

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, as well as Social Services Law Sections 461 and 461-e, 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 2.61, as follows:

2.61. Prevention of COVID-19 transmission by covered entities.

(a) Definitions.

- (1) “Covered entities” 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;
 - (iii) hospices as defined in section 4002 of the Public Health Law; and
 - (iv) adult care facility under the Department’s regulatory authority, as set forth in Article 7 of the Social Services Law.

(2) “Personnel,” for the purposes of this section, shall mean all persons employed or affiliated with a covered entity, 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 COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.

(3) “Fully vaccinated,” for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations. Unless otherwise specified by the Department, documentation of vaccination must include the manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site, in one of the following formats:

(i) record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner’s signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system; or

(iii) any other documentation determined acceptable by the Department.

(c) Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, absent receipt of an exemption as allowed below. Covered entities shall require all personnel to receive at least their first dose before engaging in activities covered under paragraph (2) of subdivision (a) of this section. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in subdivision (d) of this section.

(d) Exemptions. Personnel shall be exempt from the COVID-19 vaccination requirements set forth in subdivision (c) of this section as follows:

(1) Medical exemption. If any licensed physician, physician assistant, or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of member of a covered entity's personnel, based upon a pre-existing health condition, the requirements of this section 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, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services), and any reasonable accommodation may be granted and must likewise be documented in such record. Covered entities shall document medical exemptions in personnel records or other appropriate records in accordance with applicable privacy laws by: (i) September 27, 2021 for general hospitals and nursing homes; and (ii) October 7, 2021 for all other covered entities. For all covered

entities, documentation must occur continuously, as needed, following the initial dates for compliance specified herein, including documentation of any reasonable accommodation therefor.

(e) Upon the request of the Department, covered entities must report and submit documentation, in a manner and format determined by the Department, for the following:

- (1) the number and percentage of personnel that have been vaccinated against COVID-19;
- (2) the number and percentage of personnel for which medical exemptions have been granted;
- (3) the total number of covered personnel.

(f) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of this section and submit such documents to the Department upon request.

(g) The Department may require all personnel, whether vaccinated or unvaccinated, to wear an appropriate face covering for the setting in which such personnel are working in a covered entity. Covered entities shall supply face coverings required by this section at no cost to personnel.

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

(vi) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 is added to read as follows:

(5) collects documentation of COVID-19 or documentation of a valid medical exemption to such vaccination, for all personnel pursuant to section 2.61 of this title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 751.6 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (6) of subdivision (c) of Section 763.13 is added to read as follows:

(6) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making

such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 766.11 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (8) of subdivision (d) of Section 794.3 is added to read as follows:

(8) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (q) of Section 1001.11 is added to read as follows:

(5) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is added to read as follows:

(18) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is added to read as follows:

(14) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is added to read as follows:

(15) Operator shall collect documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

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, 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. 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.

Social Service Law (SSL) Section 461 requires the Department to promulgate regulations establishing general standards applicable to Adult Care Facilities (ACF). SSL Section 461-e authorizes the Department to promulgate regulations to require adult care facilities to maintain certain records with respect to the facilities residents and the operation of the facility.

Legislative Objectives:

The legislative objective of PHL Section 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, 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. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional

curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

The vaccine mandate for health care workers, which required general hospital and nursing home personnel to receive their first dose of COVID-19 vaccine by September 27, 2021, and required all other covered entities to receive their first dose of COVID-19 vaccine by October 7, 2021, has greatly increased the percentage of health care workers who are vaccinated against COVID-19. COVID cases, hospitalizations, and deaths are decreasing in New York State, and the continuation of these regulations will help ensure that the epidemiology curve continues downward in furtherance of the New York State Department of Health’s mission to reduce morbidity and mortality. These regulations are helping New York State reduce sickness and death from COVID-19.

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen more than 10-fold, and over 99 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 10 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and

congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

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

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, as well as any reasonable accommodations. 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.

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 PHL 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 ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. They must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations.

Although the costs to the State or local governments cannot be determined with precision, the Department does not expect these costs to be significant. State facilities should already be ensuring COVID-19 vaccination among their personnel, subject to State directives. Further, these entities are expected to realize savings as a result of the reduction in COVID-19 in personnel and the attendant loss of productivity and available staff.

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:

Covered entities operated by local governments will be subject to the same requirements as any other covered entity subject to this regulation.

Paperwork:

This measure will require covered entities to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Duplication:

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

Alternative Approaches:

One alternative would be to require covered entities to test all personnel in their facility before each shift worked. This approach is limited in its effect because testing only provides a person's status at the time of the test and testing every person in a healthcare facility every day is impractical and would place an unreasonable resource and financial burden on covered entities if PCR tests couldn't be rapidly turned around before the commencement of the shift. Antigen tests have not proven as reliable for asymptomatic diagnosis to date.

Another alternative to requiring covered entities to mandate vaccination would be to require covered entities to mandate all personnel to wear a fit-tested N95 face covering at all times when in the facility, in order to prevent transmission of the virus. However, acceptable face coverings, which are not fit-tested N95 face coverings have been a long-standing requirement in these covered entities, and, while helpful to reduce transmission it does not prevent transmission and; therefore, masking in addition to vaccination will help reduce the numbers of infections in these settings even further.

Federal Requirements:

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

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

Contact Person:

Ms. Katherine E. Ceroalo
NYS Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 –FAX
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a covered entity as defined in the emergency regulation. Currently, 5 general hospitals, 79 nursing homes, 75 certified home health agencies (CHHAs), 20 hospices and 1,055 licensed home care service agencies (LHCSAs), and 483 adult care facilities (ACFs) are small businesses (defined as 100 employees or less), independently owned and operated affected by this rule. Local governments operate 19 hospitals, 137 diagnostic and treatment facilities, 21 nursing homes, 12 CHHAs, at least 48 LHCSAs, 1 hospice, and 2 ACFs.

Compliance Requirements:

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Professional Services:

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

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. 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.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Small Business and Local Government Participation:

Due to the emergent nature of COVID-19, small businesses and local governments were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity to provide comments during the notice and comment period.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

While this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.”

The following 44 counties have an estimated population of less than 200,000 based upon 2020 United States Census data:

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County		

Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon 2019 United States Census population projections:

Albany County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange County	

Reporting, recordkeeping, and other compliance requirements; and professional services:

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy

and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. 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.

Minimizing Adverse Impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department’s understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Rural Area Participation:

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity to provide comments during the notice and comment period.

JOB IMPACT STATEMENT

Nature of Impact:

Covered entities may terminate personnel who are not fully vaccinated and do not have a valid medical exemption and are unable to otherwise ensure individuals are not engaged in patient/resident care or expose other covered personnel.

Categories and numbers affected:

This rule may impact any individual who falls within the definition of “personnel” who is not fully vaccinated against COVID-19 and does not have a valid medical exemption on file with the covered entity for which they work or are affiliated.

Regions of adverse impact:

The rule would apply uniformly throughout the State and the Department does not anticipate that there will be any regions of the state where the rule would have a disproportionate adverse impact on jobs or employment.

Minimizing adverse impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department’s understanding that many facilities across the State

have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.