

**Frequently Asked Questions (FAQ)
Regarding Title 10, Section 2.59
“Regulation for Prevention of Influenza Transmission by
Healthcare and Residential Facility and Agency Personnel”
September 24, 2013**

Overview

1. Q: When did this regulation go into effect?

A: The regulation was effective upon publication of the notice of final rulemaking in the State Register on July 31, 2013.

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

A: 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.

***** Updated Answer *****

3. Q: What kinds of healthcare facilities, residential facilities and agencies does the regulation apply to?

A: 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. Every facility and agency regulated under these Articles must have an operating certificate that states the locations and activities for which the facility or agency is licensed.

For example, All-Inclusive Care of the Elderly (PACE) program personnel are covered by this regulation only if the program is operated under an Article 36 operating certificate.

Likewise, a facility or shelter within the oversight of 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 is covered by this regulation only if the facility or shelter holds an operating certificate pursuant to Article 28, 36 or 40 of the Public Health Law.

Entities/personnel to which this regulation does NOT apply include (but are not limited to):

- Assisted living facilities
- Adult homes

- Private practices
- Managed Long Term Care programs regulated by Article 44 of the Public Health Law
- Mental/behavioral health facilities regulated by Article 31 of the Public Health Law; however, the regulation does apply to mental/behavioral health units regulated under Article 28
- Personal assistants operating under the Consumer Directed Personal Assistant Program (CDPAP)

If you still don't know whether your facility or agency has an operating certificate issued pursuant to Article 28, 36, or 40 of the Public Health Law, please contact your supervisor, an executive officer of your facility or agency, or your facility's or agency's legal counsel.

4. Q: What are the regulation's main provisions?

A: The regulation requires facilities and agencies as described above to require that personnel who are not vaccinated against influenza wear a surgical or procedure mask while working in areas where patients, residents, or clients may be present during the time when the Commissioner determines that influenza is prevalent. 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.

5. Q: What is the purpose of the regulation?

A: The regulation is intended to protect patients, residents, and clients 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 patients, residents, and clients.

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

A: 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.

7. Q: If a facility or agency has policies and procedures in place that are stricter than those proposed in this regulation, can those policies and procedures remain in place?

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

8. Q: When should mask wear begin and how long must it continue?

A: 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:

Influenza Season	Dates "Widespread"	# Weeks "Widespread"
------------------	--------------------	----------------------

2007-2008	January 12-April 19	15
2008-2009 (H1N1 pandemic)	January 31-April 11 June 6-July 11	17
2009-2010	October 3-December 12	11
2010-2011	December 25-April 9	16
2011-2012	March 10-May 19	11
2012-2013	November 24 – April 20	22

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).

9. Q: Who must wear a mask under the new regulation?

A: 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, residents, or clients to the disease.

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

A: Unvaccinated healthcare personnel must wear masks wherever patients, residents, or clients are typically present. This would include, but not be limited to, patient or resident rooms, nurses’ stations, hallways and elevators where patients or residents are typically present, cafeterias if patients may be present (except when the unvaccinated healthcare worker is eating), and clients' homes when providing home care.

***** New 9/24/2013 *****

11. Q: Who is considered a patient, resident, or client for the purposes of this regulation?

A: Both inpatients and outpatients, and overnight residents or adult day care participants in a covered program, who are cared for in covered facilities or by covered agencies, are considered patients, residents, or clients. Persons presenting for registration or admission will become patients, residents, or clients at some point during the process and so should be considered patients, residents, or clients. Therefore, registration, reception, and front desk staff who interact with such persons are “personnel” and are covered by this regulation.

Recent patients, residents, or clients who have been discharged are not considered patients, residents, or clients.

Immunization

**** New 9/24/2013 ****

12. Q: Can a home care agency administer flu shots to their employees?

A: Yes, a home care agency may provide vaccines to their staff. The agency must follow New York State Education Department, Office of the Professions Guidelines for “Non-Patient Specific Standing Orders and Protocol Guidelines” found at <http://www.op.nysed.gov/prof/nurse/immunguide.htm> and the agency must be capable of properly storing the vaccine. Additional questions may be directed to the NYS Department of Health, Bureau of Immunization at 518-473-4437. Additional information can be found at the following webpages:

<http://www.immunize.org/clinic/>

<http://www.immunize.org/vis/>

13. Q: 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?

A: Yes. Influenza vaccines generally contain three or four strains of influenza virus. Having had influenza during a season does not protect against other strains in the vaccine. 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 one or more times during the current influenza season.

14. Q: It takes one to two weeks after vaccination to develop protective immunity. Do covered personnel need to wear a mask during that period?

A: No, it is not required that persons wear a mask during the weeks immediately after vaccination. It may be difficult for facilities, residences, and agencies to track which employees need to wear masks by various vaccination dates 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 can voluntarily implement 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.

**** Updated answer ****

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

A: The Joint Commission on Accreditation of Health-Care Organizations approved an infection-control standard requiring 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 Article 21-A requires nursing homes, adult homes, enriched housing programs, and adult day healthcare programs to provide or arrange for influenza vaccination

to employees, and many long term care facilities have voluntarily chosen to offer influenza vaccine free of charge to these employees.

Documentation and Reporting

**** Updated answer ****

16. Q: What must be reported to NYSDOH?

A: 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). The first report will open on November 1, 2013 on the Health Electronic Response Data System (HERDS) and will be due by November 15, 2013. Reporting information and instructions are available on the NYSDOH web page about this regulation

(http://www.health.ny.gov/diseases/communicable/influenza/seasonal/providers/prevention_of_influenza_transmission/), and questions may be sent to immunize@health.state.ny.us.

**** New 9/24/2013 ****

17. Q: What constitutes adequate documentation of influenza immunization for the purposes of this regulation?

A: At a minimum, documentation must include the name and business address of the individual who ordered or administered the vaccine and the date of vaccination. In general, this documentation must be generated by the individual who actually ordered or administered the vaccine.

However, the Department is aware that some vaccination cards currently in use do not include the business address of the individual who ordered or administered the vaccine. Therefore, for initial implementation of this regulation, if the documentation does not include the business address of the individual who ordered or administered the vaccine, but is otherwise acceptable, the immunized individual may provide that information.

The following forms of electronic submission also would be acceptable under the regulation:

- A New York State Immunization Information System (NYSIIS) record
- An electronic medical record
- An electronic statement from the provider of the vaccine giving the date the vaccine was given and the name and address of the provider.

In addition, facilities and agencies covered by the regulation may accept electronic files from other institutions documenting vaccination status of shared personnel (e.g. health professional students or healthcare personnel who work at more than one institution). Such files must include the required information under this regulation (name and address of the individual who ordered or administered the vaccine and the date of vaccination). If the immunization was not administered by the institution providing the file, then that institution must have received acceptable documentation of immunization per this regulation and should indicate so in the file. Documentation of vaccination status from institutions not covered under the regulation (e.g., health professional schools) must meet the same documentation requirements that apply to covered facilities or agencies.

*** *New 9/24/2013* ***

18. Q: Must the required documentation include the lot # of the vaccine?

A: No. The vaccination card or other documentation provided by an employee may include this additional information, but it is not required by this regulation. Manufacturer lot numbers should be documented in the vaccine recipient's permanent medical record. The required documentation for the purposes of this regulation includes the date of the vaccination and the name and business address of the individual who ordered or administered the vaccination.

*** *New 9/24/2013* ***

19. Q: Does "self-attestation" suffice as documentation that influenza vaccination was obtained elsewhere?

A: No. Documentation must be prepared by the individual who ordered or administered the vaccine, either by providing such documentation directly to the facility or agency (with the consent of the person vaccinated) or by providing a vaccination card or similar record to the person vaccinated, who can then present it to the facility or agency.

HIPAA

*** *New 9/24/2013* ***

20. Q: Does HIPAA require that a facility, agency or other institution obtain an individual's consent before disclosing his or her immunization information, for purposes of either:

(a) Information sharing between facilities, agencies, or other institutions that share personnel such as professional schools, or between groups within such an institution (such as Employee Health and unit managers responsible for enforcement)?

or

(b) Placing an indicator on the individual's badge, or any similar visual indicator, which identifies his or her vaccination status?

A: If an individual consents to his or her vaccination status being shared in a particular manner, such as those outlined above, there is no HIPAA violation.

If the individual's immunization is administered by his or her facility, agency, or other institution, consent could be obtained at the time of immunization. In the case of immunizations administered elsewhere, consent could be obtained when the individual provides his or her immunization documentation.

Depending on how immunization information is collected and stored, an individual's consent may not be required to disclose such information. Please consult with legal counsel for your facility or agency to determine whether, based on your facility's or agency's procedures, your immunization records constitute "protected health information" for purposes of HIPAA, or whether other privacy laws may apply.

Enforcement

21. Q: How will these regulatory requirements be enforced by facilities and agencies?

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

22. Q: Who will be monitoring hospitals and diagnostic and treatment centers (D&TC) for compliance?

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

**** New 9/24/2013 ****

24. Q: How should my facility or agency monitor compliance with mask wear for unvaccinated staff?

A: Healthcare facilities, residential facilities and agencies are expected to monitor compliance with this regulation as they would compliance with other infection prevention and control activities (e.g., hand hygiene, Standard and Transmission-based Precautions) and employee health requirements (e.g., tuberculin skin testing, measles and rubella vaccination/immunity status).

**** New 9/24/2013 ****

24. Q: What can be the consequences for non-compliant personnel?

A: Each facility and agency will be expected to follow its own personnel policies and procedures regarding discipline.

Masks and Mask Wear

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

A: Masks should be changed:

- after leaving the room or completing care of a patient, resident, or client on isolation precautions;
- whenever it is soiled or might have become soiled; or
- per the protocols of the facility or agency.

26. Q: What types of masks can be worn to meet the requirements of this regulation?

A: 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.

27. Q: If a person has a medical contraindication to influenza vaccination, does that person have to wear a mask?

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

28. Q: Will personnel with a medical contraindication to influenza vaccination need to be reassigned for the duration of the flu season?

A. No. Such personnel will be required to wear a mask during the influenza season. However, reassignment of such personnel to an area where patients, residents or clients are not typically present would avoid the requirement that such personnel wear masks.

*** *New 9/24/2013* ***

29. Q: What effect will this regulation have on unvaccinated healthcare personnel who have a medical contraindication to prolonged mask wear?

A: NYSDOH is not aware of any medical contraindication to wearing a surgical mask for any length of time. For those few healthcare personnel who cannot receive influenza immunization or who refuse to do so (for any reason), and who also are unable or refuse to wear a mask of the type required by this regulation, facilities and agencies may develop policies for reassignment to duties for which mask wear is not required, during the time when influenza is declared prevalent.

*** *New 9/24/2013* ***

30. Q: Can you define what constitutes a documented medical contraindication to wearing a mask of the type required by this regulation?

NYSDOH is not aware of any medical contraindications to wearing a mask of the type required by this regulation. If a covered person is unimmunized and reports an inability to wear a mask (thereby raising the issue of re-assignment during the time when influenza is declared prevalent), it is up to the facility or agency to determine whether documentation will be required and, if so, what type is acceptable.

*** *New 9/24/2013* ***

31. Q: Will facilities and agencies be reimbursed for the cost of providing masks?

A: No. The masks provided to personnel under this regulation are considered infection control consumables, similar to personal protective equipment (PPE) and alcohol hand rub, and as such will not be reimbursed.

*** *New 9/24/2013* ***

32. Q: Are Home Care personnel expected to change masks from house to house?

A: Yes.

*** *New 9/24/2013* ***

33. Q: Are masks required in facility or agency areas that are technically public, but in which patients, residents, or clients are usually not present? (For example, cafeterias not frequented by patients, open lobby areas, etc.)

A: Each facility and agency is responsible for defining locations where masks are to be worn, guided by the language in the regulation that states that personnel must “wear a surgical or procedure mask while in areas where patients or residents may be present”. The Department

interprets this to mean those areas where patients are typically present and, therefore, the likelihood exists that patients could be exposed to influenza. Additionally, FAQ No. 41 notes that “personnel could potentially expose patients, residents, or clients either through sharing a 6-foot space with an individual (person-to-person contact) or a surface that comes in contact with an individual (equipment-to-person contact).”

To use the example of hospital cafeterias, there may be some hospitals where the cafeterias are used almost exclusively by employees and other personnel, even if not officially designated as employee areas, and patients are not typically present. In that situation, it could be permissible not to require mask use while in the cafeteria. On the other hand, there may be other hospitals where it’s typical to see patients (whether inpatients or outpatients) eating or visiting with family members in the hospital cafeterias. In those facilities, mask use by unvaccinated personnel would be required (except while eating). Similar reasoning should be applied to other common areas of facilities.

**** New 9/24/2013 ****

34. Q: Are healthcare personnel required to wear masks while out in the community with patients, residents, or clients, such as while on outings with facility residents or while travelling on public transportation or shopping with home healthcare clients?

A: This regulation is based on the reasonable expectation that patients, residents, and clients should not be exposed to influenza in their homes or medical care facilities by the personnel 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 accompanying patients, residents, or clients are not required to wear masks while away from client homes or off facility grounds in areas where the general public is present, such as on public transportation, at community events, and in shops.

Covered Personnel

35. Q: Does “personnel” to whom this regulation applies include visitors, such as family members?

A: No. This regulation does not apply to visitors to facilities, such as family members of patients or residents. Facilities which have visitors are encouraged to establish policies for when visitor restrictions should be put in 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.

36. Q: Who determines whether someone affiliated with a covered facility or agency is subject to the new regulation?

A: Each facility or agency makes this determination and is responsible for developing medically appropriate protocols based upon the potential for personnel to expose patients, residents, or clients to influenza.

37. Q: How can it be determined which personnel could potentially expose patients, residents, or clients to influenza?

A: Influenza is transmitted primarily by large-particle respiratory droplets that do not remain suspended in the air. Therefore, personnel could potentially expose patients, residents, or clients either through sharing a 6-foot space with an individual (person-to-person contact) or a surface that comes in contact with an individual (equipment-to-person contact).

38. Q: Are food service workers affected by this regulation?

A: Food service workers are affected if they meet the criteria for personnel who could potentially expose patients, residents, or clients 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, resident, or client becoming infected via contaminated food or plates is considered low and probably negligible. Therefore, food service workers who only work in a kitchen in an area of a facility where patients or residents are not present and who do not come into close proximity with patients or residents 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, residents, or clients to respiratory droplets. Therefore, food service workers who work in a cafeteria where patients or residents might be present would be affected, and food service workers who deliver trays to patient or resident units or who stock kitchens on patient or resident units would be affected.

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

A: No. The requirement only applies to personnel who could themselves directly expose patients, residents, or clients to influenza.

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

A: Yes.

41. Q: Does the regulation apply to pharmacists?

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

***** New 9/24/2013 *****

42. Q: Does the regulation apply to speech therapists and speech pathologists?

A: Yes, speech therapists and speech pathologists who are unvaccinated must wear a mask. However, a speech therapist or speech pathologist with a documented medical contraindication to influenza immunization which is listed in the Advisory Committee on Immunization Practices (ACIP) statement on influenza vaccination (<http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>) may remove the mask

only during those times when it is necessary to deliver care, such as during modeling of speech.

*** *New 9/24/2013* ***

43. Q: Which contractors are covered personnel?

A: Contractors must comply with this regulation if they (1) function as employees or staff of the regulated facility or agency; or (2) are under the facility's or agency's direct control. This includes, but is not limited to nurses and other healthcare professionals contracted to provide care to patients, residents, or clients.

Contractors who do not meet this definition are considered visitors and are NOT subject to this regulation. Examples of contractors who are NOT subject to this regulation include, but are not limited to:

- contracted construction/plumbing/electrical workers hired for a specific job(s)
- medical equipment vendors
- snack vending machine service personnel
- one-time or sporadically occasional entertainers hired by contract
- EMS, ambulette, or other transportation services personnel in a contract relationship with a covered facility or agency, but who do not meet the definition of functioning as employees or staff of the facility or agency or being under the facility's or agency's direct control
- lab and radiology technicians who provide services to an agency or facility by contract (e.g., enter a nursing home intermittently to draw blood or perform X-rays), but who do not meet the definition of functioning as employees or staff of the contracting facility or agency, or who are not under that facility's or agency's direct control, are not personnel of the contracting agency or facility. However, if the technician is simultaneously an employee of another agency or facility covered by the regulation, such as a hospital, the technician is covered as personnel of that agency or facility.

*** *New 9/24/2013* ***

44. Q: Which volunteers are covered personnel?

A: Volunteers who have a formal relationship with the facility or agency and who provide regularly scheduled volunteer services must comply with the regulation. Volunteers who do not meet this definition are considered visitors and are not required to wear a mask.

Examples of individuals who are NOT subject to this regulation include:

- one-time or sporadically occasional volunteers, such as entertainers
- participants in the NYS Long Term Care Ombudsman Program
- visiting school groups (although covered facilities should carefully consider the prudence of allowing groups of children to visit areas where patients or residents might be present when influenza is prevalent).

*** *New 9/24/2013* ***

45. Q: Are accrediting organization personnel covered personnel?

A: The terms of the regulation do not apply to accrediting organization personnel. However, the Department is reaching out to the accrediting organizations to urge them to adopt similar policies for their personnel who visit health care facilities

**** New 9/24/2013 ****

46. Q: Are DOH employees covered personnel?

A: The terms of the regulation do not apply to DOH employees. However, the Department has applied the same requirements on DOH employees when they enter regulated health care facilities through personnel policies.

**** New 9/24/2013 ****

47. Q: Are registration, reception, and front desk staff covered personnel?

A: Yes. Registration, reception, and front desk staff who interact with persons presenting for registration/admission are considered covered personnel because persons presenting for registration or admission will become patients, residents, or clients at some point during the process.

County Health Departments

48. Q: Are county health departments covered by the regulation?

A: 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.

**** Updated answer ****

49. Q: Which staff in county health departments are covered by the regulation?

A: Staff in county health departments who carry out Article 28, 36 or 40 program functions or who encounter patients seeking those program services are covered when they are in areas where patients are typically present.