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**Circular Letter: DHCQ 09-08-518**

**To: Hospital CEOs**

**From: Jean Pontikas**  
Interim Director, Bureau of Health Care Safety and Quality

**Date: August 27, 2009**

**Re: EMERGENCY REGULATION - INFLUENZA VACCINATION OF  
EMPLOYEES AT HOSPITALS**

This letter is to advise licensed hospitals that on August 12, 2009 the Public Health Council (PHC) approved promulgation of emergency amendments to the hospital licensure regulation (See attachment A, 105 CMR 130.325). The amendments require hospitals to ensure that all employees are vaccinated against (1) seasonal influenza virus, no later than December 15, 2009 and annually thereafter, and (2) novel or pandemic virus (such as H1N1) as directed in guidelines to be issued by the Commissioner of Public Health. Similar amendments also were adopted by the PHC for hospitals and long-term care facilities. The amendments are explained below and in the PHC memorandum of August 12, 2009 available on the Department of Public Health's (Department) website [www.mass.gov/dph](http://www.mass.gov/dph).

The amendments were promulgated on an emergency basis to ensure that hospitals begin vaccinating employees as soon as seasonal and H1N1 influenza vaccines become available. The emergency amendments are effective **September 14, 2009**, upon filing with the Office of the Secretary of the Commonwealth and will remain in effect for 3 months. Within this 3 month period, the Department will conduct a public hearing and comment period and return to the PHC for final promulgation of the amendments. Please consult the Department's website for an announcement of the hearing.

**Background – Vaccination of Health Care Workers**

These emergency amendments are part of the effort to protect workers in health care settings and the patients they care for by making influenza vaccination readily available to all employees. Influenza vaccination is the most effective method of preventing influenza virus infection and its potentially serious complications. The majority of health care workers are not vaccinated against seasonal influenza, despite the recommendation of numerous professional agencies and organizations including the Centers for Disease Control and Prevention (CDC), the National Foundation for Infectious Diseases (NFID), the Infectious Diseases Society of America (IDSA) and The Joint Commission. According to the CDC, only 44% of health care workers received influenza vaccine during the 2006-2007 season.<sup>1</sup>

The Department has developed a coordinated plan to address the unique challenges presented by the emergence of the novel H1N1 virus while continuing to prepare for seasonal influenza. An essential component of this initiative is to ensure that health care workers and consequently their patients are protected from seasonal and H1N1 influenza viruses by being vaccinated.

### **Emergency Amendments: Seasonal Influenza**

The amendments require hospitals to establish programs to ensure that all employees (including medical staff, contractors and certain volunteers) are vaccinated against seasonal influenza virus, no later than December 15, 2009, and annually thereafter.

The amendments require hospitals to notify every employee of the seasonal influenza vaccination requirement and the risks and benefits of vaccination. Hospitals may use a Vaccine Information Statement (VIS) for this purpose. VISs are available at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. It is the hospital's responsibility to provide a copy of the most up-to-date version of the VIS prior to administering vaccine.

The amendments require hospitals to provide or arrange for vaccination of all employees who cannot provide proof of current immunization against influenza, at no cost to the employee, unless the employee declines vaccination. Employees (such as contractors performing administrative functions) who do not physically work at or come to the licensed hospital site are not required to be vaccinated under these amendments.

A hospital is not required to ensure vaccination of an employee if (a) the vaccine is medically contraindicated for that employee, (b) vaccination is against the employee's religious beliefs, or (c) the employee refuses the vaccine. An employee who declines vaccination must sign a declination statement and certify that he/she received information about the risks and benefits of vaccination. Electronic signatures are acceptable for declination forms. A Sample Influenza Declination Form (Attachment B) and Sample Vaccination Declination Tracking Form (Attachment C) are included for your information.

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<sup>1</sup> CDC Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practice (ACIP), 2009.MMWR 2009; 58(Early Release):1-52

The amendments provide that a hospital is not required to provide or arrange for influenza vaccination when the vaccine is unavailable for purchase, shipment or administration by a third-party, or if the Commissioner issues an order or guidelines restricting the use of a vaccine.

The amendments require hospitals to (1) maintain a central system to track the vaccination status of each employee including declinations and (2) maintain documentation of vaccination status in each employee's personnel file. The Department interprets the term "personnel file" broadly to include electronic or other individual or aggregate file(s) or document(s) that allows a hospital to easily determine the vaccination status of a particular employee. If a hospital is unable to provide or arrange for influenza vaccination for any employee, it must document the reasons such vaccination could not be provided or arranged. If a contractor is on site, a hospital may accept a blanket statement from the contracting company attesting to the vaccination status of its employees, as long as the contracting company certifies that it is maintaining a central system with the information required by the regulation and can make it available to the hospital or the Department upon request.

The amendments require hospitals to collect and submit data to the Department in accordance with guidelines to be issued by the Commissioner. Specific reporting guidelines for collection and submission of data for the 2009-2010 flu season will be issued shortly in a separate letter.

### **Emergency Amendments: Novel or Pandemic Influenza (H1N1)**

In addition to requiring that hospitals ensure annual vaccination of all employees against seasonal influenza virus, the amendments authorize the Commissioner of Public Health to issue guidelines as needed to require hospitals to vaccinate all or some employees against novel or pandemic viruses, such as H1N1. The Commissioner is expected to issue guidelines in the coming weeks directing hospitals to ensure that all or some employees are vaccinated against H1N1 influenza. As provided in the amendments, the Commissioner's H1N1 employee vaccination guidelines will address:

- (1) Categories and priority of employees to be vaccinated
- (2) Type of vaccine(s) to be administered
- (3) Date by which employees must be vaccinated
- (4) Data collection and reporting requirements

Once the Commissioner issues guidelines directing hospitals to implement a novel or pandemic (H1N1) employee vaccination program, the amendments require hospitals to comply with the same requirements that apply to seasonal influenza for (1) employee notification of risks and benefits, (2) provision of vaccination without charge to designated employees, (3) declination of vaccination, and (4) documentation of employee vaccination status.

In contrast to seasonal influenza, hospitals are not required to implement a novel or pandemic (H1N1) influenza vaccination program until guidelines have been issued by the Commissioner. This letter does **not** constitute the issuance of guidelines related to

H1N1, but rather is intended to inform hospitals about the emergency amendments and the potential H1N1 vaccination obligations that are likely to arise this flu season.

### **Availability of H1N1 Vaccine**

The H1N1 vaccine is now in production, with efficacy and safety studies ongoing. Some doses of H1N1 influenza vaccine will be available starting in October. However, fewer doses are expected to be available than previously projected. All H1N1 vaccine will be supplied by the federal government at no cost to providers in both the public and private sectors. State health departments will be responsible for allocating all doses of H1N1 vaccine.

The first shipments of H1N1 vaccine are likely to be directed to priority populations such as children, pregnant women, those of all ages at higher risk of complications of influenza infection, as well as healthcare workers and emergency medical services personnel with direct patient contact. It is expected that most people will require two doses of vaccine, 3-4 weeks apart. In addition, it is expected that H1N1 vaccine will be able to be co-administered with seasonal flu vaccine. The Department will post the latest guidance about priority groups and all other recommendations related to H1N1 vaccine on the Department flu website <http://www.mass.gov/dph/flu>.

In order to facilitate allocation of H1N1 vaccine to providers in Massachusetts, the Department is developing an on-line system to register all public and private provider sites interested in receiving and administering novel H1N1 vaccine (including private providers, hospitals, local health departments, regional public health coalitions, visiting nurses associations, hospitals, pharmacists and commercial community vaccinators). The Department expects to go live with this registration system in early September. Information about accessing the registration site will be disseminated broadly through email and in collaboration with professional organizations and trade associations, and will be posted on the Department's flu website <http://www.mass.gov/dph/flu>

The task of administering millions of doses of seasonal and pandemic influenza vaccine is enormous. The Department will work closely with health care facilities, agencies, local health officials, and health care professionals to promote and support enhanced seasonal flu hospitals. *Any guidelines issued by the Commissioner requiring hospitals, hospitals and long-term care facilities to implement employee vaccination programs for H1N1 will be mailed directly to licensed facilities and posted on the Department's website.*

### **Latest Information on Influenza Outbreak and Vaccination**

You will find helpful information about flu vaccine, including the risks and benefits of getting vaccinated, and H1N1 guidance, on the Centers for Disease Control and Prevention's (CDC's) website at <http://www.cdc.gov/flu>. For the latest updates on influenza also please visit the Department's website at [www.mass.gov/dph/flu](http://www.mass.gov/dph/flu). The Department's latest guidance and requirements about vaccine ordering, storage, provision of information and documentation can be found at <http://www.mass.gov/dph/imm>, and then click on "Vaccine Management." Standing orders for vaccines and hospital protocols can be found by going to <http://www.mass.gov/dph/imm> and clicking on "Model Standing Orders."

## **What Hospitals Should Do Now**

The Department advises hospitals to begin the seasonal influenza vaccination of employees immediately upon receipt of the vaccine. The amendments require hospitals, when feasible, to ensure that all employees have been vaccinated with seasonal influenza vaccine by December 15, 2009. Hospitals are allowed to determine the order in which employees are vaccinated provided that, when feasible, all employees are vaccinated by December 15<sup>th</sup>.

There is still some seasonal influenza vaccine available to purchase from vaccine distributors. Once the vaccination season is under way, the Influenza Vaccine Availability Tracking System (IVATS) becomes operational. IVATS (<http://www.preventinfluenza.org/ivats/>) enables healthcare providers to view at a glance which distributors have vaccine available to sell (See Attachment D - Partial List of Seasonal Flu Distributors). Hospitals can also get helpful information at the Flu Supply News website which lists the phone numbers and website addresses of the vaccine distributors (<http://www.flusupplynews.com/resources.cfm>).

Given the anticipated issuance of H1N1 vaccination guidelines by the Commissioner, the Department also advises hospitals to begin to plan for an additional round of vaccination, with the two-dose H1N1 vaccine. As explained above, the H1N1 vaccine is expected to be available beginning in October.

If you have questions about the emergency amendments, please contact [DPH.DHCQ@massmail.state.ma.us](mailto:DPH.DHCQ@massmail.state.ma.us)

### Attachments:

- A. August 12, 2009 Amendments
- B. Sample Influenza Vaccine Declination Form
- C. Sample Vaccination Declination Tracking Form
- D. Partial List of Seasonal Flu Vaccine Distributors

## Attachment A

### Proposed Amendments to 105 CMR 130.000: Hospital Licensure

**105 CMR 130.000 is amended by inserting the following new section as 105 CMR 130.325:**

**130.325: Requirement that Employees Be Vaccinated Against Influenza**

**(A) Definitions**

(1) For purposes of 105 CMR 130.325, "employee" means an individual who is a volunteer with direct patient contact or an individual employed (whether directly, by contract with another entity, as an independent contractor or as a member of the medical staff) by a hospital, on a part-time or full-time basis, whether or not such individual provides direct patient care.

(2) For purposes of 105 CMR 130.325, the requirement for "influenza vaccine" or "vaccination" means immunization by either influenza vaccine, inactivated or live; attenuated influenza vaccine including seasonal influenza vaccine pursuant to 105 CMR 130.325(B); and/or other influenza vaccine pursuant to 105 CMR 130.325(C).

(B) Each hospital shall ensure that every employee is vaccinated with seasonal influenza vaccine unless such employee declines vaccination in accordance with 105 CMR 130.325(F). When feasible, and consistent with any guidelines of the Commissioner of Public Health or his/her designee, each hospital shall ensure that every employee is vaccinated with seasonal influenza vaccine no later than December 15, 2009 and annually thereafter.

(C) Each hospital also shall ensure that every employee is vaccinated against other pandemic or novel influenza virus(es) as specified in guidelines of the Commissioner or his/her designee, unless such employee declines vaccination in accordance with 105 CMR 130.325(F). Such guidelines may specify:

- (1) the categories of employees that shall be vaccinated and the order of priority of vaccination of employees, with priority for those employees with responsibility for direct patient care;
- (2) the influenza vaccine(s) to be administered;
- (3) the dates by which employees must be vaccinated; and
- (4) any required reporting and data collection relating to the employee vaccination requirement of 105 CMR 130.325(C).

(D) Each hospital shall provide every employee with information about the risks and benefits of influenza vaccine.

(E) Each hospital shall notify every employee of the influenza vaccination requirements of 105 CMR 130.325 and shall, at no cost to any employee, provide or arrange for vaccination of all employees who cannot provide proof of current immunization against influenza, as required pursuant to 105 CMR 130.325(B) and (C), unless such employee declines vaccination in accordance with 105 CMR 130.325(F).

(F) Exceptions.

(1) A hospital shall not require an employee to receive an influenza vaccine pursuant to 105 CMR 130.325(B) or (C) if:

- (a) the vaccine is medically contraindicated, which means that administration of influenza vaccine to that employee would likely be detrimental to the employee's health;
- (b) vaccination is against the employee's religious beliefs; or
- (c) the employee refuses the vaccine.

(2) An employee who declines vaccination for any reason shall sign a statement declining vaccination and certifying that he or she received information about the risks and benefits of influenza vaccine.

(G) Unavailability of Vaccine. A hospital shall not be required to provide or arrange for influenza vaccination during such 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 hospital shall obtain and administer influenza vaccine in accordance with 105 CMR 130.325 as soon as vaccine becomes available.

(H) Documentation.

(1) A hospital shall require and maintain in each employee's personnel file a certificate(s) of vaccination against influenza pursuant to 105 CMR 130.325(B) and (C) or the employee's declination statement pursuant to 105 CMR 130.325(F).

(2) Each hospital shall maintain a central system to track the vaccination status of every employee.

(3) If a hospital is unable to provide or arrange for influenza vaccination for any employee, it shall document the reasons such vaccination could not be provided or arranged for.

(I) Reporting and Data Collection.

Each hospital shall report information to the Department documenting the hospital's compliance with the employee vaccination requirements of 105 CMR 130.325, in accordance with reporting and data collection guidelines of the Commissioner or his/her designee.

Authority: M.G.L. c. 111, §§ 5, 6, and 51 through 56

**Attachment B**

**Sample Influenza Vaccine Declination Form**

Facility Name: \_\_\_\_\_

You have given me the opportunity to be vaccinated with the influenza vaccine at no charge to myself.

I have received, read and understand information about the risks and benefits of the vaccine.

However, (please indicate one of the following choices)

- I decline the influenza vaccine at this time. I understand that I may change my mind at any time and accept influenza vaccination, if vaccine is available.
- I have already received the influenza vaccine for this flu season and am thus declining it at this time. I received the vaccine at \_\_\_\_\_.

\_\_\_\_\_  
Employee's Name (Print)

\_\_\_\_\_  
Employee's Signature

\_\_\_\_\_  
Date



**Attachment D**

**Partial List of Seasonal Flu Vaccine Distributors**

ABO Pharmaceuticals	877-226-2266 <a href="mailto:fluvaccine@abopharmaceuticals.com">fluvaccine@abopharmaceuticals.com</a>
Atlantic Biologicals	800-509-7592 <a href="mailto:vaccine@atlanticbiologicals.com">vaccine@atlanticbiologicals.com</a>
Berna Products	800-533-5899
Besse Medical	800-543-2111
Blood Diagnostics	800-948-9834 <a href="mailto:orders@ivig.com">orders@ivig.com</a>
Dubin Medical, Inc.	800-929-4364 <a href="mailto:sales@dubinmedical.com">sales@dubinmedical.com</a>
FFF Enterprises	800-843-7477 <a href="mailto:ffccustomer care@fffenterprises.com">ffccustomer care@fffenterprises.com</a>
GIV, Inc.	800-521-7468 <a href="mailto:customersfirst@giv.com">customersfirst@giv.com</a>
Henry Schein	800-772-4346
Insource, Inc.	800-366-3829 <a href="mailto:customersfirst@insourceonline.com">customersfirst@insourceonline.com</a>
Nationwide Medical/Surgical	800-997-8846 <a href="mailto:petersecord@nationwidemedical.net">petersecord@nationwidemedical.net</a>
sanofi pasteur	800-822-2463 <a href="http://www.vaccineshoppe.com">www.vaccineshoppe.com</a>
Smith Drug	800-572-1216
STAT Pharmaceuticals	800-748-5665 <a href="mailto:sales@fluvaccine.com">sales@fluvaccine.com</a>
Waltco Medical	972-290-9033 <a href="mailto:fluvaccine@waltcomedical.com">fluvaccine@waltcomedical.com</a>