

Frequently Asked Questions for Hospitals, Diagnostic and Treatment Centers Licensed under Article 28 , Home care services agencies licensed under Article 36 of the PHL and Hospice programs certified under Article 40 of the PHL Regarding Title 10, Subpart 66-3 Regulation

Overview Information

Q. When does this emergency regulation go into effect?

A. The emergency regulation became effective on August 13, 2009.

Q. What are the regulations main provisions?

A. The requires hospitals, diagnostic and treatment centers licensed under Article 28 of the Public Health Law (PHL), home care services agencies licensed under Article 36 of the PHL including certified home health agencies, licensed home care services agencies, long term home health programs including AIDS home care programs, and hospice programs certified under Article 40 of the PHL to document that existing staff have had influenza vaccinations each year by November 30 and that new staff entering on or after November 30th have influenza vaccinations.

Q. What is the purpose of the regulation?

A. The regulation is intended to protect patients from acquiring influenza from infected health care workers. Influenza can be severe and cause death in persons with underlying medical conditions. There is a large body of evidence that health care workers can pose a risk to patients by transmitting influenza infection; this risk can be lessened significantly by health care worker vaccination. Voluntary vaccination programs of health care workers have not achieved high rates of coverage.

Q. Are long term care facilities affected by this regulation?

A. No. Nursing homes, adult homes and adult day treatment facilities and any other organization providing residential housing and supportive services to 5 or more persons, over the age of 65 who are unrelated to the operator are subject to PHL Article 21A, which requires that nursing homes “offer” flu vaccine each year to their employees.

Q. When should an organization begin influenza vaccination?

A. Influenza vaccination should begin as soon as the vaccine is available and be completed no later than November 30th each year.

Q. What if there is a shortage or delay of vaccine?

A. The regulation has a provision that allows the Commissioner of Health to waive the regulation or parts of the regulation, such as the November 30th deadline, if there is influenza vaccine shortage or shipping delay.

Q. Will there be enough influenza vaccine available to vaccinate all health care personnel?

A. There is more than an adequate supply of seasonal influenza vaccine for the 2009-10 season. If you need to find seasonal influenza vaccine, the National Influenza Vaccine Summit has established a system that may help. IVATS (the Influenza Vaccine Availability Tracking System) has been designed to assist healthcare providers in trying to determine which wholesale distributors or manufacturers have influenza vaccine for sale. Simply go to the

Summit's website (www.preventinfluenza.org) and click on the icon that says "Does your clinic need influenza vaccine"" within the "For Healthcare Professionals" block on the right-hand side. The supply of novel H1N1 vaccine is still not known at this time.

H1N1 Vaccine

Q. Does the new regulation apply to the novel H1N1 influenza vaccine?

A. If the novel H1N1 vaccine is released as a fully licensed vaccine, as expected, this regulation will also require immunization against H1N1 as well as seasonal influenza this coming season. Further information will be provided when the Department receives updates on the vaccine, its licensure status and availability this fall.

Q. If the H1N1 vaccine is required does that mean HCP would receive 3 shots this year?

A. Yes. Vaccination would include:

- One dose of seasonal influenza vaccine and
- Two doses of novel H1N1 influenza vaccine.

However, we anticipate that there will be sufficient doses of the live attenuated influenza vaccine (LAIV) for seasonal influenza vaccine which is administered nasally and a nasal H1N1 vaccine may also be available. The Advisory Committee on Immunization Practices (ACIP) recommends that HCP for whom LAIV is not contraindicated be allowed to receive it, with the exception of those who are in contact with patients who are severely immunosuppressed during periods when they require a protective environment (e.g., persons with bone marrow transplants who are hospitalized and in protective isolation). These HCP should receive trivalent inactivated influenza vaccine (TIV) instead. HCP who have close contact with persons having lesser degrees of immunosuppression (e.g., persons with diabetes, persons with asthma taking corticosteroids, or persons infected with HIV) are especially encouraged to receive LAIV if they themselves are healthy, not pregnant, and are younger than age 50 years. HCP use of LAIV might also increase availability of inactivated influenza vaccine for persons at high risk.

Who is Included

Q. Who must receive an influenza vaccine under the new regulation?

A. The regulation applies to all personnel who

- are affiliated with hospitals, diagnostic and treatment centers, home care agencies licensed under Article 36 of the PHL including certified home health agencies, licensed home care services agencies, long-term home health program including AIDS home care programs, and hospices, **and**
- are paid or unpaid, including but not limited to employees, members of the medical staff, contract staff, students, and volunteers, **and either**
 - have direct contact with patients, **or**
 - perform duties that, if they were ill, could infect patients or staff with direct patient contact.

Q. How can it be determined which personnel have “direct contact”?

A. “Direct contact” refers to persons who, if they were infected with influenza, could transmit the disease to a patient. Large-particle respiratory droplets that do not remain suspended in the air primarily transmit influenza. Therefore, direct contact would be either through

sharing a 6-foot space with a patient (person-to-person contact) or a surface that comes in contact with a patient (equipment-to-patient contact).

Q. Do staff members who routinely interact with direct care staff (see above) but don't have patient contact need to be vaccinated?

A. Yes. The regulation includes persons not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from direct care staff (e.g., clerical, dietary, housekeeping, maintenance, and volunteers who work in patient areas or have contact with staff who do (see next question).

Q. Do staff members who have only incidental contact with direct care staff need to be vaccinated?

A. No. Staff who have only incidental contact with direct care staff in the course of their work or volunteer activities do not need to be vaccinated. Examples would be passing through nonpatient unit hospital hallways, using public rest rooms, eating in the cafeteria, or riding in nonpatient transport hospital elevators.

Q. Must students, trainees and others who temporarily rotate through the hospital be vaccinated?

A. Yes. Hospitals can work with the programs that send students, trainees and others to hospitals to ensure that they are vaccinated.

Q. Is the hospital required to vaccinate individuals and students who rotate through the hospital?

A. This would depend on the agreement that the hospital has with the training institution. In many cases, the hospital requires that the school ensure that each student is appropriately immunized and screened for tuberculosis prior to clinical practice.

Q. If a nursing home is attached to a hospital or located within a hospital complex, shouldn't the same regulation apply to nursing home staff?

A. There are differences between Article 21-A and the newly passed regulation. Article 21-A is a statute and the statute has to be changed by the State Legislature, which has not addressed the change at the current time. However, the nursing home or other entity covered by Article 21-A and described above can choose to be more restrictive than Article 21A and require annual influenza vaccination of their staff in their policies.

Q. Does the regulation apply to pharmacists?

A. It applies only if the pharmacy in which the pharmacist works is part of an entity to which the regulation applies and the pharmacist meets the criteria of identified personnel.

Exemptions

Q. Are there any exemptions for immunization?

A. Medical contraindications recognized by ACIP will be permitted. These ACIP contraindications and precautions will be posted on the NYSDOH website to guide determinations made by individual practitioners as to the existence of a medical contraindication.

Q. Can Physician Assistants (PA) certify medical exemptions?

A. Yes, a licensed physician assistant can authorize a medical exemption. This will be clarified in subsequent emergency regulations and in the final regulation.

Q. Doesn't the state have to allow religious exemptions to vaccination?

A. There is no legal requirement to allow religious exemptions to influenza vaccination. Health care personnel who care for ill patients have a responsibility to protect their patients from the inadvertent transmission of a communicable disease. Currently, HCP with direct patient care have been required to show immunity to measles and rubella and undergo annual screening for tuberculosis, which is usually carried out by a skin test injection, as a condition of employment, without religious exemptions permitted. Only medical exemptions to vaccines and tuberculosis screening are permitted.

Q. What if the health care worker does not fall into a priority group for H1N1 vaccine?

A. All health care personnel are a priority group due to high degree of exposure to H1N1 infections and as a potential transmitter of the H1N1 virus to patients. If supply is limited, vaccination with novel H1N1 influenza vaccine will be restricted to those health care personnel who have direct patient contact.

Q. What if a health care worker refuses to be vaccinated?

A. Each organization must take whatever steps are needed to comply with this regulation. Since current public health regulation also mandate that direct care staff be immune to measles and rubella and receive annual tuberculosis screening, the organization may want to adopt a similar managerial or personnel policy for dealing with individuals without medical exemptions who refuse to be vaccinated or tested. One option for workers who refuse influenza vaccination is reassignment to duties not covered by the regulation.

Q. Can a health care worker who refuses to be vaccinated be fired?

A. Again, steps like reassignment to non-covered duties is suggested. Each organization must comply with this regulation, just as the organization assures that health care personnel must be immunized against measles and rubella.

Q. Who will be monitoring hospitals for compliance and what will be the consequences for non-compliance with the regulation?

A. The Office of Health Systems Management (OHSM) has oversight of hospitals and has systems in place for addressing issues of non-compliance.

Q. How will hospitals document medical exemptions for NYSDOH surveyors?

A. The NYSDOH will create a medical exemption form that hospitals and others may use to document medical exemptions.

Home Care Agencies

Q. Is the home care agency required to vaccinate individuals and students who rotate through the agency?

A. This would depend on the agreement that the home care agency has with the training institution. In many cases, the county health department requires that the school ensure that

each student is appropriately immunized and screened for tuberculosis prior to clinical practice.

Q. How will home care agencies document medical exemptions for NYSDOH surveyors?

A. Documentation must be present in the personnel file that indicates covered personnel have received the required immunizations. If an individual has not received the required immunizations, the personnel file should contain appropriate medical exemption documentation. The NYSDOH will create a medical exemption form that county health department, hospitals and others may use to document medical exemptions.