

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

Effective Date: 11/19/14

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:

Section 2.59 is amended 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.

(4) "Patient or resident," for the purposes of this section, shall mean any person receiving services from a healthcare or residential facility or agency, including but not limited to inpatients and outpatients, overnight residents, adult day health care participants, and home care and hospice patients, as well as any person presenting for registration or admission at a healthcare or residential facility or agency.

(5) "Influenza vaccine" or "vaccine," for the purposes of this section, means a vaccine currently licensed for immunization and distribution in the United States by the Food and Drug Administration (FDA), for active immunization for the prevention of influenza disease caused by influenza virus(es), or authorized for such use by the FDA pursuant to an Emergency Use Authorization (EUA) or as an Emergency Investigational New Drug (EIND).

(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]:

(1) a document, prepared by the licensed healthcare practitioner who administered the vaccine, indicating that one dose of influenza vaccine was administered, and specifying the vaccine formulation and the date of administration; or

(2) for personnel employed by a healthcare employer other than the healthcare or residential facility or agency in which he or she is providing service, an attestation by the employer that the employee(s) named in the attestation have been vaccinated against influenza for the current influenza season, and that the healthcare employer maintains documentation of vaccination of those employees, as described in paragraph (1) of this subdivision; or

(3) for student personnel, an attestation by the professional school that the student(s) named in the attestation have been vaccinated against influenza for the current influenza season, and that the school maintains documentation of vaccination of those students, as described in paragraph (1) of this subdivision.

(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] are typically present, except that:

(1) when personnel provide services outside the home of a patient or resident, and not inside a healthcare or residential facility, mask wear shall not be required by this section, provided that this paragraph shall not be interpreted as eliminating any requirement that personnel wear a mask pursuant to standard and transmission-based precautions not addressed by this section;

(2) personnel required to wear a mask by this subdivision, but who provide speech therapy services, may remove the mask when necessary to deliver care, such as when modeling speech; and

(3) for any person who lip reads, personnel required to wear a mask by this subdivision may remove the mask when necessary for communication.

[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.

(g) Healthcare and residential facilities and agencies shall supply surgical or procedure masks required by this section at no cost to personnel.

(h) Nothing in this section shall be interpreted as prohibiting any healthcare or residential facility or agency from adopting policies that are more stringent than the requirements of this section.

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:

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 promotes the health and safety of the patients and residents they serve and support efficient and continuous provision of services.

Needs and Benefits:

In general, section 2.59 of Title 10 of the NYCRR requires healthcare personnel who have not been vaccinated against influenza to wear a mask during the influenza season. These

amendments clarify certain provisions of the existing regulation and make one substantive change.

The clarifying amendments codify the Department's interpretation of section 2.59, as published by the Department in a document entitled "Frequently Asked Questions (FAQ) Regarding Title 10, Section 2.59 'Regulation for Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel'", dated September 24, 2013. The amendments clarify that the masking requirement applies in those areas where patients or residents are "typically" present, rather than "may be" present. The amendments also define "influenza vaccine" to mean a vaccine approved as an influenza vaccine by the Food and Drug Administration (FDA), or pursuant to an Emergency Use Authorization (EUA), or as an Emergency Investigational New Drug (EIND). This clarification is important because, in the event of a novel influenza virus outbreak, such as H1N1 in 2009, new vaccines and emergency use of existing vaccines may be available or necessary to meet the requirements of the regulation.

The amendments also clarify that the regulation is not intended to require mask wear while a patient or resident is receiving services outside the home or regulated facility. This regulation is based on the reasonable expectation that patients and residents should not be exposed to influenza in their homes or in medical care facilities, by the personnel who they rely upon to care for them. However, when they choose to leave the home or facility and interact with the general public in the community, they are potentially exposing themselves to influenza from any number of sources. The risk of exposure from the healthcare provider is essentially

subsumed by the risk of general community exposures. For this reason, unvaccinated healthcare personnel who are accompanying patients are not required to wear masks while away from patient homes and off facility grounds—for example, while on public transportation, at community events, and in shops.

The final clarification amendment provides that the regulation should not be interpreted as requiring mask wear by unvaccinated personnel who provide speech therapy services, during the time that such personnel are providing care. Similarly, for any person who lip reads, unvaccinated personnel may remove the mask when necessary to communicate.

These amendments also include one important substantive change, in that they revise the documentation requirement for healthcare and residential facilities and agencies. The intent of this change is to create a more flexible system for documenting vaccination status, thereby easing the regulatory burden on regulated parties. Specifically, required documentation would include only the date of vaccination and information specifying the vaccine formulation administered. Further, where the personnel of a healthcare or residential facility or agency includes contract staff and students, the facility or agency may accept an attestation from the employer or school, stating that specified persons have been vaccinated and that the employer or school maintains the required documentation.

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

These amendments do not create any new costs for regulated entities. The revised documentation requirements are expected to ease the regulatory burden on healthcare and residential facilities and agencies.

Cost to State and Local Government:

These amendments do not create any new costs for State or local government. To the extent that State or local governments operate healthcare and residential facilities and agencies, the revised documentation requirements are expected to ease the regulatory burden on these entities.

Cost to the Department of Health:

There are no additional costs to the State or local government. Existing staff will be utilized to educate healthcare and residential facilities and agencies about the revised reporting requirements.

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.

Paperwork:

These amendments will not result in any additional paperwork or electronic reporting. The revised documentation requirements are expected to ease the regulatory burden on regulated entities.

Duplication:

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

Alternative Approaches:

The alternative would be to leave the current regulation in its current form. However, doing so would continue documentation requirements for regulated parties that do not include the flexibility of this proposed amendment. There would also be no provision relating to persons who choose not to be vaccinated and who, for a medical reason, cannot wear a mask.

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 approximately 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 comply with the revised documentation requirement regarding the vaccination status of personnel.

Professional Services:

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

Compliance Costs:

These amendments do not create any new costs for small businesses or local governments. To the extent that small businesses and local governments operate healthcare and residential facilities and agencies, the revised documentation requirements are expected to ease the regulatory burden on these entities.

Economic and Technological Feasibility:

This proposal is economically and technically feasible, as it does not impose any additional burdens.

Minimizing Adverse Impact:

This amendment does not create any adverse effect on regulated parties that would require a minimization analysis.

Small Business and Local Government Participation:

Small businesses and local governments are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council, as well as during the official comment period.

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.

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 approximately 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.

Professional Services:

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

Compliance Costs:

These amendments do not create any new costs for small businesses or local governments. To the extent that healthcare and residential facilities and agencies are located in rural areas, the revised documentation requirements are expected to ease the regulatory burden on these entities.

Economic and Technological Feasibility:

This proposal is economically and technically feasible, as it does not impose any additional burdens.

Minimizing Adverse Impact:

This amendment does not create any adverse effect on regulated parties that would require a minimization analysis.

Public and Local Government Participation:

The public and local governments are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council, as well as during the official comment period.

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 8 public comments. Four were from home care agencies and associated organizations: VIP Health Care Services, PHI New York, Home Care Association of New York State, and New York State Association of Health Care Providers. One was from District Council 37, American Federation of State, County & Municipal Employees, AFL-CIO, and one was from the New York State Association of County Health Officials. One was from a local health department employee, and one was from an administrative assistant at an academic medical center. In general, all commenters support the amendments, although some expressed concerns about provisions in the original regulation that remain unchanged or suggested additional changes. Given the small number of comments received, each is summarized below with a response.

One commenter stated that although “the rule is just one more regulation to adhere to”, it has merits and positive impact. The commenter supports the change in documentation that no longer requires the name and address of the person ordering or administering the vaccine. The commenter questions why the vaccine formulation is included among the new documentation requirements and questions whether an attestation stating that the individual received the vaccine and the date of vaccine would suffice. Additionally, the commenter requests clarification on the mechanism for employers to attest to the immunization status of their employees, and questions whether the employer should be required to pay for masks for employees who refuse vaccine.

Response: Vaccine formulation is a standard part of immunization documentation. Inclusion of the formulation (e.g., brand name, generic name, or other generally accepted designation such as

“LAIV” or “IIV”) will bring the documentation requirements for this regulation in line with documentation requirements for other vaccines. Asking healthcare providers only to give an attestation for this regulation would not relieve them of the need to appropriately document receipt of the vaccine, including formulation.

Regarding the attestation of the immunization status of their employees, this amendment relieves the burden placed on regulated entities, especially those that involve contract staff.

Finally, the requirement that covered entities pay for masks for personnel who refuse vaccine is not new. 10 NYCRR 2.59 currently requires healthcare and residential facilities and agencies to supply such masks to personnel, free of charge. It is standard procedure for healthcare facilities to provide appropriate personal protective equipment.

One commenter writes “in support of the proposed amendments to the regulations pertaining to the prevention of influenza transmission by healthcare and residential facility and agency personnel.” The commenter further states that “the proposed changes will ease the regulatory burden on the agencies while still serving the intended purpose of the regulation”.

Response: The Department agrees that these amendments will lessen the burden on covered entities while maintaining the important functions of the regulation.

One commenter “supports the July 30th proposed changes” while noting concerns over provisions in the original regulation that have not been revised and suggesting additional changes. Regarding documentation of vaccination, the commenter states that the new language

eases documentation burden but urges “continued effort” in this regard. Specifically, the commenter suggested changes to reduce “duplicative and excessive reporting”. This commenter described challenges ensuring compliance with the regulation in the home care setting and “urge[d] the Department to be cognizant of the realistic challenges faced by home care agencies when judging agency efforts to ensure compliance with this mandate.” The commenter questioned the suitability of mask wear in the home care setting, but focused on provisions in the original regulation rather than the proposed amendments. The commenter noted the provision that covered facilities and agencies must supply masks to unvaccinated personnel free of charge to the personnel and suggested that agencies be compensated for the costs of doing so.

Response: The Department agrees that these proposed amendments will ease administrative burden and continues to monitor implementation.

Regarding the commenter’s suggestion about eliminating duplicative reporting (where one healthcare worker is reported more than once if working for more than one covered agency or facility), reporting is intended to focus on the vaccination statistics for the facility or agency, rather than individual healthcare workers. Because the focus of reporting is on vaccination coverage at facilities or agencies, it is appropriate to include healthcare workers who work at more than one facility or agency in each report.

The Department recognizes the challenges of ensuring compliance with mask wear in the home care setting and suggests that methods similar to those used to monitor compliance with other infection control practices (e.g., hand hygiene) should be used.

As noted above, the requirement that covered entities pay for masks for personnel who refuse vaccine is not new, and it is standard procedure for healthcare facilities to provide all appropriate personal protective equipment.

One commenter expressed opposition to the regulation, while supporting the proposed amendments as improvements. Specifically, the commenter stated that the proposals allowing for removal of masks when outside the home in the community, during speech therapy, or when communicating with persons who lip read are “critical clarifications”. The commenter also described the previous reporting requirements in the original regulation as “daunting” and “burdensome” and supports the change to allow for attestations from contract employers regarding vaccination status. The commenter also supports the change to remove the documentation requirement of name and address of the person who ordered or administered the vaccine, noting that it “posed particular challenges” to providers. Despite overall support for the proposed amendments, the commenter expressed continued concern about the appropriateness of the regulation in the home care setting and stated that home care consumers should decide whether masks are worn. Finally, the commenter opposed including healthcare workers as part of the report from each facility or agency where they work.

Response: While understanding the commenter’s concerns about the home care setting, the Department continues to believe that home care consumers deserve the same protection from influenza as patients in other healthcare settings. A provision to relax the mask wear requirement in homes could easily be misused, especially with vulnerable patients and/or providers who prefer not to wear masks.

The Department has put considerable thought and effort into the reporting procedures. The Department believes that the current system appropriately focuses on the proportion of vaccinated personnel providing services to a facility or agency. Specifically, attempting to identify personnel who work for multiple facilities or agencies would be burdensome to facilities, agencies, and the Department. Some healthcare workers are employed by one agency but contracted to other agencies or facilities and, furthermore, some healthcare workers are directly employed by multiple agencies or facilities.

One commenter expresses opposition to the regulation itself and suggests “a more comprehensive approach to infection control.” The commenter suggests additional amendments requiring employers to provide different types of masks for personnel who have difficulty wearing one style. The commenter objects to the language allowing employers to adopt more stringent policies than are contained within the regulation. The commenter states that the amendments that provide additional guidance on where masks must be worn and provide exemptions for care outside of homes or facilities, speech therapists, and personnel communicating with individuals who lip read are “generally beneficial”, while noting that the proposed language might be open to interpretation. The commenter notes use of different terminology (“influenza vaccine” vs. “vaccine”) and suggests that this could create misinterpretation. The commenter notes that the process for requesting consent for vaccination records and de-identifying employee health information before it is sent is not described, and notes that some facilities use stickers on badges to denote vaccination status. The commenter states that there is continued confusion about which personnel are covered, and the question of who might expose patients is left open to interpretation. Finally, the commenter states that the

start and end of the “flu season” is confusing and suggests amendments to directly notify workers.

Response: Regarding the concern about employers providing different types of masks, employers are expected to provide appropriate personal protective equipment (PPE).

Although not explicitly stated in the original regulation, facilities and agencies have always been allowed to implement more stringent policies than those embodied in this regulation. Therefore, this is not a substantive change. The regulation was merely clarified in this regard.

The Department does not expect use of the terms “influenza vaccine” and “vaccine” to cause confusion in the context of this regulation.

Regarding the commenter’s concerns about consent for transmission of vaccination records, nothing in this regulation or the amendments changes current consent procedures. It would not be appropriate to attempt to duplicate consent requirements by including them within this regulation. Regarding de-identification of employee health information, in cases where facilities or agencies are providing an attestation of which employees are vaccinated, de-identification would not be appropriate because the receiving facility or agency needs to know who is vaccinated and who is not. Again, the usual procedures for obtaining consent for release of records would apply. Similarly, procedures for identifying vaccinated and unvaccinated employees must conform to applicable privacy laws and regulations.

Regarding the commenter’s concerns about parts of the regulation and amendments being open to interpretation, in the context of different settings and facility layouts, the Department believes that the language in the regulation and amendments—referring to areas where patients or residents are “typically” present—provides the appropriate level of guidance.

The Department believes that notification to healthcare facilities and agencies, which can then notify their employees, is the best way to communicate the mask requirement. Additionally, the beginning and end of mask wear are reported on the Department’s web site.

One commenter recommends that the Department amend regulations affecting the Early Intervention (EI) program such that EI providers are subject to mask wear requirements if unvaccinated for influenza. The commenter states a belief that regulations obligate the Department to implement mask wear requirements for EI providers.

Response: EI providers are not “personnel” within the meaning of the regulation. The Department believes that the regulation is appropriately limited to healthcare personnel.

One commenter stated that the addition of vaccine formulation among the documentation requirements “makes things much more complicated”.

Response: As noted in the response to a previous comment, the formulation of vaccine is a standard part of immunization documentation, similar to what is required for measles and rubella vaccine documentation requirements.

One commenter suggested that a distinction be made between mental health facilities and other medical facilities. The commenter states that some patients leave the patient areas on a pass and might travel through various administrative or non-patient areas of the hospital. The commenter also asks if there are boundaries within which facilities must stay if they adopt more stringent policies than required by the regulation and notes several examples of additional institutional requirements.

Response: Mental health facilities that do not otherwise meet the definition of “healthcare or residential facility or agency” are not covered by this regulation. The Department believes that the regulation appropriately protects patients and residents from transmission of influenza from healthcare workers. The facility is expected to use reasonable judgment in determining whether a given area is one in which patients or resident are typically present, such that unvaccinated personnel must wear masks during the influenza season.

Regarding the statement that facilities may adopt more stringent policies, as noted in a previous response, this is not a change from the original regulation but rather a clarification. Questions regarding the boundaries of a facility’s or agency’s authority to issue employee policies, which may be more stringent than this regulation, are beyond the scope of this document and should be directed to legal counsel for the facility or agency.