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TO: Commissioner John Auerbach and Members of the Public Health Council

FROM: Jean Pontikas, Interim Director, Bureau of Health Care Safety and Quality
Alfred DeMaria, Jr., MD, Medical Director, Bureau of Infectious Disease
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DATE: August 12, 2009

RE: Request for Emergency Promulgation of Proposed Amendments to:

- (1) 105 CMR 130.000 (Hospital Licensure), 105 CMR 140.000 (Licensure of Clinics), 105 CMR 150.000 (Licensure of Long-Term Care Facilities) – Relating to Employee Influenza Vaccinations; and
- (2) 105 CMR 700.000 (Implementation of the Controlled Substances Act) – Authorizing Administration of Vaccines by Designated Health Care Professionals

H1N1 Overview

The Commonwealth of Massachusetts is involved in a full-scale mobilization of resources to ensure that the state is prepared for pandemic influenza this fall. These steps involve coordinating with our partners at the federal, state, tribal, and local levels. As part of this effort, the Department is preparing for widespread vaccination for both seasonal flu and H1N1. Department staff now proposes a number of emergency regulatory amendments that would facilitate and encourage administration of influenza vaccine.

In Massachusetts, almost 1,400 residents have been lab-confirmed with H1N1 and ten have died. Because testing is not done for every case, the true number of individuals who have been infected with H1N1 in the Commonwealth is probably in the tens of thousands. There have been over 300 deaths in the US since the beginning of the outbreak. Nationally, 86% of deaths occurred in patients with an underlying health condition.

The outlook for the fall and winter influenza season is uncertain. The influenza season in the Southern hemisphere is underway and being observed carefully. Influenza activity is high, but behaving in a way typical of seasonal influenza, and the basic epidemiology of H1N1 has not changed appreciably. Based on evidence from the Southern hemisphere, the novel H1N1 is

likely to co-circulate with seasonal influenza strains, perhaps becoming the dominant strain. The flu season may well occur earlier and be more severe than usual.

Preparing for Widespread Vaccination

All indications are that there will be a pandemic H1N1 influenza vaccine available starting as early as September. The federal government has contracted to develop enough H1N1 vaccine for widespread use in the fall of 2009. The vaccines are now in the development stages and will have to be tested for safety before wide-scale production begins. If all goes according to plan, the first shipment of H1N1 vaccine will reach states by September, with additional vaccine shipments arriving regularly through the fall and winter.

The first shipment is likely to be targeted for priority populations such as children, 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. It is expected that most people will require two doses of vaccine, 3-4 weeks apart. All of the vaccine will be available free-of-charge for all providers and patients. The Department will be responsible for the allocation of doses to both public and private sector providers. These providers may include community and commercial vaccinators as well as health care providers.

There are concurrent plans to immunize large segments of the population with the seasonal flu vaccine. This vaccine will arrive in the state in record large amounts as early as August. There will be some logistical complications in conducting vaccination campaigns for both the seasonal and the H1N1 flu, and the Department will be working closely with local health officials and agencies to promote and support enhanced seasonal flu clinics. The task of administering millions of doses of seasonal and pandemic influenza vaccine is enormous. Under the time constraints presented, with the magnitude of the task, every possible option for mass vaccination must be readied.

The Department has begun organizing to meet the challenge of a possible H1N1 vaccination campaign by building upon its annual efforts for seasonal flu vaccination. In addition to the traditional channels for vaccine distribution, the Department is putting in place a number of steps to greatly expand its capacity, including enrolling many thousands of providers in the Immunization Program's vaccine distribution system, establishing a statewide record-keeping mechanism, providing funding to local health departments to set up a large number of public clinics, and enlisting the help of school nurses, pharmacists, and paramedics to expand the pool of those capable of vaccinating the public.

In addition, the Department will be reaching out to organizations such as the Massachusetts Medical Society, Massachusetts Hospital Association, Massachusetts Nurses Association, and others to assist with expanding the cadre of qualified vaccinators available. Since it is anticipated that seasonal flu vaccine will be available beginning in August, the Immunization Program is also recommending that the seasonal flu vaccine efforts start earlier to ease the response after the arrival of the H1N1 vaccine.

The emergency amendments to regulations being proposed today are part of the effort to protect the health care workforce and to expand vaccination capacity in the event of a pandemic. The first set of amendments requires clinics and hospitals to establish and implement an influenza vaccination program to ensure that all employees are offered vaccination for seasonal influenza on an annual basis, and vaccination for pandemic or novel strains of

influenza, such as H1N1, as directed in guidelines of the Commissioner. A similar requirement is already in place for employees at long term care facilities licensed by the Department.

Seasonal and pandemic/novel influenza puts great demand on the healthcare delivery system by making many people sick over a short period of time, so that every available healthcare worker may be necessary to provide care. Health care workers with direct patient care responsibility are at the frontline of exposure to influenza. Health facility employees without direct patient care responsibility also must be protected from seasonal and pandemic influenza, because their work is essential to the efficient and effective delivery of health care. In addition, exposed healthcare workers and other health facility employees can themselves become vectors of disease transmission. Therefore, the Centers for Disease Control (CDC) and Prevention, the Joint Commission for the Accreditation of Health Care Organizations (Joint Commission), the National Foundation for Infectious Diseases, the Association of Professionals in Infection Control and Epidemiology, the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, and many other professional organizations endorse the universal, annual vaccination of healthcare workers and health facility employees. Influenza immunization programs are now a Joint Commission standard for hospitals. Two years ago, the Department mandated that all long-term care facilities offer their employees influenza vaccine. Last year, vaccination of staff at acute care hospitals against influenza was made a reportable measure of quality of patient safety efforts. The purpose of the emergency amendments requiring hospitals, clinics and long-term care facilities to make seasonal and novel/pandemic influenza vaccination available to all employees is to increase vaccination rates, to reduce the incidence of illness among health care workers, and to reduce transmission rates.

The second set of emergency amendments would allow the Commissioner to authorize a health care professional, such as a dentist, paramedic or pharmacist, to administer a vaccine for the prevention of a pandemic or novel influenza virus where the Commissioner determines that there are not sufficient health care professionals available for timely vaccine administration. Such administration would be in accordance with the order of a practitioner and training and other requirements related to administration established by order of the Commissioner.

Regulations Concerning Influenza Vaccination of Employees of Licensed Health Facilities

The Department is proposing emergency amendments to require hospitals (105 CMR 130.000) and clinics (105 CMR 140.000) licensed by the Department to implement vaccination programs to ensure that all employees of those facilities are vaccinated with seasonal influenza vaccine no later than December 15 each year, when feasible. The proposed amendments to the clinic licensure regulation also apply to out-of-hospital dialysis units (OHDU) because the OHDU regulation incorporates by reference the amendments to the clinic regulation at 105 CMR 145.900. Although the seasonal vaccination requirement already exists for long-term care facilities, staff also is proposing minor amendments to the long-term care licensure regulation to make the regulatory language consistent for hospitals, clinics and long-term care facilities (105 CMR 150.000). The proposed amendments to (1) 105 CMR 130.000: Hospital Licensure, (2) 105 CMR 140.000: Licensure of Clinics, and (3) 105 CMR 150.000: Licensing of Long-Term Care Facilities are included as **Attachment A**.

In addition to employee vaccination programs for seasonal influenza, the proposed amendments allow the Commissioner of Public Health to issue guidelines as necessary to require hospitals, clinics and long-term care facilities licensed by the Department to ensure that employees are vaccinated against other novel/pandemic influenza virus(es) as vaccines

become available, such as H1N1. The proposed amendments require the Commissioner to issue guidelines in the event of an outbreak of novel/pandemic influenza specifying (1) the categories and priority of employees to be vaccinated, (2) the influenza vaccines to be administered, (3) the dates by which employees must be vaccinated, and (4) any required reporting and data collection.

Both the seasonal and novel/pandemic influenza vaccination amendments require clinics, hospitals, and long-term care facilities to: (1) notify employees of the influenza vaccination requirement, (2) provide or arrange for vaccination of all employees who cannot provide proof of current immunization against influenza, at no cost to any employee, and (3) provide employees with information about the risks and benefits of influenza vaccine. Licensed health facilities are not required to provide or arrange for influenza vaccination when 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. However, facilities must obtain and administer seasonal and novel/pandemic influenza vaccine, if applicable, as soon as vaccine becomes available.

Licensed health facilities may not require an employee to receive an influenza vaccine if (1) the vaccine is medically contraindicated, (2) against the employee's religious beliefs, or (3) the employee refuses the vaccine for any other reason. An employee who declines vaccination must sign a statement declining vaccination and certifying that he or she received information about the risks and benefits of influenza vaccine.

Licensed health facilities are required to maintain in each employee's personnel file a certificate(s) of vaccination against influenza, or the employee's declination statement. Facilities must maintain a central system to track the vaccination status of every employee. If a facility 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 for.

The proposed amendments require facilities to report information to the Department documenting the facility's compliance with the employee vaccination requirement, in accordance with reporting and data collection guidelines that may be issued by the Commissioner. Last year the Department required acute care and state hospitals to report the number of employee vaccinations given in 2008-2009 to the Betsy Lehman Center as part of the Healthcare Associated Infection Program. The Department required reporting of influenza vaccine administration in acute care facilities based on a facility's administration of vaccine to its own employees, using the total employees as the denominator and the employees who received hospital-supplied vaccine as the numerator. The employee vaccination rate, using the above definition and through March 2009, was a range of 33% to 78%, with a mean of 51% and a median of 50%. These were low estimates of total influenza vaccination, because the Department did not count vaccination from other sources/sites and the denominator contained off-site employees with possibly no contact with patients or direct care staff. This year the Department will issue guidelines requiring all licensed hospitals, clinics and long-term care facilities to report employee vaccination rates for seasonal and H1N1 influenza vaccine, allowing the Department to assess the effectiveness of the proposed employee vaccination requirement.

The proposed amendments allow an employee to decline vaccination for any reason, but require that the employee sign a statement declining vaccination after being fully informed of the risks and benefits of vaccination. There is a vigorous debate about whether health facility vaccination programs that mandate that all employees be vaccinated – without allowing an

employee to opt-out -- are the most effective way to increase vaccination rates. Mandatory programs raise serious ethical, legal and practical issues because of the coercive nature of such programs, potential liability concerns, and the potential damage to workplace relationships when cooperation is most needed to address a possible pandemic. The proposed amendments reflect a balanced approach by requiring facilities to educate their employees about the benefits and risks of vaccination and to make vaccination readily available to all employees at no cost. In addition, the proposed amendments allow the Department to track vaccination rates by facility. Public reporting of vaccination rates by facility offer facilities and their employees an additional incentive to voluntarily increase vaccination rates.

Regulations Authorizing Administration of Vaccines by Designated Health Care Professionals

As part of the preparation for handling an outbreak of H1N1 flu, the Drug Control Program (DCP) is bringing to the Public Health Council the attached amendments to regulations governing the implementation of the Controlled Substances Act, M.G.L. c. 94C. At present, M.G.L. c. 94C and related Department regulations, 105 CMR 700.000, limit the persons who may lawfully administer controlled substances (i.e., prescription medications, including vaccines). Currently, only certain licensed health care providers, such as physicians, nurses, physician assistants, nurse practitioners and pharmacists may administer vaccine. Section 7(g) of c. 94C, however, permits the Commissioner to authorize by regulation the registration of persons for a specific activity or activities, including administration of controlled substances. The proposed amendments would invoke s. 7(g) to enlarge the number of health care professionals who may be able to administer vaccines and therefore expedite the administration of flu vaccine in the event that large numbers of people need to be vaccinated in a short period of time. The proposed amendments are attached to this memo as **Attachment B**.

The proposed amendments would authorize the Commissioner to designate health care professionals licensed or certified by the Department, such as dentists and paramedics, to administer flu vaccine for the prevention of a pandemic or novel influenza virus where the Commissioner determines that there are not sufficient health care professionals available for timely vaccine administration. The regulations authorize the Commissioner to issue an order designating the persons who may administer the vaccine and the conditions under which the vaccine may be administered. In addition, the regulations require that the vaccine be administered under an order or prescription of a practitioner authorized to prescribe vaccines. The vaccinators must administer in accordance with the order/prescription and the Commissioner's order.

The proposed regulations require a person administering vaccine to be properly trained and supervised, in accordance with the Commissioner's order. Also, the person administering must comply with the order of the Commissioner and the prescriber's order with respect to proper storage, handling and return of the vaccines, record keeping of administration, responses to adverse events, and safe and appropriate administration of vaccines.

Rationale for Emergency Promulgation

The Department is asking the Public Health Council to promulgate these amendments as emergency regulations to provide hospitals, clinics and long-term care facilities with as much time as possible to implement employee vaccination programs in advance of the 2009-2010 influenza season. We are facing an urgent situation entering the 2009-2010 influenza season, with the potential simultaneous circulation of both seasonal influenza viruses and the pandemic

novel H1N1 strain. It is expected that the seasonal flu vaccine will be available beginning in August, and H1N1 vaccine sometime after that. The Department is recommending that seasonal flu vaccination efforts at hospitals, clinics and long-term care facilities begin as soon as practicable, with the aim of ultimately protecting employees in a timely fashion against seasonal influenza as well as H1N1 influenza.

Emergency regulations are effective upon approval by the Public Health Council and subsequent filing with the Secretary of the Commonwealth. Staff anticipates filing these amendments in September, and returning to the Public Health Council for final approval at the November 18 meeting. If the usual process for adoption of regulations were followed, in contrast, the earliest realistic effective date of these regulations would be December 11, 2009.

Conclusion

The proposed emergency amendments are a part of the Department's efforts to prepare for the possibility of a significant outbreak of H1N1 influenza in the fall of 2009. The first set of amendments requires clinics, hospitals, and long-term care facilities to establish and implement an influenza vaccination program to ensure that all employees are offered vaccination for seasonal influenza on an annual basis and vaccination for other strains of influenza, such as H1N1, as directed in guidelines of the Commissioner of Public Health. The second set of regulations provides an additional option for expanding the Commonwealth's capacity to administer vaccine for the prevention of a pandemic or novel influenza virus in the event that the Commissioner determines that there are not sufficient numbers of health care professionals available for timely administration of vaccine.

It is requested that you approve the attached regulations for filing as emergency regulations. Staff plans to hold a public hearing on the regulations in September, 2009 and after that return to the Council with a request for final approval.