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 Centers for Disease Control and Prevention (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 at covered entities, 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 personnel 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. The vaccine mandate has decreased and will continue to decrease COVID cases, hospitalizations, and deaths.

The COVID-19 vaccines are safe and effective. Full COVID-19 vaccination offers the benefit of helping to reduce the number of COVID-19 infections, 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 absences.

**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.

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## 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:**

Organizations that include as members health care and residential facilities that are small businesses and local governments were consulted on the proposed regulations. Any member of the public had an opportunity to submit comments during a 60-day public comment period on the Proposed Rule from December 15, 2021 until February 14, 2022. In addition, four separate Emergency Rules required personnel to receive the primary series of the vaccine since August 26, 2021. These Emergency Rules were approved by the Public Health and Health Planning Council at public meetings that took place on August 26, 2021, November 18, 2021, January 11, 2022, and March 17, 2022. Members of the public were permitted to speak and did speak at these meetings.

## 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:**

Organizations that include as members health care and residential facilities that are located in rural areas were consulted on the proposed regulations. Any member of the public had an opportunity to submit comments during a 60-day public comment period on the Proposed Rule from December 15, 2021 until February 14, 2022. In addition, four separate Emergency Rules required personnel to receive the primary series of the vaccine since August 26, 2021. These Emergency Rules were approved by the Public Health and Health Planning Council at public meetings that took place on August 26, 2021, November 18, 2021, January 11, 2022, and March 17, 2022. Members of the public were permitted to speak and did speak at these meetings.

## 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.

## SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (NYSDOH) received thousands of comments from members of the public. A summary of the comments received on the Proposed Rule and the Department's responses are below. Based on the comments received, no changes were necessary to the Proposed Rule.

**Comment:** The majority of comments received stated that the proposed regulation caused a violation of rights or violated State or federal law.

**Response:** Federal and State courts have already decided and determined that vaccine mandates, including this one in particular, are constitutional and legal. See *We the Patriots USA, Inc. v. Hochul*, 2021 U.S. App. LEXIS 33691, 2d Cir., Nov. 12, 2021, injunction *denied* by 142 S. Ct. 552 (Supreme Court of the United States, December 13, 2021, upholding the constitutionality of this regulation).

**Comment:** Many commenters expressed concern that NYSDOH lacked legal authority to establish these regulations.

**Response:** Rule making by executive agencies such as NYSDOH, including this regulation, is well established and set forth in Article 2 of the State Administrative Procedure Act. The specific statutory authority for this regulation is set out in the Regulatory Impact Statement. NYSDOH routinely establishes requirements for personnel who work in health care and residential facilities regulated by NYSDOH.

**Comment:** A number of comments were received concerning medical exceptions not being accepted.

**Response:** Under this regulation, regulated facilities are permitted to grant covered personnel a medical exemption after a licensed physician, physician assistant, or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of a personnel member, based upon a pre-existing health condition. 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.

**Comment:** Many commenters expressed concern about the effectiveness of the COVID-19 vaccination.

**Response:** To date we know that fully vaccinated people with an infection ("breakthrough infection") are less likely to develop serious illness, be hospitalized or die than those who are unvaccinated and get COVID-19. Breakthrough infections occur and are more likely with more recent variants of SARS-CoV-2; however, with vaccine, there is less morbidity and mortality.

**Comment:** Comments were received questioning what constitutes a covered entity for purposes of the regulation.

**Response:** This regulation is applicable to personnel of General Hospitals, Nursing Homes, Diagnostic and Treatment Centers, Hospices, Home Care Services Agencies, and Adult Care Facilities. The rule is applicable to personnel in these facilities who could potentially expose patients, residents, or other personnel to COVID-19.

**Comment:** Commenters expressed concern about the safety of the COVID-19 vaccine

**Response:** COVID-19 vaccines are safe and effective. More than 584 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020, through May 23, 2022. COVID-19 vaccines were evaluated in tens of thousands of participants in clinical trials. The vaccines met the Food and Drug Administration's (FDA's) rigorous scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization (EUA).

**Comment:** Comments were received concerning the shortage of health care workers and the impact these regulations have on the shortage of workers. Commenters also noted the impact the proposed regulation could have on patient care, to the extent workers leave the health care field because of the requirement to be vaccinated against COVID-19.

**Response:** NYSDOH has decided as a matter of policy that personnel of health care and residential facilities who could potentially expose patients, residents, or other personnel to COVID-19 should be vaccinated to prevent patients, residents, or other personnel from getting COVID-19, a disease that has killed over one million people in the United States to date. NYSDOH does not believe this regulation will affect labor force participation in the long run any more than the current requirements for personnel for rubella, measles, tuberculosis, and influenza. Healthcare-acquired infection is a significant cause of morbidity and mortality, and the Department prioritizes the prevention of infections that patients and residents can get as a result of receiving care and treatment in NYSDOH-regulated health care and residential facilities.

**Comment**: Commenters expressed confusion and concern about how the term "fully vaccinated" was defined.

**Response:** As stated in NYSDOH guidance, complete guidance regarding vaccination can be found in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. At this time, "fully vaccinated" means that personnel have received the "primary series" of the vaccine.

**Comment:** Many commenters expressed concern that the vaccine mandate is "coercion" in violation of 21 CFR, Subchapter A, Part 50, Subpart B (informed consent of human subjects who participate in research involving human subjects).

**Response:** Health care providers and residential facilities that participate in the Medicare and Medicaid programs must follow federal conditions of participation. Under those conditions of participation, the federal government also requires personnel who work for such Medicare and Medicaid providers to be vaccinated against COVID-19 (*see* https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/guidance-interim-final-rule-medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-0). This regulation applies to personnel who work at health care and residential facilities regulated by NYSDOH, not to human subjects who participate in research involving human subjects.

## ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (NYSDOH) received thousands of comments from members of the public. A summary of the comments received on the Proposed Rule and the Department's responses are below. Based on the comments received, no changes were necessary to the proposed rulemaking.

**Comment:** The majority of comments received stated that the proposed regulation caused discrimination, invasion of privacy, and a violation of Constitutional rights, the New York State Human Rights Act, Title VII of the Civil Rights Act of 1964 and HIPAA. Commenters also felt that the proposed regulation violated their right to religious freedom. In addition, commenters also stated that the regulation violates their bodily autonomy.

**Response:** This regulation reduces morbidity and mortality by reducing the incidence of COVID-19. The United States Supreme Court held long ago that a State's inherent police power encompasses laws and regulations to protect public health and safety, including measures such as mandatory vaccination. See *Jacobson v. Massachusetts*, 197 U.S. 11 (Supreme Court of the United States, February 20, 1905, upholding a city regulation, promulgated in the midst of an epidemic pursuant to a state statute, mandating that all inhabitants of a city be vaccinated against smallpox or face a criminal penalty in the form of a fine). In addition, the federal and State courts have already decided and determined that compulsory vaccination laws without a religious exemption are constitutional. See *F.F. v. N.Y.*, 194 AD3d 80, cert. *denied* by 2022 U.S. LEXIS 2545 (Supreme Court of the United States, May 23, 2022, upholding New York State Laws of 2019, Chapter 35's repeal of the religious exemption to the requirement that children must be vaccinated to attend school); *We the Patriots USA, Inc. v. Hochul*, 2021 U.S. App. LEXIS

33691, 2d Cir., Nov. 12, 2021, injunction *denied* by 142 S. Ct. 552 (Supreme Court of the United States, December 13, 2021, upholding the constitutionality of this regulation).

While there is no express religious exemption in the regulation, covered entities must 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. Although the 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.

The federal privacy regulation known as "HIPAA" (45 CFR Parts 160 and 164) does not limit the power of State public health authorities to conduct public health activities, and HIPAA permits covered entities to disclose health information to public health authorities as required or authorized by State law. See 42 USC 1320d-7(b); 45 CFR §§160.203(c); 164.512(a), (b), and (d).

Finally, this regulation only applies to personnel who choose to work for health care and residential facilities regulated by NYSDOH and does not take away any individuals right to bodily autonomy.

No changes to the regulation are necessary as a result of these comments.

**Comment:** Many commenters expressed concern that the regulation appears to confer new powers to NYSDOH and that such powers can only come from legislative action. These

commenters also expressed that the Commissioner of Health should not be allowed to implement regulations for New York State, because they are not an elected official.

**Response:** Rule making by executive agencies such as NYSDOH, including this regulation, is well established and set forth in Article 2 of the State Administrative Procedure Act.

The New York State Legislature has given NYSDOH and the Public Health and Health Planning Council the power to establish regulations for health care and residential facilities. Public Health Law (PHL) § 225 gives the Public Health and Health Planning Council the power and duty to approve and amend the State Sanitary Code to prevent the spread of communicable diseases, as well as regulations that set out the operational standards for health care facilities, and provides the legal authority for the establishment of 10 NYCRR § 2.61. PHL § 2803 provides authority for 10 NYCRR § 405.3(b)(10)(vi), the requirement for General Hospital personnel, 10 NYCRR § 415.19(a)(5), the requirement for Nursing Home personnel, and 10 NYCRR § 751.6(d)(7), the requirement for Diagnostic and Treatment Center personnel. PHL § 3612 provides authority for 10 NYCRR § 763.13(c)(6), the requirement for Certified Home Health Agency, Long Term Home Health Care Program and AIDS Home Care Program personnel, and 10 NYCRR § 766.11(d)(7), the requirement for Licensed Home Care Services Agency personnel. PHL § 4010 provides authority for 10 NYCRR § 794.3(d)(8), the requirement for Hospice personnel. Social Services Law (SSL) § 461-l provides authority for 10 NYCRR § 1001.11(q)(5), the requirement for Assisted Living Program personnel. SSL § 461 provides authority for 18 NYCRR § 487.9(a)(18), the requirement for Adult Home personnel, 18 NYCRR § 488.9(a)(14), the requirement for Enriched Housing Program personnel, and 18 NYCRR § 490.9(a)(15), the requirement for Residence for Adults personnel.

In addition, the same authority has been used to require all persons who work at hospitals, nursing homes, diagnostic and treatment centers, hospices, and home care services agencies to demonstrate immunity to measles and rubella. Thus, NYSDOH routinely establishes requirements for personnel who work in health care and residential facilities regulated by NYSDOH.

No changes to the regulation are necessary as a result of these comments.

**Comment:** A number of comments were received concerning medical exceptions not being accepted. Commenters expressed concern about medical exceptions not being accepted due to their providers fearing the loss of their license and noted that the current medical exemptions do not recognize anything beyond severe asphyxiation reactions to the vaccine.

**Response:** Under this regulation, regulated facilities are permitted to grant covered personnel a medical exemption after a licensed physician, physician assistant, or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of a personnel member, based upon a pre-existing health condition. When personnel have a medical exemption, the COVID-19 immunization requirement is inapplicable only until such immunization is found no longer to be detrimental to such person'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. No changes to the regulation are necessary as a result of these comments.

**Comment:** Many commenters expressed concern about the effectiveness of the COVID-19 vaccination. These commenters claimed that the vaccine does not prevent transmission or spread of COVID-19 and that even vaccinated people may spread the disease. Commenters also raised concerns that repeated vaccinations could reduce the human body's ability to mount an effective immune response to newly occurring variants of the virus. Commenters also suggested that natural immunity is more effective than the COVID-19 vaccination or that effective treatments such as ivermectin are available, so vaccinations should not be required.

**Response:** Vaccine effectiveness is a measure of how well vaccination protects people against outcomes such as infection, symptomatic illness, hospitalization, and death. Vaccine effectiveness is typically measured through observational studies specifically designed to estimate individual protection from vaccination under "real-world" conditions. To date we know that fully vaccinated people with an infection ("breakthrough infection") are less likely to develop serious illness, be hospitalized or die than those who are unvaccinated and get COVID-19. Breakthrough infections occur and are more likely with more recent variants of SARS-CoV-2; however, with vaccine, there is less morbidity and mortality. People who get vaccine breakthrough infections after being fully vaccinated can still be contagious and should practice other mitigation measures to protect their community (e.g., masking, social distancing). No vaccine is 100% effective against infection. Getting a vaccine, especially after infection, can strengthen individual immunity and decrease transmission and severe complications from COVID-19 infections.

Regarding comments pertaining to natural immunity, recovery from many viral infectious diseases is followed by a period of infection-induced immunologic protection against reinfection. This phenomenon is widely observed with many respiratory viral infections, including both

influenza and the endemic coronaviruses, for which acquired immunity also wanes over time making individuals susceptible to reinfection. Vaccinations, not only to COVID-19, produce a predictable immune response offering protection to both the infected and uninfected. One study, available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm?s_cid=mm7032e1_w, showed that, for people who already had COVID-19, those who do not get vaccinated after their recovery are more than twice as likely to get COVID-19 again than those who get fully vaccinated after their recovery. Studies (*see* https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html), including one conducted by NYSDOH, have shown that infection with variants prior to the Delta variant offer substantial protection against infection with the Delta variant, on par with completion of a primary vaccine series. However, because becoming infected with SARS-CoV-2 carries significant risks, being up to date on vaccines (with booster doses, as eligible) is the only safe choice. More recent studies of the current Omicron variant have shown that the protection afforded by prior infection is substantially weaker, once again pointing to vaccination as the superior strategy. Further, substantial immunologic evidence and a growing body of epidemiologic evidence indicate that vaccination after infection significantly enhances protection and further reduces risk of reinfection. The CDC has even altered their interval guidance to incorporate immunity from infection into the timing of the vaccine. All COVID-19 vaccines currently available in the United States are effective at preventing COVID-19. Getting sick with COVID-19 can offer some protection from future illness, sometimes called "natural immunity," but the level of protection people get from having COVID-19 may vary depending on how mild or severe their illness was, the time since their infection, and their age. Getting a COVID-19 vaccination is also a safer way to build protection than getting sick with COVID-19. COVID-19 vaccination

helps protect individuals by creating an antibody response without having to experience sickness, increased risk for severe illness from COVID-19 including long-term health issues, or spreading COVID-19 to others.

Based on the totality of medical and public health evidence regarding both safety and effectiveness, the NYSDOH as well as the CDC continue to recommend COVID-19 vaccination for all eligible persons, including those who have been previously infected with SARS-CoV-2. No changes to the regulation are necessary as a result of these comments.

**Comment:** Comments were received questioning what constitutes a covered entity for purposes of the regulation. Commenters were concerned that NYSDOH could add or take away from that list at its discretion.

**Response:** This regulation is applicable to personnel of General Hospitals, Nursing Homes, Diagnostic and Treatment Centers, Hospices, Home Care Services Agencies, and Adult Care Facilities. The rule is applicable to personnel in these facilities who could potentially expose patients, residents, or other personnel to COVID-19. As explained above, NYSDOH routinely establishes requirements for personnel who work for regulated health care and residential facilities. No changes to the regulation are necessary as a result of these comments.

**Comment:** Commenters expressed concern about the safety of the COVID-19 vaccine and mentioned people having adverse reactions to the COVID-19 vaccine and vaccines in general. These commenters were also concerned about the CDC's Vaccine Adverse Event Reporting System and the COVID-19 vaccines not being fully FDA approved. Commenters also stated that pharmaceutical companies do not have any legal liability if their vaccines cause harm, injury, or

death, so there is no accountability or incentive to improve their product to make it safe and effective.

**Response:** COVID-19 vaccines are safe and effective. More than 584 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020, through May 23, 2022. COVID-19 vaccines were evaluated in tens of thousands of participants in clinical trials. The vaccines met the Food and Drug Administration's (FDA's) rigorous scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization (EUA). In August 2021, the FDA approved the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years and older. In January 2022, the FDA approved the Moderna vaccine for individuals 18 years and older. FDA-approved vaccines undergo the agency's standard process for reviewing the quality, safety, and effectiveness of medical products.

In rare cases, people have experienced serious health events after COVID-19 vaccination. Any health problem that happens after vaccination is considered an adverse event. An adverse event can be caused by the vaccine or can be caused by a coincidental event not related to the vaccine, such as an unrelated fever, that happened following vaccination.

To date, the systems in place to monitor the safety of these vaccines have found four serious types of adverse events following COVID-19 vaccination such as Thrombosis with Thrombocytopenia Syndrome (TTS), myocarditis/pericarditis and reports of death occurring close to vaccination. Reports of adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) following vaccination, including deaths, do not necessarily mean that a vaccine was the ultimate cause of death as opposed to a person having received a vaccine and developing a life-threatening condition. Serious side effects that could cause a long-term health

problem are extremely unusual following any vaccination, including COVID-19 vaccination. The benefits of COVID-19 vaccination outweigh the known and potential risks.

In rare instances of a serious side effect, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a petition for compensation. For a vaccine company to receive all the liability protections offered by the National Childhood Vaccine Injury Act of 1986, as amended, the company must comply in all material respects with all applicable requirements under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (including regulations issued under such provisions).

No changes to the regulation are necessary as a result of these comments.

**Comment:** Comments were received asking about the timing and receipt of a booster dose of the COVID-19 vaccine.

**Response:** The regulation only requires that covered personnel be "fully vaccinated" against COVID-19, not that they receive booster doses in addition to the primary series. No changes to the regulation are necessary as a result of these comments.

**Comment:** Comments were received concerning the shortage of health care workers and the impact these regulations have on the shortage of workers. Commenters also noted the impact the proposed regulation could have on patient care, to the extent workers leave the health care field because of the requirement to be vaccinated against COVID-19.

**Response:** NYSDOH has decided as a matter of policy that personnel of health care and residential facilities who could potentially expose patients, residents, or other personnel to

COVID-19 should be vaccinated to prevent patients, residents, or other personnel from getting COVID-19, a disease that has killed over one million people in the United States to date. NYSDOH does not believe this regulation will affect labor force participation in the long run any more than the current requirements for personnel for rubella, measles, tuberculosis, and influenza. Healthcare-acquired infection is a significant cause of morbidity and mortality, and the Department prioritizes the prevention of infections that patients and residents can get as a result of receiving care and treatment in NYSDOH-regulated health care and residential facilities. No changes to the regulation are necessary as a result of these comments.

**Comment**: Commenters expressed confusion and concern about how the term "fully vaccinated" was defined. Commenters noted that the terms seemed somewhat vague and that it was not clear how many vaccination doses were required. Some commenters recommended use of the term "up to date" or some other language that more clearly specifies which vaccines are required.

**Response:** As stated in NYSDOH guidance (available at: https://coronavirus.health.ny.gov/system/files/documents/2022/01/healthcare-worker-booster-requirement-faqs_0.pdf, FAQ 21), complete guidance regarding vaccination can be found in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, available here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html. At this time, "fully vaccinated" means that personnel have received the "primary series" of the vaccine. This regulation or NYSDOH

guidance may be updated or amended in the future as recommendations regarding vaccination from the CDC change. No changes to the regulation are necessary as a result of these comments.

**Comment:** Comments were received about a lack of public outreach and awareness of the requirement for covered entities to ensure covered personnel are fully vaccinated against COVID-19. In addition, commenters claimed that NYSDOH did not consult with rural areas, local governments, or small businesses.

**Response:** Four separate Emergency Rules have required personnel to receive the primary series of the vaccine since August 26, 2021. These Emergency Rules were approved by the Public Health and Health Planning Council at public meetings that took place on August 26, 2021, November 18, 2021, January 11, 2022, and March 17, 2022. The Proposed Rule was presented for information to the Public Health and Health Planning Council on November 18, 2021. The Final Rule was approved by the Public Health and Health Planning Council at a public meeting that took place on June 2, 2022. Members of the public were permitted to speak and did speak at these meetings. The meeting materials and recorded webcasts of the meetings are all available on the Department's website at: https://www.health.ny.gov/facilities/public_health_and_health_planning_council/. In addition, members of the public had an opportunity to submit comments during a 60-day public comment period on the Proposed Rule from December 15, 2021, until February 14, 2022. Organizations that include as members health care and residential facilities that are small businesses, local governments, and facilities in rural areas were consulted on the proposed regulations. No changes to the regulation are necessary as a result of these comments.

**Comment:** Many commenters expressed concern about their distrust in the government. Commenters alleged that the regulation was a form of slavery and control and that they wanted to leave New York State because of regulations such as this.

**Response:** These comments are outside the scope of the proposed regulation. No amendments were made as a result of these comments.

**Comment:** Many comments were made about COVID-19 not being considered a state of emergency due to the virus having a high survival rate. Some commentators mentioned that COVID-19 is now a seasonal virus like the flu. A few commenters also alleged that there has been no physical and/or tangible evidence that COVID-19 has occurred over the past two years.

**Response:** This Final Rule adopts the Proposed Rule that was proposed on December 15, 2021. This is not an Emergency Rule and does not require an emergency justification. No changes to the regulation are necessary as a result of these comments.

**Comment**: A comment was received expressing that taxpayer funded entities may not be allowed the power to require individuals to submit to a medical procedure and/or provide protected private medical information.

**Response:** This regulation applies to personnel who choose to work for health care and residential facilities regulated by NYSDOH. As noted above, it is just like the long-standing requirement that such personnel get measles and rubella vaccine. No changes to the regulation are necessary as a result of these comments.

**Comment:** A few commenters mentioned mental health side effects as a result of COVID-19 and the various mandates and regulations that have been effectuated in response to COVID-19.

**Response:** NYSDOH acknowledges and appreciates the sacrifices that healthcare workers have made during the COVID-19 pandemic. No changes to the regulation are necessary as a result of these comments.

**Comment:** Many commenters expressed concern that the vaccine mandate is "coercion" in violation of 21 CFR, Subchapter A, Part 50, Subpart B (informed consent of human subjects who participate in research involving human subjects).

**Response:** Health care providers and residential facilities that participate in the Medicare and Medicaid programs must follow federal conditions of participation. Under those conditions of participation, the federal government also requires personnel who work for such Medicare and Medicaid providers to be vaccinated against COVID-19 (*see* https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/guidance-interim-final-rule-medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-0). This regulation applies to personnel who work at health care and residential facilities regulated by NYSDOH, not to human subjects who participate in research involving human subjects. No changes to the regulation are necessary as a result of these comments.

**Comment:** A comment was received asking for clarification of the goal for this regulation when we have continued progress in vaccine development. The commenter does not understand why permanent adoption, as opposed to emergency regulation, is appropriate.

**Response:** Pursuant to Section 202(6) of the State Administrative Procedure Act (SAPA), an agency may adopt a regulation on an emergency basis when immediate adoption of a rule is necessary for the preservation of the public health, safety or general welfare and compliance with the normal rulemaking process would be contrary to the public interest. As such, emergency regulations are meant to be temporary in nature. This regulation is now being adopted using the normal, non-emergency, rule-making process pursuant to the SAPA § 202. Although this regulation, in contrast to an emergency regulation, does not have an expiration date, it is not necessarily permanent. It may be amended or repealed in the future if warranted. No changes to the regulation are necessary as a result of these comments.

**Comment:** Comments were received expressing that illegal immigrants and government officials are not mandated to be vaccinated against COVID-19.

**Response:** These comments are outside the scope of the proposed regulation. No amendments were made as a result of these comments.