



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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Circular Letter: DHCQ 09-12-526

TO: Acute Care Hospital Chief Executive Officers, Infection Preventionists, and Chief Nursing Officers

FROM: Alice Bonner, Director, Bureau of Health Care Safety and Quality

DATE: December 10, 2009

RE: Reporting and Data Collection Guidelines for Seasonal Influenza Vaccination of Personnel at Massachusetts Acute Care Hospitals for the 2009-2010 Influenza Season

The purpose of this letter is to provide instructions for the mandatory reporting by acute care hospitals of seasonal influenza vaccination rates of hospital personnel for the 2009-2010 influenza season. The guidance included in this document applies to **seasonal influenza vaccination**, not pandemic influenza A H1N1 2009 vaccination.

Background:

The Department promulgated emergency regulations requiring all licensed hospitals to offer seasonal influenza vaccine to employees on September 14, 2009 (105 CMR 130.325). On the same date, the Commissioner of Public Health issued guidelines as authorized by the regulations, requiring licensed hospitals to offer influenza A H1N1 vaccination.

The emergency regulations were amended by the Public Health Council in November, and have an effective date of December 11, 2009. One important change is the replacement of the word "employees" with "personnel" in the definition of individuals who must be offered vaccine. The final regulation requires that hospitals offer influenza vaccine to all "personnel," defined as "an individual or individuals employed by or affiliated with the hospital, 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 staff, contract employees or staff, students, and volunteers who either work at or come to the licensed hospital site, whether or not such individual(s) provides direct patient care."

The September 14, 2009 guidelines have been amended effective December 11, 2009, and are attached to this letter.

The regulations require hospitals to report information to the Department, documenting compliance with the personnel vaccination requirement, in accordance with reporting and data collection

guidelines of the Commissioner (105 CMR 130.325(I)). This document summarizes those reporting and data collection guidelines.

Annual Reporting:

The Department has made minor changes to the methodology for hospital reporting of seasonal influenza vaccination data for 2009-2010 based on reports received from hospitals for the 2008-2009 season. No later than April 15, 2010, acute care hospitals are required to report the following to the Department:

- The number of personnel immunized for seasonal influenza by a hospital from August 1, 2009 through March 31, 2010;
- The number of personnel immunized for seasonal influenza outside the hospital from August 1, 2009 through March 31, 2010;
- The number of personnel declining seasonal influenza immunization from August 1, 2009 through March 31, 2010; and
- The total number of hospital personnel as of August 1, 2009.

The instructions for completing and submitting the required data form is in Attachment A. The reporting form is in Attachment B.

Seasonal influenza vaccination is an effective method of preventing influenza virus infection and its potentially serious complications. The Department is committed to working with you to ensure that patients and personnel are protected. Thank you for your ongoing participation in this important initiative.

If you have any questions concerning the reporting requirements, please contact Roberta Bernstein at roberta.bernstein@state.ma.us or 617-753-8062.

Attachment A

Influenza Vaccination of Personnel in Massachusetts Acute Care Hospitals Instructions for Completing and Submitting the Data Collection Form

I. General Instructions

Report for Seasonal Influenza Vaccination Only: This reporting process covers vaccination for seasonal influenza only, NOT pandemic influenza A H1N1 2009 vaccine. Please do not include data for pandemic influenza A H1N1 2009 vaccine.

Reporting for Institutions with Multiple Campuses:

Please report on each campus consistent with the way your hospital reports healthcare associated infections to NHSN (National Healthcare Safety Network). If unsure about this, please consult your hospital's Infection Control Program, or call Roberta Bernstein at the Massachusetts Department of Public Health (contact information directly below).

For Questions or to Provide Feedback:

Please contact the Massachusetts Department of Public Health:
roberta.bernstein@state.ma.us (617-753-8062).

II. Instructions for Completing Each Item on the Data Collection Form

A. General Information

1. **Facility Name:** Write in the name of your hospital.
2. **Contact Information:** Write in the name, phone number, email address and position/title of the person at your hospital whom MDPH should contact if there are any questions about influenza vaccination data submitted. This may or may not be the person completing this form.

B. Seasonal Influenza Vaccination of Personnel: 2009-2010 Flu Season

Required Data:

3. **Number of hospital personnel who received seasonal flu vaccination from the hospital:** Write in the number of hospital personnel who received the current season's influenza vaccine from the hospital (via hospital vaccination programs or Employee Health) **from August 1, 2009 through March 31, 2010**. For the purposes of the vaccination program, personnel is defined as:

“an individual or individuals employed by or affiliated with the hospital, 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 staff, contract employees or staff, students, and volunteers who either work at or come to the licensed hospital site, whether or not such individual(s) provides direct patient care.”

Personnel, such as contractors performing administrative functions, who do not work at or come to the licensed health facility are not required to be vaccinated.

4. **Number of hospital personnel:** Write in the total number of hospital personnel on August 1, 2009.
5. **Number of hospital personnel who received seasonal flu vaccination outside of the hospital:** Write in the number of hospital personnel who received the current season's influenza vaccine OUTSIDE the hospital (for example from private physician's office, community clinic, etc.) from August 1, 2009 through March 31, 2010.
6. **Number of hospital personnel who declined the current season's influenza vaccine from August 1, 2009 through March 31, 2010.**

Optional Data:

7. **Comments:**

III. Submitting Completed Data Forms to the Massachusetts Department of Public Health

When to Submit Data Forms to MDPH:

The due date for submission of this form is April 15, 2010. Items 1- 6 must be completed for all forms submitted at this date. Item 7 (comments) is optional.

How to Submit Data Forms to MDPH:

Hard copies of data forms should be submitted to the Massachusetts Department of Public Health, by mail or by fax.

Massachusetts Department of Public Health,
Attn: Roberta Bernstein
99 Chauncy Street
Boston, MA 02111

Fax: 617-753-8125. Attn: Roberta Bernstein

Facilities should keep copies of all data forms submitted in a secure file for future reference.

For Questions or to Provide Feedback:

Please contact the Massachusetts Department of Public Health:
Roberta.bernstein@state.ma.us (617-753-8062)

A Note on Data Collection Methods and Sources

As you vaccinate, keep track of recipients' hospital employment status. Use data collection methods that work with your hospital's systems, FOR EXAMPLE:

- For **number of hospital personnel**, use your hospital's human resources department or payroll database.
- For **number of hospital personnel who received seasonal flu vaccination from the hospital**, use vaccination logs, count vaccination consent forms, extract data from vaccination information forms kept by Employee Health, or review attestation or declination forms.

- For ***number of personnel who received seasonal flu vaccination OUTSIDE the hospital***, review attestation forms or declination forms, survey personnel, or extract data from vaccination information forms kept by Employee Health.
- For ***number of personnel who declined seasonal flu vaccination***, review declination forms or declination tracking forms.

ATTACHMENT B

Seasonal Influenza Vaccination of Personnel in Massachusetts
Acute Care Hospitals
Data Collection Form

I. General Information

1. Facility Name: _____

2. Contact Information

Name: _____

Phone Number: _____

Email Address: _____

Position/Title: _____

II. Data: Seasonal Influenza Vaccination of Personnel Data as of March 31, 2010:

Required Data

3. Number of hospital personnel who received **seasonal** flu vaccination (from the hospital) **from 8/1/09 thru 3/31/10. Please do not include doses of pandemic influenza A H1N1 2009 vaccine.**

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4. Number of hospital personnel on **August 1, 2009:**

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5. Number of hospital personnel who received **seasonal** flu vaccination outside of the hospital **from 8/1/09 thru 3/31/10. Please do not include doses of pandemic influenza A H1N1 2009 vaccine.**

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6. Number of hospital personnel who declined **seasonal** flu vaccination **from 8/1/09 thru 3/31/10. Please do not include declination of pandemic influenza A H1N1 2009 vaccine.**

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Optional Data

7. Comments:

DUE DATE FOR SUBMISSION OF THIS FORM TO MDPH: APRIL 15, 2010

Hard copies of data forms should be submitted to the Massachusetts Department of Public Health, by mail or by fax.

Massachusetts Department of Public Health,
Attn: Roberta Bernstein, 99 Chauncy Street, Boston, MA 02111

Fax: 617-753-8125. Attn: Roberta Bernstein

Attachment C

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 decline vaccination sign 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. See 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 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.