Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel

Effective Date: 7/31/13

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 2 is amended to add a new section 2.59, as follows:

2.59 – Prevention of influenza transmission by healthcare and residential facility and agency personnel

(a) Definitions.

(1) "Personnel," for the purposes of this section, shall mean all persons employed or affiliated with a healthcare or residential facility or agency, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with influenza, they could potentially expose patients or residents to the disease.

(2) "Healthcare and residential facilities and agencies," for the purposes of this section, shall include:

(i) any facility or institution included in the definition of “hospital” in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;

(ii) any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies; and

(iii) hospices as defined in section 4002 of the Public Health Law.

(3) “Influenza season,” for the purposes of this section, shall mean the period of time during which influenza is prevalent as determined by the Commissioner.

(b) All healthcare and residential facilities and agencies shall determine and document which persons qualify as “personnel” under this section.

(c) All healthcare and residential facilities and agencies shall document the influenza vaccination status of all personnel for the current influenza season in each individual’s personnel record or other appropriate record. Documentation of vaccination must include the name and address of the individual who ordered or administered the vaccine and the date of vaccination.

(d) During the influenza season, all healthcare and residential facilities and agencies shall ensure that all personnel not vaccinated against influenza for the current influenza season wear a

surgical or procedure mask while in areas where patients or residents may be present. Healthcare and residential facilities and agencies shall supply such masks to personnel, free of charge.

(e) Upon the request of the Department, a healthcare or residential facility or agency must report the number and percentage of personnel that have been vaccinated against influenza for the current influenza season.

(f) All healthcare and residential facilities and agencies shall develop and implement a policy and procedure to ensure compliance with the provisions of this section. The policy and procedure shall include, but is not limited to, identification of those areas where unvaccinated personnel must wear a mask pursuant to subdivision (d) of this Section.

Subparagraph (v) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:

(v) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (4) of subdivision (a) of Section 415.19 of Part 415 is added to read as follows:

(4) Collects documentation of vaccination against influenza, or requires wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (6) of subdivision (d) of Section 751.6 is added to read as follows:

(6) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (5) of subdivision (c) of Section 763.13 is added to read as follows:

(5) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (6) of subdivision (d) of Section 766.11 is added to read as follows:

(6) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

Paragraph (6) of subdivision (d) of Section 793.5 is added to read as follows:

(6) documentation of vaccination against influenza, or wearing of a surgical or procedure mask during the influenza season, for personnel who have not received the influenza vaccine for the current influenza season, pursuant to section 2.59 of this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 225 (5), 2800, 2803 (2), 3612 and 4010 (4). PHL 225 (5) authorizes the Public Health and Health Planning Council (PHHPC) to issue regulations in the State Sanitary Code pertaining to any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises.

PHL Article 28 (Hospitals), Section 2800 specifies that "Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article."

PHL Section 2803 (2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL

Article 28, and to establish minimum standards governing the operation of health care facilities. PHL Section 3612 authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies and providers of long term home health care programs. PHL Section 4010 (4) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

Legislative Objectives:

The legislative objective of PHL 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional curative care for the terminally ill. The requirement of surgical or procedure masks of unvaccinated healthcare and residential facility and agency personnel in these facilities will promote the health and safety of the patients and residents they serve and support efficient and continuous provision of services.

Needs and Benefits:

Transmission of influenza from healthcare and residential facility and agency personnel to patients and residents is a serious public health and patient safety issue. Influenza is a leading

cause of morbidity and mortality among hospitalized patients as well as persons admitted to or residing in other types of health care facilities. Healthcare and residential facility and agency personnel are at increased risk of acquiring influenza because of their contact with ill patients and residents, and personnel can transmit influenza to their patients and residents if they become ill. It is beyond dispute that vaccination is the most effective measure to prevent influenza, for health care facility personnel and their patients.

Accordingly, for the past two decades, the Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) has strongly recommended that all healthcare personnel be vaccinated against influenza. With the Department's encouragement, some healthcare and residential facilities and agencies have voluntarily implemented strategies to increase influenza vaccination rates among their personnel; however, these efforts have met with limited success.

Despite ACIP recommendations and national and State efforts to increase voluntary influenza vaccination rates, vaccination rates among healthcare and residential agency personnel in New York State have remained unacceptably low. In the 2011-2012 influenza season, hospitals in New York State reported healthcare personnel vaccination rates ranging from 11.1% - 97.8%, with an average of 48.4%. Thirty-four hospitals reported vaccination rates of 50% or lower, and nine of these hospitals reported vaccination rates lower than 25%. Nursing homes reported an average personnel vaccination rate of 45.0%.

Now, like much of the rest of the nation, New York State is experiencing the worst seasonal influenza season in a decade. Notably, the 2012-13 influenza season is worse than in any season since ACIP set the national standard of medical care for influenza vaccination by recommending that all persons be vaccinated each year. The intensity of this year's influenza season is a reminder that influenza is unpredictable and may cause serious illnesses, deaths and healthcare disruption during any year. Additional steps must be taken to prevent the toll of influenza in health care facilities to the extent possible.

In response to this increased public health threat, New York State has taken active steps to prevent and control transmission of seasonal influenza, in addition to its annual promotional campaign encouraging influenza vaccination. On January 12, 2013 Governor Cuomo issued an Executive Order declaring a disaster emergency and temporarily modifying sections of the State Education Law to permit children ages 6 months to 18 years to be vaccinated by pharmacists. Yet the seriousness of the continuing influenza threat, and the failure of healthcare and residential facilities and agencies to achieve acceptable vaccination rates through voluntary programs, necessitates further action.

Although masks are not as effective as vaccination, evidence indicates that wearing a surgical or procedure mask will lessen transmission of influenza from patients experiencing respiratory systems. It is also known that persons incubating influenza may shed the influenza virus before they have noticeable symptoms of influenza. According to the CDC, the use of surgical or procedure masks by infectious patients may help contain their respiratory secretions and limit exposure to others. The CDC also recommends that patients who may have an

infectious respiratory illness wear a mask when not in isolation and that healthcare personnel wear a mask when in close contact with symptomatic patients. Further, the Infectious Disease Society of America recommends that healthcare personnel who are not vaccinated for influenza wear masks.

Accordingly, the Department is issuing these regulations to require all unvaccinated personnel in healthcare and residential facilities and agencies to wear surgical or procedure masks during the time when the Commissioner determines that influenza is prevalent. Requiring unvaccinated personnel to wear a mask is a reasonable step to lessen the risk of transmission to patients and residents, because unvaccinated personnel may be infectious before they are obviously ill, may contract a mild respiratory illness that is not recognized as influenza, and are at increased risk of becoming infected with influenza through patient or resident contact. All of these factors increase the risk of transmitting influenza to patients and residents.

The proposal has been discussed with a number of organizations representing the affected parties. These include the Healthcare Association of New York State, the Greater New York Hospital Association, 1199 SEIU New York City, the Medical Society of the State of New York, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians. Other organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). This agenda and the proposal will be posted on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

Healthcare and residential facilities and agencies must determine and document whether personnel have, or have not, been vaccinated against influenza for the current influenza season in each individual's personnel or other appropriate record. Those individuals who were not vaccinated for influenza must wear a surgical or procedure mask during the influenza season, as determined by the Commissioner. While there is a wide market of varying products and pricing, on average, the price of a surgical or procedure mask varies between approximately 10 to 25 cents per mask, subject to the quantity ordered. Thus, the cost of 1,000 masks could range from $100 to $250. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism, including personnel working less effectively or being unable to work.

Cost to State and Local Government:

The State operates several healthcare facilities subject to this regulation. Most county health departments are licensed under Article 28 or Article 36 of the Public Health Law and are therefore also subject to regulation. Similarly, certain counties and the City of New York operate facilities licensed under Article 28. These State and local public facilities would be required to document the influenza vaccination status of their personnel and, during the influenza season, provide surgical or procedure masks for those not vaccinated.

Although the costs to the State or local governments cannot be determined with precision, the Department does not expect these costs to be significant, for several reasons. State and local

facilities should already be providing masks for personnel who may come into contact with patients with respiratory symptoms and for whom contact and droplet infection control precautions should be practiced.

Further, these entities are expected to realize savings as a result of the reduction in influenza in personnel and the attendant loss of productivity and available staff. Influenza creates an estimated health burden of $87 billion per year in the United States. Influenza vaccination of healthy adults is estimated to result in a savings of $47 annually per person in reduced physician visits and fewer sick days. There are also potential savings to Medicaid and other payors based on decreasing influenza cases with the concomitant reduction in healthcare costs.

If masks achieve even a fraction of these savings by reducing costs to the State and local governments, the savings will more than cover the cost of the program, and public health will be improved.

Cost to the Department of Health:

There are no additional costs to the State or local government, except as noted above. Existing staff will be utilized to conduct surveillance of regulated parties and to monitor compliance with these provisions.

Local Government Mandates:

There are no additional programs, services, duties or responsibilities imposed by this rule upon any county, city, town, village, school district, fire district or any other special district,

except as they apply to facilities operated by local governments, except as noted above for local health departments.

Paperwork:

This measure will require healthcare and residential facilities and agencies to document whether personnel have, or have not, been vaccinated against influenza for the current influenza season. It will require these facilities and agencies to document the influenza vaccination status of all personnel for the current influenza season in each individual's personnel record or other appropriate record. Upon the request of the Department, a facility or agency must report the number and percentage of personnel that have been vaccinated against influenza for the current influenza season. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section

Duplication:

This regulation will not conflict with any state or federal rules.

Alternative Approaches:

One alternative to requiring a surgical or procedure mask for personnel unvaccinated for influenza would be to require all personnel to be vaccinated for influenza. The Department weighed these two options and, in balancing various factors related to each, determined that promoting vaccination, but requiring unvaccinated personnel to wear a surgical or procedure mask, is the most effective and least burdensome way to immediately reduce the potential for transmission of influenza at this time.

Federal Requirements:

There are no minimum standards established by the federal government for the same or similar subject areas.

Compliance Schedule:

This proposal will go into effect upon a Notice of Adoption in the New York *State Register*.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

Any facility defined as a hospital pursuant to Article 28, a home services agency by PHL Article 36, or a hospice by PHL Article 40 will be required to comply. In New York State there are 228 general hospitals, 1198 hospital extension clinics, 1239 diagnostic and treatment centers, and 635 nursing homes. There are also 139 certified home health agencies (CHHAs), 97 long term home health care programs (LTHHCP), 19 hospices and 1164 licensed home care services agencies (LHCSAs).

Of those, it is known that 3 general hospitals, approximately 237 diagnostic and treatment centers, 40 nursing homes, 69 CHHAs, 36 hospices and 860 LHCSAs are small businesses (defined as 100 employees or less), independently owned and operated, affected by this rule. Local governments operate 18 hospitals, 40 nursing homes, 42 CHHAs, at least 7 LHCSAs, and a number of diagnostic and treatment centers and hospices.

Compliance Requirements:

All facilities and agencies must document the vaccination status of each personnel member as defined in this regulation for influenza virus, in their personnel or other appropriate record. Each facility must develop a policy and procedure which requires all personnel who have not been vaccinated for influenza during the current influenza season to wear a surgical or procedure mask.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

Facilities and agencies will need to provide surgical or procedure masks to those personnel not vaccinated for influenza during a current influenza season. While there is a wide market of varying products and pricing, on average, the price of a surgical or procedure mask varies between approximately 10 to 25 cents per mask, subject to the quantity ordered. Thus, the cost of 1,000 masks could range from $100 to $250. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism, including personnel working less effectively or being unable to work.

Although the cost to small businesses and local governments cannot be determined with precision, the Department does not expect this cost to be significant, for several reasons. Small businesses and local governments should already be providing masks for personnel who may

come into contact with patients with respiratory symptoms and for whom contact and droplet infection control precautions should be practiced.

Further, small businesses and local governments are expected to realize savings as a result of the reduction in influenza in personnel and the attendant loss of productivity and available staff. Influenza creates an estimated health burden of $87 billion per year in the United States. Influenza vaccination of healthy adults is estimated to result in a savings of $47 annually per person in reduced physician visits and fewer sick days. There are also potential savings to Medicaid and other payors based on decreasing influenza cases with the concomitant reduction in healthcare costs.

If masks achieve even a fraction of these savings by reducing costs to small businesses and local governments, the savings will more than cover the cost of the compliance, and public health will be improved.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

The requirement to wear a surgical mask does not impose any physical limitations on the wearer, as would be the case with wearing a respirator which would provide a higher level of protection. Because healthcare and residential facility and agency personnel often wear surgical or procedure masks for a variety of reasons, including both protecting patients and residents and

themselves from communicable disease risks, and because some healthcare facilities in the state already require unvaccinated personnel to wear masks during influenza season, this will not present an undue burden or stigma on healthcare and residential facilities and agencies, or their personnel.

Further, most of the healthcare facilities are already required by state law or soon will be required by federal law to maintain records of the influenza vaccination status of their personnel. Finally, the requirement is to be in effect only when influenza is prevalent as determined by the Commissioner. This enables the requirement to be tailored to the circumstances of any particular influenza season and to be in effect only when there is the greatest risk of influenza transmission.

For these reasons, these regulations do not impose an addition burden on the regulated parties.

Small Business and Local Government Participation:

The proposal has been discussed with a number of organizations representing the affected parties. These include the Healthcare Association of New York State, the Greater New York Hospital Association, 1199 SEIU New York City, the Medical Society of the State of New York, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians. Other organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). The Department will be seeking local government input prior to proposing a permanent regulatory amendment.

This agenda and the proposal will be posted on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

RURAL AREA FLEXIBILITY ANALYSIS

Effect of Rule:

Any facility defined as a hospital pursuant to Article 28, a home services agency by PHL Article 36, or a hospice by PHL Article 40 will be required to comply. In New York State there are 228 general hospitals, 1198 hospital extension clinics, 1239 diagnostic and treatment centers, and 635 nursing homes. There are also 139 certified home health agencies (CHHAs), 97 long term home health care programs (LTHHCP), 19 hospices and 1164 licensed home care services agencies (LHCSAs). Of those, it is known that 47 general hospitals, approximately 90 diagnostic and treatment centers, 159 nursing homes, 92 certified home health agencies, 19 hospices, and 26 LHCSAs are in counties serving rural areas. These facilities and agencies will not be affected differently than those in non-rural areas.

Compliance Requirements:

All facilities and agencies must document the vaccination status of each personnel member as defined in this regulation for influenza virus, in their personnel or other appropriate record. Each facility must develop a policy and procedure which requires all personnel who have not been vaccinated for influenza during the current influenza season to wear a surgical or procedure mask.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

Facilities and agencies will need to provide surgical or procedure masks to those personnel not vaccinated for influenza during a current influenza season. While there is a wide market of varying products and pricing, on average, the price of a surgical or procedure mask varies between approximately 10 to 25 cents per mask, subject to the quantity ordered. Thus, the cost of 1,000 masks could range from $100 to $250. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism, including personnel working less effectively or being unable to work.

Although the cost to facilities and agencies in rural areas cannot be determined with precision, the Department does not expect this cost to be significant, for several reasons. Facilities and agencies in rural areas should already be providing masks for personnel who may come into contact with patients with respiratory symptoms and for whom contact and droplet infection control precautions should be practiced.

Further, facilities and agencies in rural areas are expected to realize savings as a result of the reduction in influenza in personnel and the attendant loss of productivity and available staff. Influenza creates an estimated health burden of $87 billion per year in the United States. Influenza vaccination of healthy adults is estimated to result in a savings of $47 annually per person in reduced physician visits and fewer sick days. There are also potential savings to Medicaid and other payors based on decreasing influenza cases with the concomitant reduction in healthcare costs.

If masks achieve even a fraction of these savings by reducing costs to facilities and agencies in rural areas, the savings will more than cover the cost of the compliance, and public health will be improved.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

The requirement to wear a surgical mask does not impose any physical limitations on the wearer, as would be the case with wearing a respirator which would provide a higher level of protection. Because healthcare and residential facility and agency personnel often wear surgical or procedure masks for a variety of reasons, including both protecting patients and residents and themselves from communicable disease risks, and because some healthcare facilities in the state already require unvaccinated personnel to wear masks during influenza season, this will not present an undue burden or stigma on healthcare and residential facilities and agencies, or their personnel.

Further, most of the healthcare facilities are already required by state law or soon will be required by federal law to maintain records of the influenza vaccination status of their personnel. Finally, the requirement is to be in effect only when influenza is prevalent as determined by the Commissioner. This enables the requirement to be tailored to the circumstances of any particular influenza season and to be in effect only when there is the greatest risk of influenza transmission.

For these reasons, these regulations do not impose an addition burden on the regulated parties.

Public and Local Government Participation:

The proposal has been discussed with a number of organizations representing the affected parties. These include the Healthcare Association of New York State, the Greater New York Hospital Association, 1199 SEIU New York City, the Medical Society of the State of New York, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians. Other organizations that represent the affected parties are given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). This agenda and the proposal will be posted on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed amendment, that it will have no impact on jobs and employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The Department received 14 public comments; eleven were opposed to the regulation, two supportive, and one recommended mandatory influenza vaccination for healthcare personnel (HCP) but did not address the issue of masks. Eleven comments were from professional organizations: CareGivers, District Council 37 American Federation of State, County & Municipal Employees (AFSCME), Empire State Association of Assisted Living (ESAAL), American Council on Science and Health (ACSH), New York State Nurses Association (NYSNA), Home Care Association of New York State (HCA), New York State Association of County Health Officials (NYSACHO), Civil Service Employees Union (CSEA), LeadingAge, Genesee Region Home Care Association (Genesee Region HCA), New York Committee for Occupational Safety and Health (NYCOSH). One comment was from the New York City Department of Health and Mental Hygiene (NYCDOHMH). Two comments were from private individuals. The comments were categorized into six groups.

<u>There is a lack of supportive evidence on mask use to prevent influenza transmission; use alternate means to prevent transmission.</u>

(CareGivers, NYSNA, CSEA, LeadingAge, Genesee Region HCA, NYCOSH, District Council 37 AFSCME, Private Individual)

Commenters suggested that the proposed regulations are contrary to Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA) recommendations on mask use and the hierarchy of controls. One stated that evidence is lacking

that mask use will reduce influenza transmission and noted that CDC states that no studies definitively show that masks prevent influenza transmission. Another commenter stated that CDC recommends that patients with symptoms wear masks, but HCP wear N95 respirators.

Commenters suggested alternative approaches to prevent transmission: mandatory education; focus on community vaccination to develop herd immunity; requiring hospitals to provide free, voluntary influenza vaccinations; visitation restrictions; cohorting patients exhibiting influenza-like illness with immunized staff; adequate sick leave for HCP; promoting hand hygiene and cough etiquette; strict housekeeping measures; and engineering, workplace practices, and administrative controls.

One commenter suggested that influenza vaccine has low efficacy and so all persons, regardless of vaccination status, should be required to wear masks if any are. A commenter noted that shedding may occur before symptoms and that "selective" use of masks might not limit transmission. One commenter questioned the importance of spread by asymptomatic workers, and one noted that HCP mask wear will not control transmission by visitors. Finally, a commenter suggested the possibility of masks becoming a vector of infection.

Response

Although a study directly addressing the efficacy of masks to prevent transmission by HCP has not been done, the Department has analyzed related evidence and drawn reasonable inferences to formulate its policy: In the absence of vaccination, requiring HCP and others in close proximity

to patients to wear masks is the best way to prevent influenza transmission, in addition to routine measures already in place such as hand hygiene.

CDC recommends use of masks by potentially infectious persons to help contain respiratory secretions. That principle would apply to unvaccinated HCP who are infected with influenza and potentially contagious but not yet symptomatic, as well as those HCP who are working while being infected with a mild case which is not recognized as influenza. The Infectious Diseases Society of America also recommends that unvaccinated HCP wear masks.

The Department agrees that "selective" mask wear—that is, only requiring mask wear by those HCP who are diagnosed with influenza—would not prevent transmission. Therefore, all unvaccinated HCP are required to wear masks.

Many of the alternative approaches suggested to prevent influenza transmission are already in use. Messaging to HCP around influenza prevention is common. Despite education, HCP influenza immunization rates remain unacceptably low.

Influenza transmission from HCP to patients does occur and, although vaccine efficacy may be low in some years and populations, vaccine generally provides some protection against HCP transmitting influenza. Similarly, mask wear provides some protection against HCP transmitting influenza. The goal is to reduce the risk of transmission via either method.

Infected visitors might spread influenza, and facilities and agencies have developed visitation policies. HCP, who typically move from patient to patient and therefore have more opportunity to infect multiple patients, are the focus of this regulation.

The rule is burdensome for healthcare facilities and personnel

(CareGivers, NYSNA, HCA, LeadingAge, Genesee Region HCA, ESAAL)

Several commenters stated that the cost of implementing mask wear is higher than estimated by the Department and noted the need for frequent mask changes. Commenters stated that requiring masks constituted an unfunded mandate and suggested reimbursement to cover costs. A commenter expressed concern that challenges from unions might present additional burdens, and another stated that required documentation is excessive, particularly name, address, and date of vaccination when given by an outside provider. One commenter suggested that the Department expand the pediatric vaccination reporting system rather than create a new system.

Response

Although there was general agreement on cost per mask, commenters calculated higher overall costs than estimated by the Department. However, in most settings the cost should be less than one dollar per shift per unvaccinated worker, which is a very small proportion of the budget of covered facilities and agencies. Costs can be decreased by encouraging vaccination of all eligible, willing personnel. From a health system perspective, fewer cases of influenza among HCP and fewer instances of transmission to patients may decrease costs.

Parties covered by this regulation already must maintain a health record for employees with information such as rubella status and tuberculosis testing results. It should not be a large additional burden to add influenza immunization status and to report rates. Reporting will be accomplished through the Department's Healthcare Emergency Response Data System (HERDS), which many healthcare facilities use to report influenza morbidity during the influenza season.

Regarding immunization of personnel by outside providers and required documentation, the data elements of date, provider name, and address are typically provided on immunization cards given as proof of vaccination and are needed to ensure that vaccination was obtained.

The rule imperils worker safety

(NYSNA, CSEA, LeadingAge)

Commenters speculated that mask wear might create a communication barrier, especially for patients with hearing impairment or mental health issues, and it was suggested that this is a violation of the New York State Public Employer Workplace Violence Prevention regulation. Commenters suggested that masks might be a physiologic burden for persons with lung disease, claustrophobia, etc. Finally, a commenter suggested that the regulation would require facilities to conduct additional OSHA hazard analyses.

Response

The masks called for under this regulation are light-weight surgical or procedure masks that do not form a seal and are worn in hospitals every day for hours at a time, such as in operating rooms. The regulation does not call for N95 respirators, which could potentially form a physiologic barrier. Under certain conditions, personnel covered by this regulation already have to wear masks as a matter of course in healthcare settings.

When communication barriers, violence, or other negative reactions are a concern, the Department expects facilities and agencies to use the same procedures as are used now when masks are required for other reasons. The regulation's requirement to wear masks does not violate the New York State Public Employer Violence Prevention Regulations. Currently, HCP may be required to wear a mask for a variety of reasons not related to these regulations.

OSHA regulations require that all employers evaluate their workplaces for hazards and take appropriate measures. This regulation does not require any additional hazard analysis beyond what is already required under OSHA regulations, nor does it violate OSHA laws or regulations.

The rule adversely impacts workers' rights

(NYSNA, LeadingAge, NYCOSH, Private Individual)

Commenters suggested that the regulation is coercive and punitive rather than preventative, that it could stigmatize workers, and that it is a human rights violation. There was concern that the regulation indirectly tries to achieve mandatory vaccination. Commenters suggested that it is a

privacy issue for workers because the mask might indicate that a person was not vaccinated, and that it therefore might be a Health Insurance Portability and Accountability Act (HIPAA) violation.

Response

This regulation is designed to give HCP a choice in how they protect patients from influenza – either immunization or mask wear, and while neither is perfect, both are expected to provide some level of protection for patients. A state regulation requiring that unvaccinated personnel wear masks does not violate HIPAA.

Miscellaneous concerns

(Private Individual, NYSNA, CareGivers, Genesee Region HCA, LeadingAge, ESAAL, HCA)

Home Care agencies expressed concern that the regulation cannot be enforced in the community and home care setting. One commenter stated that the regulation does not accommodate those who cannot get the vaccine. Another commenter stated that the Department's surveillance does not show that HCP transmit influenza in hospitals. There was concern that the regulation would not prevent an epidemic because no similar measures are proposed in non-healthcare settings. One commenter suggested that mask wear might create a false sense of security and make it appear acceptable to work if ill. A commenter suggested that the regulation is overly broad in that it requires mask wear by anyone in patient areas regardless of role. A commenter suggested that masks detract from a home-like environment in long-term care settings. A commenter expressed concern that the mandate might result in staffing shortages from terminations or

voluntary resignations or might discourage people from working or volunteering. Finally, a commenter suggested exceptions for cases in which persons might be frightened by masks.

Response

Agencies will need to develop policies and a means of assessing compliance, just as they currently do for other regulations that affect home care. Mask wear is the alternative method of protecting patients from influenza for HCP who are unvaccinated, regardless of the reason. Each year the Department receives numerous reports of influenza outbreaks in healthcare facilities, and it is known that HCP can transmit influenza to patients. The regulation is focused on preventing healthcare-associated transmission. Healthcare facilities and agencies should continue to stress the importance of not working when ill and enforce relevant policies. The regulation applies to any personnel who are around patients because proximity determines likelihood of transmission more than the person's role. There are circumstances outside of this regulation where mask use is required in long term care settings, and any detraction from the home-like environment can be minimized by ensuring that all eligible, willing personnel are vaccinated. The Department does not expect staffing shortages as a result of this regulation; on the contrary, fewer ill HCP should improve the staffing situation during influenza season. If any persons are frightened by masks, facilities and agencies should have plans to address those fears as they would when masks are required for other reasons.

Supportive and other comments

NYCDOHMH supports the intent of the proposal and expresses concern about the definition of the influenza season, stating that local health departments (LHDs) should be able to make the determination themselves.

NYSACHO states that the past influenza season highlights the need to promote vaccinations and put other measures in place, notes that lower than optimal HCP vaccination rates are concerning, and states that the regulation is "an important step in ensuring that patient care comes first." Further, masks can potentially decrease transmission and there is a "need for strong policies to minimize the risk that unvaccinated healthcare workers pose to patients and co-workers". Finally, they state that the "proposed regulation balances workers' rights and patient safety while providing for appropriate flexibility".

ACSH suggest a policy mandating influenza immunization for all HCP.

Response

The definition of the influenza season for the purpose of this regulation is based on State surveillance data and determined by the Commissioner. The Commissioner may consider data and input from LHDs and other knowledgeable entities. The Department agrees that this regulation will improve patient safety, while providing an alternative way to protect patients for HCP who cannot be vaccinated or who refuse to be vaccinated.

Conclusion

After careful review and consideration of all comments the Department determined that the regulation will be published for final adoption with no changes.