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Frequently Asked Questions (FAQs) Regarding the Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation

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

A: 10 NYCRR Section 2.61 was effective on August 26, 2021, when it was filed with the Department of State. The amendment adding the booster requirement and any subsequent vaccinations as recommended by the Centers for Disease Control and Prevention (CDC) was effective on January 21, 2022, when it was filed with the Department of State. Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, and to have received any booster or supplemental dose as recommended by the CDC, absent receipt of a medical exemption.

2. Q: Does this emergency regulation supersede the Section 16 Commissioner's Order that was issued on August 18, 2021?

A: Yes. This regulation supersedes the Section 16 Order dated August 18, 2021. The Section 16 Order was vacated, and general hospitals and nursing homes that were subject to that Section 16 Order must now comply with this emergency regulation.

COVERED ENTITIES

3. Q: What are the “covered entities” that must comply with this regulation?

A: The regulation applies to any healthcare facility licensed under Article 28 of the Public Health Law (including general hospitals, nursing homes, diagnostic and treatment centers, and adult day healthcare programs); agencies and programs licensed under Article 36 of the Public Health Law (including certified home health agencies, licensed home care services agencies, long term home health care programs, AIDS Home Care Programs, and limited licensed home care services agencies); any hospice licensed under Article 40 of the Public Health Law; and any assisted living or adult care facility regulated by the Department under the Social Services Law (including adult homes, assisted living programs, enriched housing programs, and residences for adults).

Every covered entity regulated under the regulation has an operating certificate that states the locations and activities for which the facility, agency, or program is licensed. For example, Programs of All-Inclusive Care for the Elderly (PACE) personnel are covered by this regulation because care is delivered under Article 28 and Article 36 operating certificates. Likewise, a facility or shelter within the oversight of the Office for People with Developmental Disabilities (OPWDD), Office of Mental Health (OMH), Office of Addiction Services and Supports (OASAS), Office of Children and Family Services (OCFS), Department of Corrections and Community Supervision (DOCCS), or Office for the Prevention of Domestic Violence (OPDV) is covered by this regulation only if the facility or shelter holds an operating certificate as a covered entity under the regulation.

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

- Private medical and therapist practices
- Entities certified under Article 44 of the Public Health Law, such as Managed Long Term Care plans; however, the regulation does apply to covered entities (e.g., certified home health agencies or licensed home care services agencies) that are owned or operated by or in conjunction with an Article 44 entity.
- Mental/behavioral health facilities regulated by Article 31 of the Mental Hygiene Law; however, the regulation does apply to mental/behavioral health units of healthcare facilities that are also regulated under Article 28
- Fiscal Intermediaries and Personal Assistants under the Consumer Directed Personal Assistant Program (CDPAP).

4. Q: Is a private practice a “covered entity”?

A: No. There are limited exceptions to the Education Law §6532 prohibition on the regulation of the private practice of medicine, including the exception in PHL §230-a (Infection control standards). Notwithstanding Education Law §6532, PHL §230-a gives the Department of Health the authority to establish regulations describing scientifically accepted barrier precautions and infection control practices as standards of professional medical conduct for private physician practices. Failure to use scientifically accepted barrier precautions and infection control practices as established by the Department is professional misconduct under Education Law §6530(47). The Department’s infection control requirements for private practices are in 10 NYCRR Part 92.

5. Q: Is a University Faculty Practice a “covered entity”?

A: One type of private practice is a university faculty practice corporation under Not-for-Profit Corporation law §1412. Such practices may be affiliated with a medical school or affiliated with a teaching hospital. Private practices are not “covered entities” under the regulation.

COVERED PERSONNEL

6. Q: What personnel are covered?

A: Covered entities that are subject to the [Prevention of influenza transmission by healthcare and residential facility and agency personnel](#) regulation (“flu mask reg”) should begin by identifying the personnel covered by the flu mask reg, because such personnel are personnel under the Prevention of COVID-19 Transmission by Covered Entities regulation as well.

10 NYCRR Section 2.61(a)(2) defines “personnel.” Personnel includes employees and non-employee members of the medical and nursing staff, contract staff, students, and volunteers “who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.”

7. Q: What personnel “could potentially expose other covered personnel”?

A: This regulation is intended to reduce exposure by personnel who are not vaccinated against COVID-19 and do not have a medical exemption, to other covered personnel, in

addition to reducing exposure to patients and residents of facilities, agencies, and programs. Personnel may include members of the workforce who have no direct patient or resident contact if the personnel engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel. Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of Section 2.61.

8. 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, agency, or program; or (2) are under the covered entity's direct control. This includes, but is not limited to, nurses and other healthcare professionals contracted to provide care to patients or residents. 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
- 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 entity, but who do not meet the definition of functioning as employees or staff of the facility, agency, or program, or being under the entity's direct control
- Laboratory and radiology technicians who provide services to a covered entity by contract (e.g., enter a nursing home intermittently to draw blood or perform medical imaging procedures), but who do not function as employees or staff of the covered entity and are not under the covered entity's direct control, are not personnel of the contracting covered entity.
- Law enforcement officers entering the facility in their official capacity.

9. Q: Which volunteers are covered personnel?

A: Volunteers who have a formal relationship with the covered entity and who provide regularly scheduled volunteer services must comply with the regulation. Examples of individuals who are NOT subject to this regulation include:

- One-time or sporadically visiting volunteers
- Participants in the NYS Long Term Care Ombudsman Program

10. Q: Are private companies and private duty healthcare providers covered by the regulation while working in a covered entity?

A: If a person is providing private duty healthcare services, and those services are being provided in a covered entity, the Department expects the private duty provider to coordinate those services with, and receive approval from, such covered entity. Such approval constitutes an affiliation with the covered entity. Therefore, private duty healthcare providers must comply with the regulation. Private companions who do not provide healthcare services (i.e., hired by the patient/resident or family member to provide companionship only) are not considered to be affiliated with the covered entity and therefore are not required to comply with regulation. However, they are encouraged to do so in the interest of protecting the patients or residents of the covered entity.

11. Q: Are covered entities responsible for vaccination of government employees or contractors engaged in health care oversight or similar assessment activities?

A: No, they are not.

COMPLIANCE DATES

12. Q: What are the dates for initial compliance?

A: Covered facilities must document compliance with the emergency regulation regarding booster vaccinations that was filed and effective on January 21, 2022, by February 21, 2022. As indicated in FAQ #1, facilities have been required to ensure that personnel receive the primary series of a COVID-19 vaccine since August 26, 2021.

13. Q: After the initial dates for compliance, how long do covered facilities have to document COVID-19 vaccination or a valid medical exemption for new hires?

A: Documentation must occur continuously, as needed, following the dates for initial compliance, including documentation of any reasonable accommodation therefor.

14. Q: Do Nursing Homes and Adult Care Facilities need to comply with 10 NYCRR Subpart 66-4 in addition to 10 NYCRR Section 2.61?

A: Yes.

EXEMPTIONS

15. Q: Does the regulation include a medical exemption?

A: Yes, there is a medical exemption.

Personnel shall be medically exempt from the COVID-19 vaccination requirements as follows. A licensed physician or certified nurse practitioner must certify that immunization with COVID-19 vaccine is detrimental to the health of a personnel member, based upon a pre-existing health condition. The requirements of Section 2.61 relating to COVID-19 immunization shall be inapplicable only until such immunization is found no longer to be detrimental to such personnel member's health. The nature and duration of the medical exemption must be stated in the personnel employment medical record, or other appropriate record, and must be in accordance with generally accepted medical standards. The Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services (ACIP) publishes generally accepted medical standards for COVID-19 vaccination medical exemptions. Reasonable accommodations may be granted and must be documented.

16. Q: What are the applicable ACIP COVID-19 vaccination contraindications and precautions at the time of the publication of this guidance?

A: Current COVID-19 vaccine contraindications and precautions are posted on the CDC's website at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications>.

At the time of publication of this guidance, the CDC considers the following to be contraindications to vaccination with COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate (within 4 hours) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the COVID-19 vaccine

The CDC defines an immediate allergic reaction to a vaccine or medication as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory

distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

A list of ingredients in COVID-19 vaccines is available at
<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html/#Appendix-C>

In addition, the CDC recognizes the following conditions as precautions to COVID-19 vaccines:

- Current moderate to severe acute illness
 - This is a temporary precaution, until the individual has recovered
- History of an immediate allergic reaction to any other (not COVID-19) vaccine or injectable therapy (excluding allergy shots)
- History of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine
- A contraindication to one type of COVID-19 vaccine (e.g., mRNA COVID-19 vaccines) have precautions to another type of COVID-19 vaccine (e.g., Janssen/Johnson & Johnson vaccine).

The following are generally not considered contraindications to the COVID-19 vaccination:

- A localized reaction at the site of the injection occurring > 4 hrs to days after a COVID-19 vaccination
- Common side effects from a prior dose of COVID-19 vaccination, such as fever, chills, headache, fatigue, cough, vomiting diarrhea
- A vasovagal reaction after a dose of COVID-19 vaccination
- Allergic reactions to such things as medications, pets, food, venoms or other products that are not contained in the COVID-19 vaccines.
- Having a prior autoimmune condition/reaction to a prior vaccine like Guillain-Barre Syndrome
- Living with or having a regular household contact who is immunocompromised
- Being immunocompromised, either because of a health condition or by use of a medication for another condition but that can lead to immunosuppression (ie, daily steroids or chemotherapy).

17. Q: May personnel with medical exemptions continue normal job responsibilities?

A: Yes, provided that they comply with all applicable requirements for personal protective equipment, including masking.

18. Q: Do personnel with medical exemptions need to undergo COVID-19 testing?

A: This regulation does not require personnel with medical exemptions to undergo COVID-19 testing; however, COVID-19 testing may nevertheless be required under existing regulations and guidance, including [NH 21-17 Revised Nursing Home COVID-19 Testing Requirements](#).

19. Q: Do medical exemptions last forever?

A: No. The nature and expected duration of the medical exemption must be stated in the personnel employment medical record, or other appropriate record. The medical exemption is applicable only until COVID-19 immunization is found no longer to be detrimental to the personnel member's health.

20. Q: Does this regulation include a religious exemption?

A: No, there are no religious exemptions provided for through the regulation. However, covered entities should follow federal, state and local laws and guidance to determine, on a case by case basis, whether and in what circumstances it may be appropriate to provide reasonable accommodations for personnel, who, because of sincerely held religious beliefs, do not get vaccinated against COVID-19. While this regulation does not preclude such reasonable accommodation requests and considerations, covered entities cannot permit unvaccinated individuals to continue in “personnel” positions such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients, or residents to the disease. (10 NYCRR Section 2.61(a)(2) defines “personnel” covered by this regulation). Covered entities could consider other reasonable accommodations to eliminate the risk of such exposure.

DOCUMENTATION

21. Q: Are there any specific vaccines that are excluded when determining whether personnel are “fully vaccinated”?

A: According to the CDC, only people who have completed a primary series of a COVID-19 vaccine that is either approved or authorized for emergency use by the U.S. Food and Drug Administration (FDA) or the World Health Organization (WHO) are “fully vaccinated.” People who received a COVID-19 vaccine that has neither been authorized by the FDA or the WHO are not fully vaccinated. Current lists of vaccine authorized by the FDA and WHO are available at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines> and <https://covid19.trackvaccines.org/agency/who/>. Complete guidance on what constitutes “fully vaccinated” can be found in the [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#).

22. Q: How can a covered entity determine whether a record from a foreign nation is an “official record”?

A: Covered entities must develop and implement a policy and procedure to ensure compliance with the provisions of the regulation. Such policies and procedures should prevent fraudulent documentation to the extent reasonably practicable.

23. Q: Is documentation that personnel has already had COVID-19 acceptable in lieu of vaccination?

A: No. The COVID-19 vaccination requirement is still applicable to personnel who have already had COVID-19.

24. Q: Is there a standard medical exemption form that covered entities can use?

A: The standard medical exemptions forms used by schools to document medical exemptions for students can be found [here \(State DOH form\)](#) and [here \(NYC Dept of Education form\)](#). These forms can be adapted for use by covered entities.

BOOSTERS

- 25. Q: If CDC Recommends a booster 5 months after the primary series, and 5 months after the primary series is April 1, 2022, what is the date by which personnel must get the booster?**

A: Personnel have 30 days from the day they become eligible, so personnel in this example must get the booster by May 1, 2022. But see FAQ #26 below.

- 26. Q: Are there personnel who are not eligible for a booster or supplemental dose exactly 5 months after the primary series?**

A: Yes, facilities may have to determine on a case by case basis when personnel should have received a booster or supplemental dose as recommended by the CDC. For example, certain personnel may need a temporary medical exemption from receiving a booster in connection with having tested positive for or having been treated for COVID-19. In such cases or other cases that require interpretation of CDC recommendations, personnel may not be eligible for the booster 5 months after the primary series. Facilities may have to exercise operational discretion to determine when personnel are eligible for a booster, provided that they do require and communicate to their personnel that effective immediately, personnel have to have received any booster or supplemental dose as recommended by the CDC, absent receipt of a medical exemption, and they have a reasonable system for documenting compliance with this requirement.