



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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**TO: Interested Parties
Health Care Organizations and Professional Associations
Dentistry, Nursing, Medical and Pharmacy Schools**

**From: John Auerbach, Commissioner, Department of Public Health
Jean Pontikas, Interim Director, Bureau of Health Care Safety and Quality
Grant Carrow, Deputy Director, Bureau of Health Care Safety and Quality**

Date: September 14, 2009

**Re: IMPLEMENTATION OF EMERGENCY REGULATIONS AUTHORIZING
ADMINISTRATION OF VACCINE BY DESIGNATED HEALTH CARE
PROFESSIONALS AND RELATED COMMISSIONER'S ORDER AND
GUIDELINES**

Introduction

This memorandum is to inform you that the Department of Public Health has promulgated and is implementing emergency regulations effective on September 14, 2009 which authorize the Commissioner of Public Health to designate certain health care professionals and medical and nursing students to administer seasonal influenza and H1N1 vaccine. The regulatory amendments are part of the Department's planning and preparation for pandemic influenza A H1N1 this fall.

An overview of the emergency regulations (Attachment A), the Commissioner's Order contemplated by the emergency regulations, the associated guidelines, the public hearing process and implementation issues are provided below.

We are also providing the following attachments that implement the emergency regulations:

- 1) Commissioner's Order (Order) authorizing administration of seasonal and pandemic H1N1 influenza vaccine by designated health care professionals and medical and nursing students(Attachment B)

- 2) Guidelines referenced in the Order which address the conditions under which the designated health professionals may administer influenza vaccine (Attachment C)

Emergency Regulations

In brief, the emergency amendments authorize the Commissioner to issue an order designating health care professionals, licensed or certified by the Department, or medical or nursing students enrolled in approved or accredited programs, to administer vaccine for the prevention of pandemic, novel or seasonal influenza virus. Such an order may be issued in the event the Commissioner determines that there are or will be insufficient health care professionals available for timely vaccine administration. In addition, the regulations require that the vaccine be administered under an order or prescription of a practitioner authorized to prescribe vaccines.

Commissioner's Order and Associated Guidelines

The attached Commissioner's Order which identifies the additional groups that may administer seasonal and pandemic H1N1 influenza vaccines is effective on September 14, 2009. The Order designates dentists, paramedics, pharmacists, and medical and nursing students as authorized vaccinators. A copy of the guidelines concerning training and supervision of vaccine administration and the conditions under which the designated individuals may administer influenza vaccines, are attached as Attachment C. The written protocols concerning storage, handling and other parameters of vaccine management that are also referenced in the Order, are addressed below and in the attached guidelines.

Please note that the Commissioner's Order and associated guidelines and written protocols may change throughout the flu season dependent upon emerging conditions and as needed.

Implementation Issues

With respect to questions concerning liability, the federal Public Readiness and Emergency Preparedness Act of 2006 (PREP Act; 42 U.S.C. § 247d-6d) provides immunity from tort liability under state and federal law for health care professionals authorized under state law to administer H1N1 vaccine. This immunity extends to the licensed professionals newly designated as H1N1 vaccinators by the regulations and Commissioner's Order. It does not extend to students, so medical and nursing students should consult their school concerning liability coverage they may have through the school. It should also be noted that PREP Act immunity does not extend to seasonal flu vaccination. The liability issues surrounding administration of seasonal flu will be no different than in prior flu seasons.

In terms of reimbursement, while the H1N1 vaccine will be provided at no charge, reimbursement for vaccine administration is a matter between providers and third party payers. Seasonal flu vaccine will be available as in previous flu seasons. Reimbursement for seasonal vaccine and administration is similarly a matter for providers and third party payers.

Organizations, facilities or agencies operating flu clinics may determine whether to engage newly authorized vaccinators in administering seasonal and H1N1 vaccine.

Regulatory Process

The Public Health Council voted to approve an emergency regulation regarding potential vaccinators at its August 12, 2009 meeting; however, that regulation was not formally filed. Instead, a revised emergency regulation was adopted by the Public Health Council at its regularly scheduled meeting on September 9, 2009 and will take effect on September 14, 2009, upon filing with the Office of the Secretary of the Commonwealth.

The basis for the emergency regulation is explained in detail in the Public Health Council memoranda available on the DPH website www.mass.gov/dph. The amendments approved by the Public Health Council on September 9, 2009 include licensed health care professionals and medical and nursing students as potential vaccinators to administer seasonal influenza vaccine as well as pandemic H1N1 influenza vaccine.

A public hearing comment period will be held on October 9, 2009 concerning the emergency regulations. Comments are invited either in person or in writing at the hearing and written testimony may be submitted until October 16, 2009. Please consult the DPH website at www.mass.gov/dph under "Regulations and Policies" for an announcement of the hearing, to be made on or after September 14, 2009.

Availability of H1N1 Vaccine

The H1N1 vaccine is now in production, with efficacy and safety studies ongoing. Initial quantities of H1N1 influenza vaccine will be available starting in October. 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 ages 6 months to 24 years old, pregnant women, and 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 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's flu website <http://www.mass.gov/dph/flu>.

In order to facilitate allocation of H1N1 vaccine to providers in Massachusetts, the Department has developed an on-line system to register all public and private medical provider sites interested in receiving and administering novel H1N1 vaccine (including private medical providers, hospitals, local health departments, regional public health coalitions, visiting nurses associations, clinics, pharmacies and commercial community vaccinators). The Department has developed an on-line registration system for H1N1 vaccine. Information about accessing the registration site is being 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 flu clinics.

Written Protocols

The Department's written clinical protocols covering the 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." Protocols for standing orders for vaccines, vaccine administration and clinics can be found by going to <http://www.mass.gov/dph/imm> and clicking on "Model Standing Orders." Additional guidance and other resources for immunization training can also be found on the DPH website.

Latest Information on Influenza Outbreak and Vaccination

There is 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.

Contact Information

If you have any questions concerning the proposed emergency amendments, please contact the Bureau of Health Care Safety and Quality at DPH.DHCQ@massmail.state.ma.us. Questions concerning vaccine administration, management, and training should be directed to the Immunization Program at 617-983-6800.

The Commissioner's Order (Attachment B) and related Guidelines (Attachment C) will also be available on the DPH website at www.mass.gov/dph under "Regulations and Policies" or at the direct link below:

http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Government&L2=Laws%2c+Regulations+and+Policies&L3=Department+of+Public+Health+Regulations+%26+Policies&L4=Proposed+Amendments+to+Regulations&sid=Eeohhs2&b=terminalcontent&f=dph_legal_vaccine&csid=Eeohhs2