Overview

When does this regulation go into effect?

The regulation will be effective upon publication of a notice of final rulemaking in the State Register which will occur on July 31, 2013.

What section of regulations contains the new regulation? Who issued the requirement, and what is the legal basis?

The Department proposed this regulation for adoption by the Public Health and Health Planning Council (PHHPC). PHHPC’s authority to adopt the regulation is located in Public Health Law Sections 225, 2800, 2803, 3612, and 4010. These provisions are located in a new Section 2.59 of the State Sanitary Code within Title 10 of the New York Codes Rules and Regulations (10 NYCRR) entitled: “Prevention of influenza transmission by healthcare and residential facility and agency personnel.” References to Section 2.59 are located in Sections 405.3, 415.19, 751.6, 763.13, 766.11, and 793.5 of 10 NYCRR.

What kinds of healthcare facilities, residential facilities and agencies does the regulation apply to?

The regulation applies to any healthcare facility, residential facility or agency licensed under Article 28 of the Public Health Law (including but not limited to general hospitals, nursing homes, diagnostic and treatment centers, and adult day healthcare facilities), Article 36 of the Public Health Law (including but not limited to certified home health agencies, long term home healthcare programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies), and any hospice established pursuant to Article 40 of the Public Health Law.

What are the regulation’s main provisions?

The regulation requires facilities, residences, and agencies as described above to require that personnel who are not vaccinated against influenza wear a surgical or procedure mask during the influenza season while working in areas where patients may be present. These entities also must document the number and percentage of personnel vaccinated against influenza for the current season and provide these data to the Department upon request.

What is the purpose of the regulation?

The regulation is intended to protect patients from acquiring influenza from infected healthcare workers. Influenza can be severe and cause death in persons with underlying medical conditions. There is a large body of evidence that healthcare workers can pose a risk to patients by transmitting influenza infection. The regulation has the added benefit of protecting healthcare workers who are unvaccinated from acquiring influenza from their patients.

Have any facilities/residences/agencies in New York State already implemented requirements that unvaccinated healthcare workers wear masks?

Yes. DOH is aware of several healthcare facilities across the State which have instituted policies requiring that unvaccinated healthcare workers wear masks during influenza season.
If a facility/residence/agency has policies and procedures in place that are stricter than those proposed in this regulation, can those policies and procedures remain in place?

Facilities/residences/agencies are free to implement stricter policies as long as the requirements of this regulation are met.

When wearing a mask under this regulation, how often does the mask need to be changed?

Masks should be changed after leaving the room or completing care of a patient/resident on isolation precautions, whenever it is soiled or might have become soiled, and per the protocol of the facility/residence/agency.

What types of masks can be worn to meet the requirements of this regulation?

This regulation requires use of either surgical or procedure masks. Per the U.S. Food and Drug Administration, such masks may be labeled surgical, laser, isolation, dental, or medical procedure facemasks. A face shield is not required. Use of N95 respirators to meet the requirements of this regulation is neither required nor recommended, although N95 respirators should be used when indicated for other reasons.

When should mask wear begin and how long must it continue?

Because influenza activity begins, peaks, and ends at different times in different years, exact dates cannot be given. At a minimum, the Commissioner would likely designate influenza "prevalent" when Department surveillance determines that influenza activity is widespread in the State. As examples, the dates of widespread activity are provided in the table below:

<table>
<thead>
<tr>
<th>Influenza Season</th>
<th>Dates &quot;Widespread&quot;</th>
<th># Weeks &quot;Widespread&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007-2008</td>
<td>January 12-April 19</td>
<td>15</td>
</tr>
<tr>
<td>2008-2009 (H1N1 pandemic)</td>
<td>January 31-April 11, June 6-July 11</td>
<td>17</td>
</tr>
<tr>
<td>2009-2010</td>
<td>October 3-December 12</td>
<td>11</td>
</tr>
<tr>
<td>2010-2011</td>
<td>December 25-April 9</td>
<td>16</td>
</tr>
<tr>
<td>2011-2012</td>
<td>March 10-May 19</td>
<td>11</td>
</tr>
<tr>
<td>2012-2013</td>
<td>November 24 – April 20</td>
<td>22</td>
</tr>
</tbody>
</table>

Additionally, the Commissioner might designate influenza "prevalent" in specific areas of the State depending upon temporal and geographic activity and might designate influenza prevalent when it is present in the State but not considered widespread, based on characteristics of the influenza season (e.g. intensity of activity, severity of illness).

Documentation and Reporting

What constitutes acceptable documentation for confirmation of influenza vaccination for personnel receiving the vaccine from another provider?

Documentation for all vaccines should include, at a minimum, a signed immunization vaccination card or statement from the provider of the vaccine giving the date the vaccine was given and the name and address of the provider.

What must be reported to the NYSDOH?

Aggregate data on personnel influenza vaccination(s) status, including the number and percentage of personnel vaccinated for the current influenza season, must be documented and made available to NYSDOH upon request. The exact frequency with which such a request may be made has not been determined, but it is expected that it would be at least twice during an influenza season (e.g. at the beginning and end).
Which personnel are covered by these regulatory requirements?

Does "Personnel" to whom this regulation applies include visitors and family members?

No. This regulation does not apply to visitors to facilities/residences or family members of patients/residents. Facilities which have visitors are encouraged to establish policies for when visitor restrictions should be put in to place to limit transmission of influenza. Many facilities do impose restrictions on visitors during influenza season, and facilities are in the best position to determine what restrictions are appropriate. It would be impracticable and disruptive to require facilities to check documentation of vaccination on visitors.

Who must wear a mask under the new regulation?

The regulation applies to all personnel who are unvaccinated for influenza for the relevant influenza season and:

- are affiliated with a facility or agency licensed under Article 28 of the Public Health Law (including but not limited to general hospitals, nursing homes, diagnostic and treatment centers, and adult day healthcare services), Article 36 of the Public Health Law (including but not limited to certified home health agencies, long term home healthcare programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies) and hospices licensed under Article 40 of the Public Health Law, and
- are paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, and
- who engage in activities such that if they were infected with influenza they could potentially expose patients or residents to the disease.

Who determines whether someone affiliated with an affected healthcare or residential facility or agency is subject to the new regulation.

The healthcare facility, residential facility or agency makes this determination and is responsible for developing medically appropriate protocols based upon the potential for personnel to expose patients or residents to influenza.

How can it be determined which personnel could potentially expose patients or residents to influenza?

Influenza is transmitted primarily by large-particle respiratory droplets that do not remain suspended in the air. Therefore, personnel could potentially expose patients or residents 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).

Where and when do masks need to be worn by personnel for whom it is required under this regulation?

Masks should be worn wherever and whenever an unvaccinated healthcare worker might expose patients to influenza. This would include, but not be limited to, patient rooms, nurses' stations, hallways and elevators where patients might be present, cafeterias if patients may be present (except when the unvaccinated healthcare worker is eating), and patients' homes when providing home care.

Are food service workers affected by this regulation?

Food service workers are affected if they meet the criteria for personnel who could potentially expose patients or residents to influenza. Influenza is typically spread by droplets and occasionally by contaminated hard surfaces. Influenza is not typically spread by food, and the chance of a patient becoming infected via contaminated food, plates, etc. is considered low and probably negligible. Therefore, food service workers who only work in a kitchen in an area of the hospital where patients are not present and who do not come into close proximity with patients while at their work station or while traveling to or from their work station would not be affected. The intent of this regulation is to
focus on common modes of transmission, such as infected personnel who could directly expose patients to respiratory droplets. Therefore, food service workers who work in a cafeteria where patients might be present would be affected, and food service workers who deliver trays to patient units or who stock kitchens on patient units would be affected.

If a person did not receive an influenza vaccine but already had influenza this influenza season, is that person still required to wear a mask?

Yes. Influenza vaccines generally contain three strains of influenza virus. A person would have to have had influenza three times during the current season, once with each strain, and have all three illnesses confirmed by a healthcare provider and strains confirmed by a laboratory, in order for the influenza vaccine to provide no additional protection. It is usually not clinically indicated to determine the strain of virus during a case of influenza, and it would be unreasonably burdensome to ask facilities, residences, and agencies to monitor which strains have infected unvaccinated personnel. Therefore, personnel should wear masks regardless of whether they have had influenza during the current influenza season.

It takes one to two weeks after vaccination to develop protective immunity. Do I need to wear a mask during this period?

Not under the requirements of this regulation. It may be difficult for facilities, residences, and agencies to track which employees need to wear masks by date of vaccination and to enforce mask wear under such conditions. Therefore, wearing a mask during the weeks immediately after vaccination is not required. However, facilities, residences, and agencies are free to institute stricter policies than required by this regulation. Personnel are encouraged to become vaccinated well before influenza season is expected to start to avoid this problem.

Do staff members who routinely interact with personnel who could potentially expose patients or residents to influenza but who don't meet such criteria themselves need to wear a mask?

No. The requirement only applies to personnel who could directly expose patients.

Must students, trainees and others wear a mask if they are temporarily rotating through the hospital, are unvaccinated against influenza, and could potentially expose patients or residents to the disease?

Yes.

Does the regulation apply to pharmacists?

The regulation applies if the pharmacist works in a healthcare facility, residential facility or agency to which the regulation applies and the pharmacist meets the criteria of identified personnel.

Does the new regulation pertain to facilities with oversight by the Office for Persons with Developmental Disabilities (OPWDD), Office of Mental Health (OMH), Office of Alcohol and Substance Abuse Services (OASAS), or Department of Corrections (DOC) or Office for the Prevention of Domestic Violence (OPDV) shelters?

The regulation covers only licensed Article 28 providers (hospitals, nursing homes, diagnostic and treatment centers, and adult day healthcare services), Article 36 providers (licensed and certified home health agencies, long term home healthcare programs and AIDS home care programs) and hospices (Article 40). If the facilities or shelters do not hold such a license/certification to operate from the NYS Department of Health, they are not covered by this regulation.

Exemptions
If a person has a medical exemption to influenza vaccination, does that person have to wear a mask?

Yes. The purpose of this regulation is to prevent influenza transmission to patients and therefore applies regardless of the reason a person is not vaccinated.

Will personnel with a medical exemption to influenza vaccination need to be reassigned for the duration of the flu season?

No. Such personnel will be required to wear a mask during the influenza season. Reassignment to an area where patients are never present would mean that the requirements of this regulation do not apply to that person.

How will these regulatory requirements be enforced by healthcare facilities, residential facilities and agencies?

Each organization must comply with this regulation, just as the organization assures that healthcare personnel must be immunized against measles and rubella.

Who will be monitoring hospitals and diagnostic and treatment centers (D&TC) for compliance and what will be the consequences for non-compliance with the regulation?

The NYS DOH Office of Health Systems Management (OHSM) has oversight responsibility for all covered providers.

Other Questions

Why doesn't NYSDOH require all healthcare facilities to offer influenza vaccination free of charge to personnel?

The Joint Commission on Accreditation of Health-Care Organizations has approved an infection-control standard that requires accredited organizations to offer influenza vaccinations to staff, including volunteers and licensed independent practitioners with close patient contact. The standard became an accreditation requirement beginning January 1, 2007. Public Health Law 21-A requires nursing homes, adult homes, enriched housing programs, and adult day healthcare programs nursing homes to offer influenza vaccination to employees free of charge.

County Health Departments

Are county health departments covered by the regulation?

County health department programs that are licensed pursuant Article 28, Article 36, or Article 40 of the Public Health Law are covered by the regulation.

Which staff in county health departments are covered by the regulation?

Staff in county health departments who carry out Article 28, 36 or 40 program functions are covered when they are in areas where patients may be present.