster 60+ y/o	16%
Ever had Tdap 18+ y/o	16%
Hep B series 18+ y/o	42%
Ever had HPV females 18-26 y/o	50%
Ever had PPV23 18-64 y/o w/ diabetes	55%
Hep B high risk 18+ y/o	61%

2. What can be done to increase adult vaccination rates?

There are many reasons for low vaccination rates among adults that have to do with the knowledge, beliefs, and practices of both providers and consumers. What is known, however, is that a person is most likely to be vaccinated if a vaccine is recommended by a trusted health care provider and the vaccine is offered on the spot.¹ See graph below.

Influenza vaccination coverage among pregnant women
by provider recommendation and offer, mid-November 2011



Source: CDC web site www.cdc.gov/flu/professionals/vaccination/pregnant-women.htm

¹ CDC. Influenza Vaccination Coverage Among Pregnant Women – U.S. 2010--11 Influenza Season. MMWR 2011;60(32);1078-1082. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6032a2.htm>

3. Why pharmacists as vaccinators?

All 50 states authorize pharmacists to administer vaccines with specific authority varying by state². Vaccination by pharmacists is convenient, efficient, and cost-effective.³ In one study, individuals aged 65 years and older who lived in states where pharmacists could provide vaccines had significantly higher influenza vaccine rates than individuals of this age who resided in states where pharmacists could not provide vaccines.⁴ A 4-year pilot project in Massachusetts in which pharmacists administered more than 9,000 doses of flu vaccine demonstrated that pharmacists could safely administer vaccines and those consumers were very satisfied with the experience of being vaccinated by pharmacists.⁵ The success of the pilot led to general authorization of pharmacist administration of influenza vaccine in Massachusetts.

Offering vaccination in non-traditional settings can enhance the capacity of the health care system to effectively deliver vaccines to adults by increasing the number and types of sites where adults can receive vaccine.⁶ Pharmacists, along with primary care providers, employers, local public health, and commercial vaccinators are necessary to ensure that all adults have access to all the recommended vaccines.

4. What are the requirements for a pharmacist to administer vaccine?

The pharmacist must have a prescription, physician directive, or standing order in order to administer vaccine.

Moreover, the pharmacist is required to receive standardized training in accordance with Department regulations at 105 CMR 700.004(B)(6)(c)1.

The goals of training programs are to:

- Provide comprehensive immunization education and training
- Provide pharmacists with the knowledge, skills, and resources necessary to establish and promote a successful immunization service
- Teach pharmacists to identify at-risk patient populations needing immunizations
- Teach pharmacists to administer immunizations in compliance with legal and regulatory standards

² MC Rothholz. Pharmacists as partners in adult vaccinations. Presented to the National Adult Immunization Coordinators Partnership. August 2011.

http://www.ct.gov/dph/lib/dph/infectious_diseases/immunization/naicp/pharmacists_and_adult_immunizations_final.pdf

³ J Fontanesi, JD Hirsch, SM Lorentz, DA Bowers, J Shafrin. Comparison of Pharmacists and Primary Care Providers as Immunizers. *Am J Pharm Benefits*. 2009;1(3):150-157.

http://www.ajmc.com/media/pdf/AJPB_Fall_Fontanesi_1-3.pdf

⁴ TE. Steyer, KR Ragucci, WS Pearson, AG Mainous. The role of pharmacists in the delivery of influenza vaccinations. *Vaccine* 2004; 22:1001-1006. <http://www.ncbi.nlm.nih.gov/pubmed/15161077>

⁵ J Calomo, et al. An overview of pharmacy-based influenza vaccination programs in Massachusetts. *NE J Pharm*. 2004:35-39.

⁶ CDC. Adult immunization programs in non-traditional settings: quality standards and guidance for program evaluation: Report of the National Vaccine Advisory Committee. *MMWR* 2000;49(No. RR-1):1-13.

<http://www.cdc.gov/mmwr/pdf/rr/rr4901.pdf>

There are three components to the certificate training program:

- 12 hour (1.2 CEU) self-study modules with case studies and assessment exam
- 8.0 hour (0.80 CEU) live seminar with final exam
- Hands-on assessment of intramuscular and subcutaneous injection technique

There are additional self-study resources.

5. How will primary care providers receive information about vaccines administered to their patients by pharmacists?

The Massachusetts Department of Public Health is in the process of rolling out a statewide Immunization Information Registry (MIIS). As providers, including pharmacists, are enrolled into the MIIS, they will be required by law (M.G.L. Chapter 111, Section 24M) to report immunization information for all patients to the MIIS. For more information on the MIIS, go to www.mass.gov/dph/miis.

6. What is the regulatory authority for this policy?

Department regulations at 105 CMR 700.004(B)(6) permit a pharmacist to “administer influenza vaccine and other immunizations designated by the Department”. The list of immunizations in the policy constitutes those “designated by the Department”.

7. Will pharmacy students and interns be allowed to administer vaccines?

No. Regulations only permit registered pharmacists to administer vaccines and do not extend to students or interns.

8. Are pharmacists required to report adverse events?

Yes. Federal rules, along with this policy, require healthcare providers, including pharmacists, to report certain adverse events to the national reporting system (Vaccine Adverse Event Reporting System, VAERS).

9. Whose job is it to advise patients on their immunization needs?

In order to increase vaccination rates and ensure that adults are protected against vaccine-preventable diseases, every member of the health care team, including pharmacists, must take responsibility for assessing the immunization status and administering needed vaccines at every health care encounter.