

Massachusetts Department of Public Health

Amended Guidelines for the Vaccination of Personnel of Licensed Clinics, Dialysis Centers, Hospitals and Long Term Care Facilities Against Seasonal Influenza and Pandemic Influenza H1N1

Effective Date: December 11, 2009

Effective December 11, 2009, the Massachusetts Department of Public Health (MDPH) promulgated final regulations requiring licensed clinics, dialysis centers, hospitals, and long-term care facilities (“health facilities”) to offer all personnel annual vaccination against seasonal influenza, and against pandemic or novel influenza viruses such as H1N1 as directed in guidelines of the Commissioner of Public Health (105 CMR 130.325; 105 CMR 140.150; and 105 CMR 150.002(D)(8)). Regulations were previously approved on an emergency basis effective September 14, 2009. MDPH provides the following updated guidelines for seasonal influenza and H1N1 influenza vaccination of health facility personnel. These updated guidelines are applicable from December 11, 2009 through June 30, 2010, unless subsequently amended or superseded.

A) Vaccination program

1) Definition of “personnel” for purposes of the vaccination program:

“an individual or individuals employed by or affiliated with the facility whether directly, by contract with another entity, or as an independent contractor, paid or unpaid, including but not limited to employees, members of the medical or clinical staff, contract employees or staff, students and volunteers who either work at or come to the licensed facility site, whether or not such individual(s) provides direct patient care.”

2) Components of the vaccination program

a) Information to be provided to all personnel. Licensed health facilities shall:

- (i) notify all personnel about the vaccination program;
- (ii) provide all personnel with information about the risks and benefits of immunization against influenza; and
- (iii) provide educational and promotional activities to encourage and improve immunization rates.

b) Offer vaccine (as described below) to all personnel at no cost to an individual:

- (i) provide each individual with the most current Vaccine Information Statement (VIS) for the vaccine prior to the administration of each dose of vaccine;
 - (ii) provide each individual with written documentation of vaccination on a personal immunization card or by other means; and
 - (iii) an individual may provide proof of current immunization against influenza in lieu of vaccination as part of this program.
- c) Declination of influenza vaccination. Personnel may decline vaccination if:
- (i) the vaccine is medically contraindicated (vaccination would likely be detrimental to the individual's health) or
 - (ii) vaccination is against an individual's religious beliefs, or
 - (iii) the individual declines the vaccination for any reason.
 - (iv) licensed health facilities must ensure that an individual who declines vaccination signs a statement declining vaccination and certifying that s/he received information about the risks and benefits of influenza vaccination. A health facility may not require an individual to indicate the reason s/he declined vaccination.
- d) Documentation of personnel influenza vaccination status
- (i) Consistent with existing information systems at the facility, a licensed health facility shall maintain a central system to track the seasonal and H1N1 vaccination status of all personnel, including declinations. If a licensed health facility is unable to provide or arrange for influenza vaccination for any individual, it must document the reasons vaccination was not provided. A record of the number of all personnel subject to the vaccination requirement, as defined in the regulations and these guidelines, shall be maintained to assess completeness of vaccination coverage.
 - (ii) A licensed health facility shall maintain documentation of each individual's vaccination status in the individual's personnel file. The MDPH interprets the term "personnel file" broadly to include electronic or other individual or aggregate file(s) or document(s) that allow a licensed health facility to easily assess the vaccination status of a particular individual.

B) Vaccines to be administered

- 1) For the 2009-2010 flu season, licensed health facilities shall provide two influenza vaccines to all personnel. They are:

- a) Licensed seasonal influenza vaccine containing the 2009-10 trivalent vaccine virus strains A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007 (H3N2)-like, and B/Brisbane/60/2008-like antigens, either as trivalent influenza vaccine for injection or live, attenuated influenza vaccine; and
- b) Vaccine containing antigens of swine-origin, influenza A H1N1 2009, as provided through the United States government.

- 2) All vaccines shall be administered according to the official package label and insert, and usual clinical practice.

C) Implementation schedule

- 1) Seasonal trivalent 2009-2010 influenza vaccine. The regulations require licensed health facilities, when feasible, to vaccinate all personnel against seasonal influenza no later than December 15, 2009 and annually thereafter. Refer to Unavailability of Vaccine below.
- 2) H1N1 2009 influenza vaccine. Licensed health facilities are directed to begin H1N1 2009 vaccination of personnel immediately upon receipt of the vaccine. Licensed health facilities should complete vaccination as rapidly as the supply and vaccination schedule allow.

D) Unavailability of Vaccine

- 1) A health facility shall not be required to provide or arrange for influenza vaccination during times that the vaccine is unavailable for purchase, shipment, or administration by a third party, or when complying with an order of the Commissioner which restricts the use of the vaccine. A health facility shall obtain and administer influenza vaccine in accordance with the regulations as soon as vaccine becomes available.

Given continuing shortages of both seasonal and H1N1 influenza vaccine, the Department recommends that health facilities prioritize the vaccination of those personnel who are involved in direct and regular care-giving of patients in such settings as inpatient care, emergency department, and outpatient clinics, particularly where the patient population may be at risk for complications. Facilities should not be concerned with meeting the December 15, 2009 timeline this year and will be deemed to be in compliance with the regulations as long as they are making good faith efforts to obtain and administer seasonal and H1N1 vaccine when supply becomes available.

E) Data collection and reporting

- 1) Each employer shall maintain a count of the total number of personnel subject to the vaccination requirement, as defined above and in regulation.

- 2) Each employer shall maintain centrally data on all vaccinations administered, vaccinations documented from another source, and vaccinations declined, to allow the facility, and MDPH upon request, to assess the completeness of influenza vaccination coverage.
- 3) All acute care hospitals licensed under M.G.L. c.111, § 51, unless such hospital is a college infirmary or a hospital that provides only mental health, behavioral health or substance abuse services, shall report to MDPH on April 15, 2010 the total number of personnel subject to the seasonal influenza vaccination requirement, and the total number of personnel vaccinated with seasonal trivalent 2009-2010 influenza vaccine as of March 31, 2010.

F) Written Protocols

- 1) MDPH's written clinical protocols covering the latest guidance and requirements for vaccine ordering, storage, provision of information and documentation can be found at <http://www.mass.gov/dph/imm> and clicking on "Vaccine Management".
- 2) Standing orders for vaccines and clinic protocols can be found by going to <http://www.mass.gov/dph/imm> and clicking on "Model Standing Orders."

G) Additional Resources

- 1) *Prevention and Control of Seasonal Influenza with Vaccines. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009 (CDC)*
<http://www.cdc.gov/mmwr/pdf/rr/rr5808.pdf>
- 2) *Use of Influenza A (H1N1) 2009 Monovalent Vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009 (CDC)*
<http://www.cdc.gov/mmwr/PDF/rr/rr5810.pdf>

H) The latest information on influenza is available on the following websites:

- 1) Centers for Disease Control and Prevention's (CDC's) at <http://www.cdc.gov/flu>
- 2) MDPH at www.mass.gov/dph/flu

Contact Information

If you have any questions concerning the guidelines please contact:

DPH.DHCQ@massmail.state.ma.us

Questions concerning vaccine administration and management should be directed to the Massachusetts Immunization Program at 617-983-6800.