UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

WE THE PATRIOTS USA, INC.,
DIANE BONO,
MICHELLE MELENDEZ,
MICHELLE SYNAKOWSKI,
Plaintiffs,
v.

KATHLEEN HOCHUL – GOVERNOR OF NEW YORK; HOWARD ZUCKER, M.D, - COMMISSIONER, NEW YORK STATE DEPARTMENT OF HEALTH
Defendants.

No. 1:21-cv-4954 (WFK) (RER)

DECLARATION OF TODD A. SPIEGELMAN

Todd A. Spiegelman, an attorney duly admitted to practice before this Court, declares under penalty of perjury that the following is true and correct:

1. I am an Assistant Attorney General in the Office of Letitia James, Attorney General of the State of New York, attorney for defendants Governor Kathy Hochul and Acting Commissioner of the New York State Department of Health ("DOH") Mary T. Bassett, M.D., M.P.H.,[1] sued in their official capacities (together, "Defendants"). This Declaration is submitted in support of Defendants' motion to dismiss the Complaint.

2. Attached hereto as Exhibit A is a true and correct copy of (i) the cover pages of the New York State Register, dated Mar. 24, 1993; and (ii) the text of a Proposed DOH Regulation entitled "Immunization of Health Care Workers," I.D. No. HLT-12-93-0033, 15 N.Y. Reg. 15, 20, which required certain healthcare workers to show proof of vaccination against measles and rubella as a condition of employment.

1 Dr. Bassett was appointed Acting DOH Commissioner on December 1, 2021 and is automatically substituted as a defendant for former DOH Commissioner Zucker pursuant to Federal Rule of Civil Procedure 25(d).

3. Attached hereto as Exhibit B is a true and correct copy of (i) the cover pages of the New York State Register, dated September 8, 1993; and (ii) the Notice of Adoption of a DOH Regulation entitled "Immunization of Health Care Workers," I.D. No. HLT-12-93-0033, 15 N.Y. Reg. 9, 10.

4. Attached hereto as Exhibit C is former DOH Commissioner Zucker's Order for Summary Action in *In the Matter of Covered Entities in the Prevention and Control of the 2019 Novel Coronavirus*, dated August 18, 2021.

5. Attached hereto as Exhibit D is DOH Emergency Regulation 10 N.Y.C.R.R. § 2.61, Prevention of COVID-19 Transmission by Covered Entities, 43 N.Y. Reg. 6, 6-9 (Sept. 15, 2021).

6. Attached hereto as Exhibit E is DOH's Frequently Asked Questions (FAQs) Regarding the August 26, 2021—Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation.

7. Attached hereto as Exhibit F is DOH Emergency Regulation 10 N.Y.C.R.R. § 2.61, Prevention of COVID-19 Transmission by Covered Entities, 43 N.Y. Reg. 4, 4-8 (Dec. 15, 2021).

8. Attached hereto as Exhibit G is DOH Emergency Regulation 10 N.Y.C.R.R. § 2.61, Prevention of COVID-19 Transmission by Covered Entities (Jan. 21, 2022).

Dated: New York, New York
January 26, 2022

/S/
Todd A. Spiegelman
Assistant Attorney General

March 24, 1993
Vol. XV
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Book 1 of 2

NEW YORK STATE REGISTER

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Office of Public Affairs and
Information Services

NEW YORK STATE
DEPARTMENT OF STATE

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SECRETARY OF STATE

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methodology for residents with neurobehavioral problems residing in discrete units in nursing facilities and there are currently no facilities approved to operate a discrete unit for these residents.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Immunization of Health Care Workers

I.D. No. HLT-12-93-00033-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:
Proposed action: Amendment of section 405.3 of Title 10 NYCRR.
Statutory authority: Public Health Law, section 2803(2)
Subject: Immunization of health care workers.
Purpose: To define a certificate of immunization for rubella and measles and remove the requirement for a serologic screening test for rubella.
Text of proposed rule: Paragraph (10) of Subdivision (b) of Section 405.3 is amended as follows:

(10) the provision for a physical examination and recorded medical history for all personnel including all employees, members of the medical staff, students, and volunteers whose activities are such that a health impairment would pose a potential risk to patients or personnel. The examination shall be of sufficient scope to ensure that no person shall assume his/her duties unless he/she is free from a health impairment which is of potential risk to the patient or which might interfere with the performance of his/her duties, including the habituation or addiction to depressants, stimulants, narcotics, alcohol or other drugs or substances which may alter the individual's behavior. The hospital is required to provide such examination without cost for all employees. The hospital shall require the following of all personnel as a condition of employment or affiliation:

(i) [immunization for rubella, consistent with good medical practice, except that women of child-bearing age shall have a screening test approved by the department, to be followed by immunization as appropriate; and] *a certificate of immunization against rubella which means:*

(a) a document prepared by a physician, physician's assistant, specialist's assistant, nurse practitioner or a laboratory possessing a laboratory permit issued pursuant to Part 58 of this Title, demonstrating serologic evidence of rubella antibodies, or

(b) a document indicating one dose of live virus rubella vaccine was administered on or after the age of twelve months, showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization, or

(c) a copy of a document described in (a) or (b) above which comes from a previous employer or the school which the employee attended as a student; and

(ii) [documentation of immunity to measles for all personnel born on or after January 1, 1957 as described below:

(a) diagnosis by a physician as having had measles disease;

(b) demonstration of serologic evidence of measles antibodies; or

(c) two doses of live virus measles vaccine with the first dose administered on or after the age of 12 months and the second dose administered more than 30 days after the first dose but after 15 months of age;] *a certificate of immunization against measles for all personnel born on or after January 1, 1957, which means:*

(1) a document prepared by a physician, physician's assistant, specialist's assistant, nurse practitioner or a laboratory possessing a laboratory permit issued pursuant to Part 58 of this Title, demonstrating serologic evidence of measles antibodies, or

(2) a document indicating two doses of live virus measles vaccine were administered with the first dose administered on or after the age of 12 months and the second dose administered more than 30 days after the first dose but after 15 months of age showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization, or

(3) a document, indicating a diagnosis of the employee as having had measles disease prepared by the physician, physician's assistant/specialist's assistant or nurse practitioner who diagnosed the employee's measles, or

(4) a copy of a document described in (a), (b) or (c) above which comes from a previous employer or the school which the employee attended as a student;

(iii) if any licensed physician, *physician's assistant, specialist's assistant* or [health care] *nurse* practitioner [practicing under the supervision of a licensed physician] certifies that immunization with measles *and/*or rubella vaccine may be detrimental to the employee's health, the requirements of [this section] *(i) and/or (ii)* above relating to *measles and/or rubella* immunization shall be inapplicable until such immunization is found no longer to be detrimental to such employee's health. The nature and duration of the medical exemption must be stated in the employee's employment medical record *and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the American Academy of Pediatrics and the Immunization Practices Advisory Committee of the U.S. Department of Health and Human Services);* and

(iv) ppd (Mantoux) skin test for tuberculosis prior to employment or affiliation and no less than every two years thereafter for negative findings. Positive findings shall require appropriate clinical follow-up but no repeat skin test. The medical staff shall develop and implement policies regarding positive outcomes;

Text of proposed rule or revised proposed rule, the regulatory impact statement, if any, and the regulatory flexibility analysis, if any, may be obtained from: Donald Macdonald, Department of Health, Bureau of Management Services, Corning Tower, Rm. 2230, Empire State Plaza, Albany, NY 12237, (518) 474-8734
Data, views or arguments may be submitted to: Same as above.
Regulatory Impact Statement

Statutory Authority:

Section 2803(2) of the Public Health Law authorizes the State Hospital Review and Planning Council with the approval of the Commissioner of Health to adopt and amend rules and regulations regarding standards for hospital operating certificates.

Legislative Objectives:

Article 28 of the Public Health Law empowers the Department of Health to protect the health of inhabitants of the State by assuring quality and efficiency of hospital and related health services. Section 2803(2) authorizes the State Hospital Review and Planning Council to adopt and amend rules and regulations pertaining to the quality of hospital care. The existing requirements of 10 NYCRR Part 405 specify immunization requirements for hospital staff. The proposed amendment will define and clarify the required certificate of immunization documentation for rubella and measles for hospital workers. The proposed amendment also deletes the requirement that women of child bearing years must have serologic screening tests for rubella. The intention of the statutory authority for this regulation is to protect patients admitted to facilities. By ensuring that all hospital employees are immune, by virtue of vaccination or serologic screening, to the communicable diseases, specified in 10 NYCRR 405.3(b)(10), the intent of the law and regulation, will be accomplished.

Needs and Benefits:

In order to uniformly implement immunization requirements, a certificate of immunization must be consistently defined. Currently, Public Health Law sections 2164 and 2165 and 10 NYCRR Subparts 66-1 and 66-2 define what constitutes the required certificates of immunization for school attendance. This amendment to 10 NYCRR section 405.3 will provide a similar definition of a certificate of immunization and thereby enable much of the proof of immunity for school attendance to be used subsequently for proof of immunity for employment in hospitals.

This amendment will also facilitate hospital review of certificates of immunization and ensure uniform implementation of the regulation by clearly defining the required documentation.

The deletion of the requirement that all women of child-bearing age have serologic screening tests for rubella immunity, even when appropriate vaccination has been documented, eliminates the additional cost for duplicative vaccination of this population.

This amendment will appropriately recognize the expansion of practitioners who can document measles and rubella immunity and certify medical exemptions based on their education and licensure. These practitioners include physician's assistants, specialist's assistants and nurse practitioners.

Costs:

Costs to Regulated Parties:

There are no additional costs incurred due to this amendment because it defines and clarifies existing required documentation.

The deletion of the requirement that female personnel of child bearing age have a serologic screening test to determine rubella immunity, even when immunization has been documented, will decrease costs to the facilities.

Costs to the State Government Other than Department of Health:

None.

Costs to Local Governments:

County and municipal hospitals will decrease costs as described above.

Costs to Department of Health:

None.

Paperwork:

No new paperwork will be generated.

Local Government Mandates:

This regulation imposes no new program, duty or responsibility on any county, town, city, village, school or fire district, or other special district.

Duplication:

This regulation does not impose requirements which duplicate, overlap or conflict with rules or legal requirements of the state or federal government.

Federal Standards:

This regulation does not impose requirements which are more stringent than existing federal standards for the same or similar areas.

Compliance Schedule:

Regulated parties will not need additional time to come into compliance with this regulation.

Alternatives:

Continued reliance on existing language of the regulation will continue to leave ambiguities regarding what appropriate documentation of immunity consist of. It will also continue to require women of childbearing age to have a rubella serologic screening test which is unnecessary if a rubella immunization has been documented.

Regulatory Flexibility Analysis

A regulatory flexibility analysis is not required because this regulation will impose no adverse economic impact on regulated parties. It clarifies an existing requirement and may decrease costs to some facilities.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Day Health Services for Patients with AIDS

I.D. No. HLT-12-93-00034-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of Part 759 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2803(2)

Subject: Diagnostic and treatment center—day health services for patients with AIDS.

Purpose: To focus on HIV medical care and the inclusion of children who are HIV positive and thereby helping sick persons to remain in the community longer.

Text of proposed rule: Pursuant to the authority vested in the State Hospital Review and Planning Council by section 2803 of the Public Health Law, Part 759 of Subchapter C of Chapter V, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended to be effective upon publication in the New York *State Register* as hereinafter indicated:

CHAPTER V
MEDICAL FACILITIES
SUBCHAPTER C
STATE HOSPITAL CODE
ARTICLE 6
DIAGNOSTIC AND TREATMENT CENTER OPERATION
(Statutory Authority: Public Health Law section 2803)

Part 759 of Article 6 of Subchapter C of Chapter V of Title 10 (Health) is hereby AMENDED to read as follows:

Part 759 [Adult] Day Health Care Services for Patients with AIDS

Section 759.1 Definitions. As used in this Subchapter, unless the context otherwise requires:

(a) For purposes of this Part, AIDS shall mean acquired immune deficiency syndrome and other human immunodeficiency (HIV) related illnesses.

(b) Registrant means a person who has AIDS or HIV illness, *or a person under the age of eighteen years old who is HIV+ and for whom the operator has structured and implemented a program specific for such person in that age group.*

(1) who is not a resident of a residential health care facility, is functionally impaired and not homebound, and requires certain preventive, *developmental,* diagnostic, therapeutic, rehabilitative or palliative items or services but does not require the continuous 24-hour-a-day inpatient care and services provided by a general hospital, or residential health care facility; and

(2) whose assessed social, *developmental* and health care needs, in the professional judgment of the physician of record, nursing staff, social services and other professional personnel of the [adult] day health care program can be met satisfactorily in whole or in part by delivery of appropriate services in such program.

(c) [Adult] Day health care means care and services provided to a registrant in a diagnostic and treatment center or approved extension site under the medical direction of a physician by personnel of the [adult] day health care program in accord with a comprehensive assessment of care needs and individualized health care plan, ongoing implementation and coordination of the health care plan, and transportation.

759.2 Applicability.

(a)(1) The operator of a diagnostic and treatment center may provide [adult] day health care services to registrants when approved pursuant to Part 710 of this Title.

(2) A diagnostic and treatment center which has been approved by the department to operate [an] *a* [adult] day health care program at its primary site may provide [adult] day health care services at an extension site approved by the department under the provisions of section 710.1 of this Chapter.

(3) A diagnostic and treatment center which does not operate a [adult] day health care program at its primary site may provide such a program at an extension site approved by the department in accordance with section 710.1 of this Chapter if there is not sufficient suitable space within the center to accommodate a full range of [adult] day health care program activities and services. The department may conduct an on-site survey of the center to determine whether the facility space and/or location is suitable for [an adult] *a* day health care program.

(b) Prior to operation of the facility's [adult] day health care services program, the operator shall apply to the department for approval in accordance with Part 710 of this Chapter and shall submit a description of the proposed program, including but not limited to: (1) need for the program, including statements on philosophy and objectives of the program; (2) range of services provided; (3) methods of delivery of services; (4) transportation arrangements for registrants; (5) physical space and use thereof; (6) number and expected characteristics of registrants to be served; (7) personnel participating in the program, including qualifications; (8) case management services and use of and coordination with existing community resources, including AIDS Centers, alcohol and substance abuse programs and rehabilitation facilities as appropriate; *(9) developmental services* [(9)] *(10)* financial policies and procedures; [(10)] *(11)* program budget; [(11)] *(12)* methods for program evaluation; and [(12)] *(13)* proximity to an identified number of potential registrants.

Section 759.3 General Requirements. The operator shall have and implement written policies and procedures which shall provide for:

(a) a written [transfer] *affiliation* agreement with a designated AIDS center or other hospital for the transfer of registrants requiring emergency care, [and] acute inpatient care services[;] *and access to clinic and ancillary services.*

(b) the appropriate transfer of registrants when applicable, to the care or supervision of other health facilities in accordance with the provisions for transfer and affiliation under Section 400.9 of this Subchapter.

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(a) Summer Flounder

(1) Only nets with cod ends having a minimum mesh size of five and one half inches diamond, or six inches square, inside measure, may be used in a directed trawl fishery for summer flounder. Any trawl vessel that has on board more than 100 pounds of summer flounder between 1 May and 31 October or more than 200 pounds of summer flounder between 1 November and 30 April will be presumed to be engaged in a directed fishery for summer flounder.

(2) Possession of any combination of mesh or liners on board a vessel engaged in a directed trawl fishery that effectively decreases the mesh below the minimum size is prohibited.

(3) Operators of trawl vessels that have on board more than 100 pounds of summer flounder between 1 May and 31 October or more than 200 pounds of summer flounder between 1 November and 30 April may not have any net, or any piece of net, that does not meet the mesh requirements contained in paragraph (a) of this subdivision on board except for the following: vessels that possess a valid Small Mesh Exemption Certificate issued by the United States Department of Commerce or that possess on board fly nets as prescribed and approved by federal regulation governing the take of summer flounder in the exclusive economic zone (EEZ), provided that no other nets or netting with mesh smaller than five and one half inches are on board.

(4) All summer flounder on vessels fishing with a cod end mesh smaller than the legal minimum size must be kept separate from other fish.

(b) Winter Flounder

(1) Only nets with cod ends having a minimum mesh size of at least four and one half inches diamond mesh, or five inches square mesh, inside measure, may be used in a directed trawl fishery for winter flounder. Any trawl vessel that has on board more than 300 pounds of winter flounder will be presumed to be engaged in a directed fishery for winter flounder.

(2) It is unlawful to have nets either in use or available for immediate use with cod ends less than four and one half inches diamond mesh, or five inches square mesh, inside measure, if 300 pounds of winter flounder are possessed on any vessel.

(3) It is unlawful to land more than 300 pounds of winter flounder unless nets with cod ends that are less than four and one half inches diamond, or five inches square mesh, inside measure, are not available for immediate use.

(4) It is unlawful to use or have available for immediate use any combination of mesh or liners that effectively decreases the mesh below the minimum size when more than 300 pounds of winter flounder are possessed or landed.

(5) For the purposes of this section, a net that conforms to one of the following specifications and that can be shown not to have been in recent use is considered to be not available for immediate use:

(i) A net stowed below deck, provided:

('a') it is located below the main working deck from which the net is deployed and retrieved; and

('b') the towing wires, including the leg wires, are detached from the net; and

('c') it is fan-folded (flaked) and bound around its circumference.

(ii) A net stowed and lashed down on deck, provided:

('a') it is fan-folded (flaked) and bound around its circumference; and

('b') it is securely fastened to the deck or rail of the vessel; and

('c') the towing wires, including the leg wires, are detached from the net.

(iii) A net that is on a reel and is covered and secured, provided:

('a') the entire surface of the net is covered with canvas or other similar material that is securely bound;

('b') the towing wires, including the leg wires are detached from the net; and

('c') the cod end is removed from the net and stowed below deck.

(6) All winter flounder on vessels fishing with a mesh cod end smaller than the legal minimum size must be kept separate from other fish.

(7) The provisions of paragraphs (b)(1), (2), (3), (4) and (5) of this Section will take effect 90 days after filing.

(c)(1) For the purposes of this section, the cod end of a trawl net used in a directed fishery for summer flounder is defined as either 75 continuous meshes forward of the terminus of the net or the terminal one third of the net, measured from the center of the chain line at the mouth of the net to the terminus of the net.

(2) The cod end of a trawl net used in a directed fishery for winter flounder is defined as either 50 continuous meshes forward of the terminus of the net or the terminal one fourth of the net, measured from the center of the chain line at the mouth of the net to the terminus of the net.

(3) The minimum mesh size is the maximum opening of any single mesh, measured when wet after use and is represented by the median value of eleven consecutive meshes taken at least five meshes from the lacings parallel to the longitudinal axis of the net.

(4) The minimum mesh size is measured by a wedge-shaped gauge having a taper of two centimeters (0.78 inch) in eight centimeters (3.14 inch) and thickness of 3.2 millimeters (0.125 inch) inserted into the meshes under a pressure or pull of five kilograms (11 pounds). The department may approve the use of other equivalent mesh measurement gauges or methods of measurement.

(5) Taper gauges as prescribed above will be available on loan from the department upon written request.

(d) No fishing vessel may use any means or device, including but not limited to chafing gear, liners, double nets, net strengtheners, ropes, lines, or chafing gear on the top of the regulated portion of a trawl net; except that, one splitting strap and one bull rope, consisting of line or rope not more than two inches in diameter, may be used if such splitting strap or bull rope does not constrict, in any manner, the top of the regulated portion of the net. However, canvas, netting, or other material may be attached to the underside of the cod end to reduce wear and prevent damage. For the purposes of this section, the "top of the regulated portion of the net" is defined as the fifty percent of the entire regulated portion of the net that will not be in contact with the ocean bottom during a tow if the regulated portion of the net were laid flat on the ocean floor.

(e) For the purposes of this section, the following definition applies:

(1) "Landed" means to have set or put on shore from any boat or vessel, or to have brought to any port or docking place, any winter or summer flounder.

Final rule as compared with last published rule: Nonsubstantial revisions were made in section 40.5(b)(7).

Text of rule, the revised regulatory impact statement, if any, the revised regulatory flexibility analysis, if any, and the assessment of public comment, if any, may be obtained from: Alice Weber, Department of Environmental Conservation, State University of New York, Bldg. 40, Stony Brook, NY 11790-2356, (516) 444-0435

Additional matter required by statute: Pursuant to Environmental Conservation Law, Art. VIII a negative declaration is on file.

Regulatory Impact Statement and Regulatory Flexibility Analysis

Although changes were made to the express terms, these changes do not affect either the regulatory impact statement or the regulatory flexibility analysis.

Assessment of Public Comment

The agency received no public comment.

NOTICE OF EXPIRATION

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given that the following notice(s) of proposed rule making cannot be reconsidered unless the Department of Environmental Conservation publishes a new notice of proposed rule making in the NYS *Register*.

I.D. No.	Proposed	Expiration Date
ENV-08-93-00029-P	February 24, 1993	August 23, 1993

DEPARTMENT OF HEALTH

NOTICE OF ADOPTION

Immunization of Health Care Workers

I.D. No. HLT-12-93-00033-A
Filing No. 1658
Filing date: Aug. 20, 1993
Effective date: Sept. 8, 1993

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:
Action taken: Amendment of section 405.3 of Title 10 NYCRR.
Statutory authority: Public Health Law, section 2803(2)
Subject: Immunization of health care workers.
Purpose: To define a certificate of immunization for rubella and measles and remove the requirement for a serologic screening test for rubella.
Text was published in the notice of proposed rule making, I.D. No. HLT-12-93-00033-P, Issue of March 24, 1993.
Final rule as compared with last published rule: No changes.
Text of rule, the revised regulatory impact statement, if any, the revised regulatory flexibility analysis, if any, and the assessment of public comment, if any, may be obtained from: Donald Macdonald, Department of Health, Bureau of Management Services, Corning Tower, Rm. 2230, Empire State Plaza, Albany, NY 12237, (518) 474-8734
Assessment of Public Comment
The agency received no public comment.

NOTICE OF ADOPTION

Notification Requirements for Nursing Home Residents

I.D. No. HLT-15-93-00008-A
Filing No. 1659
Filing date: Aug. 20, 1993
Effective date: Sept. 8, 1993

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:
Action taken: Amendment of section 415.3 of Title 10 NYCRR.
Statutory authority: Public Health Law, section 2803
Subject: Notification requirements for nursing home residents.
Purpose: To provide residents with full notification of appeal rights prior to involuntary transfer or discharge.
Text was published in the notice of proposed rule making, I.D. No. HLT-15-93-00008-P, Issue of April 14, 1993.
Final rule as compared with last published rule: No changes.
Text of rule, the revised regulatory impact statement, if any, the revised regulatory flexibility analysis, if any, and the assessment of public comment, if any, may be obtained from: Donald Macdonald, Department of Health, Bureau of Management Services, Corning Tower, Rm. 2230, Empire State Plaza, Albany, NY 12237, (518) 474-8734
Assessment of Public Comment
The agency received no public comment.

NOTICE OF ADOPTION

Methodology for Additional ESRD Units

I.D. No. HLT-21-93-00043-A
Filing No. 1690
Filing date: Aug. 24, 1993
Effective date: Sept. 8, 1993

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action.
Action taken: Addition of section 709.4 to Title 10 NYCRR.
Statutory authority: Public Health Law, section 2803(2)
Subject: Need methodology for additional ESRD units.
Purpose: To implement a need methodology for ESRD stations based on considerations other than a numerical methodology which the department currently utilizes.
Text of final rule: Part 709 is hereby amended by adding a new Section 709.4 to read as follows:

709.4 End Stage Renal Dialysis service. (a) This methodology will be utilized in the evaluation of certificate of need applications involving the construction or establishment of new or replacement dialysis stations used in the treatment of End Stage Renal Disease. It is the intent of the State Hospital Review and Planning Council that this methodology, when used in conjunction with the planning standards and criteria set forth in section 709.1 of this Part, become a statement of basic principles and planning/decision making tools for guiding and directing the development of dialysis stations for End Stage Renal Disease services throughout the state. Additionally, it is intended that the methodology will provide the health systems agencies and potential applicants with sufficient flexibility to consider the unique characteristics of their respective areas in determining need. The goals and objectives of the methodology expressed herein are expected to ensure that an adequate supply of dialysis stations are available to provide access to care to all those in need of in-facility dialysis.

(b) The factors to be considered in determining the public need for dialysis stations shall include, but not be limited to, the following:

(1) evidence that the proposed dialysis services capacity proposed will be utilized sufficiently to be financially feasible as demonstrated by a five year analysis of projected costs and revenues associated with the program;

(2) evidence that the proposed service or additional capacity will enhance access to services by patients including members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, low-income persons, racial and ethnic minorities, women, and handicapped persons), and/or appropriate rural populations;

(3) evidence that the facility's hours of operation and admission policies will promote the availability of services which are acceptable to those in need of such services, in particular, operational hours that permit individuals in dialysis to continue employment.

(4) the facility's willingness and ability safely to serve dialysis patients; and

(5) when an existing provider proposes to add twelve or more stations, evidence, derived from analysis of factors including but not necessarily limited to both existing patient referral and use patterns and projected referral and use patterns which would result from addition of the proposed stations, indicating that approval of such stations will not jeopardize the quality of service provided at or the financial viability of other existing dialysis facilities or services within the applicant's planning area. However, a finding that the proposed facility would jeopardize the financial viability of such existing facilities will not, of itself, require a recommendation of disapproval of the application.

(c) Public need for a proposed facility or station shall be deemed to exist when review and consideration of evidence concerning each of the five factors set forth in subdivision (b) of this section results in an affirmative finding.

(d) The terms and provisions hereof shall be of no further force or effect after December 31, 1994.

Final rule as compared with last published rule: Nonsubstantial revisions were made in section 709.4(a), (b)(3), (b)(5), (c) and (d).
Text of rule, the revised regulatory impact statement, if any, the revised regulatory flexibility analysis, if any, and the assessment of public comment, if any, may be obtained from: Donald Macdonald, Department of Health, Bureau of Management Services, Corning Tower, Rm. 2230, Empire State Plaza, Albany, NY 12237, (518) 474-8734
Revised Regulatory Impact Statement
Although the regulation has been changed since it was first published in the *State Register* on May 26, 1993, the changes do not necessitate any changes to the regulatory impact statement.
Revised Regulatory Flexibility Analysis
Although the regulation has been changed since it was first published in the *State Register* on May 26, 1993, the changes do not necessitate any changes to the regulatory flexibility analysis.
Assessment of Public Comment
The agency received no public comment.

NOTICE OF ADOPTION

Methodology to be Utilized in Determining the Need for ESRD Providers

I.D. No. HLT-21-93-00044-A
Filing No. 1657
Filing date: Aug. 20, 1993
Effective date: Sept. 8, 1993

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:
Action taken: Addition of section 670.6 to Title 10 NYCRR.

STATE OF NEW YORK : DEPARTMENT OF HEALTH

IN THE MATTER

OF

COVERED ENTITIES IN THE PREVENTION AND CONTROL OF THE 2019 NOVEL CORONAVIRUS

ORDER FOR SUMMARY ACTION

WHEREAS the 2019 Novel Coronavirus ("COVID-19") is an infection associated with fever and signs and symptoms of pneumonia and other respiratory illness that is easily transmitted from person to person, predominantly through droplet transmission, and has significant public health consequences; and

WHEREAS COVID-19 is a global pandemic that, to date, has resulted in 2,195,903 documented cases and 43,277 deaths in New York State alone; and

WHEREAS the Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the Delta COVID-19 variant; and

WHEREAS the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorizations (EUA) for Pfizer -BioNTech, Moderna, and Janssen COVID-19 vaccines which have been shown to be safe and effective as determined by data from the manufacturers and findings from large clinical trials; and

WHEREAS while New York State has aggressively promoted vaccination since COVID-19 vaccines first became available in December 2020, current vaccination rates are not high enough to prevent the spread of the Delta variant, which is approximately twice as transmissible as the original SARS-CoV-2 strain; and

WHEREAS data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 as are vaccinated individuals; and

WHEREAS those who are unvaccinated have over 10 times the risk of being seriously ill and hospitalized with COVID-19; and

WHEREAS since early July, cases have risen 10-fold, and 95 percent of sequenced recent positives in New York State were the Delta variant; and

WHEREAS certain settings, such as healthcare facilities, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve; and

WHEREAS unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting such virus to colleagues and/or vulnerable patients or residents; and

WHEREAS based upon the foregoing, the Commissioner of Health of the State of New York is of the Opinion that all entities identified in this Order ("covered entities"), must immediately implement and comply with the requirements identified herein, and that failure to do so constitutes a danger to the health, safety, and welfare of the people of the State of New York; and

WHEREAS the Commissioner of Health of the State of New York has determined that requiring covered entities to immediately implement and comply with the requirements set forth herein and cannot be achieved through alternative means, including the adoption of the Public Health and Health Planning Council of emergency regulations, without delay, which would be prejudicial to health, safety, and welfare of the people of the State of New York; and

WHEREAS it therefore appears to be prejudicial to the interest of the people to delay action for fifteen (15) days until an opportunity for a hearing can be provided in accordance with the provisions of Public Health Law Section (PHL) 12-a.

NOW, THEREFORE, THE HEALTH COMMISSIONER HEREBY ORDERS THAT: Pursuant to PHL § 16:

(a) Definitions.

(1) Covered entity shall mean a general hospital or nursing home pursuant to section 2801 of the Public Health Law.

(2) Covered Personnel. 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, patients, residents, or personnel working for such entity to the disease.

(3) Fully vaccinated. Covered personnel are considered fully vaccinated for COVID-19 ≥ 2 weeks after receiving either (1) the second dose in a 2-dose series (e.g., Pfizer-BioNTech or Moderna), or (2) a single-dose vaccine (e.g., Johnson & Johnson [J&J]/Janssen), authorized for emergency use or approved by the U.S. Food and Drug Administration, and holds an emergency use listing by the World Health Organization.

(4) Documentation of vaccination shall include:

(i) a 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. Unless otherwise specified by the Department.

(iv) The following elements, unless otherwise specified by the Department: manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site.

(b) Covered entities shall continuously require all covered personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021. 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 section (c) of this order.

(c) Limited exemptions to vaccination:

1. Medical exemption. If any licensed physician or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to a specific member of a covered entity's personnel, based upon a specific pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be subject to a reasonable accommodation of such health condition only until such immunization is found no longer to be detrimental to the health of such member. The nature and duration of the medical exemption must be stated in the personnel employment medical 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). Covered entities shall document medical exemptions and any reasonable accommodation in personnel records or other appropriate records in accordance with applicable privacy laws by September 27, 2021, and continuously, as needed, thereafter.
2. Religious exemption. Covered entities shall grant a religious exemption for COVID-19 vaccination for covered personnel if they hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the

employer. Covered entities shall document such exemptions and such reasonable accommodations in personnel records or other appropriate records in accordance with applicable privacy laws by September 27, 2021, and continuously, as needed, thereafter.

(d) Upon the request of the Department, covered entities must report the number and percentage of covered personnel that have been vaccinated against COVID-19 and the number of personnel for which medical or religious exemptions have been granted by covered entities in a manner and format determined by the Department.

(e) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of Order.

(f) The Department may require all covered personnel, whether vaccinated or unvaccinated, to wear acceptable face coverings for the setting in which they work. Covered entities shall supply acceptable face coverings required by this section at no cost to covered personnel.

FURTHER, I DO HEREBY give notice that any entity that receives notice of and is subject to this Order is provided with an opportunity to be heard at 10:00 a.m. on September 2, 2021, via videoconference, to present any proof that failure to implement and comply with the requirements of this Order does not constitute a danger to the health of the people of the State of New York. If any such entity desires to participate in such a hearing, please inform the Department by written notification to **Vaccine.Order.Hearing@health.ny.gov**, New York State Department of Health, Corning Tower, Room 2438, Governor Nelson A. Rockefeller Empire

State Plaza, Albany, New York 12237, within five (5) days of their receipts of this Order. Please include in the notification the email addresses of all individuals who will be representing or testifying for the entity at the hearing so that an invitation to access the hearing remotely can be provided.

DATED: Albany, New York
August 18, 2021

NEW YORK STATE DEPARTMENT OF HEALTH

BY: Howard Zucker M.D.

HOWARD A. ZUCKER, M.D., J.D.
Commissioner of Health

September 15, 2021
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DEPARTMENT OF STATE
Division of Administrative Rules

NEW YORK STATE REGISTER

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Executive Orders
Court Notices

State agencies must specify in each notice which proposes a rule the last date on which they will accept public comment. Agencies must always accept public comment: for a minimum of 60 days following publication in the *Register* of a Notice of Proposed Rule Making, or a Notice of Emergency Adoption and Proposed Rule Making; and for 45 days after publication of a Notice of Revised Rule Making, or a Notice of Emergency Adoption and Revised Rule Making in the *Register*. When a public hearing is required by statute, the hearing cannot be held until 60 days after publication of the notice, and comments must be accepted for at least 5 days after the last required hearing. When the public comment period ends on a Saturday, Sunday or legal holiday, agencies must accept comment through the close of business on the next succeeding workday.

For notices published in this issue:
– the 60-day period expires on November 14, 2021
– the 45-day period expires on October 30, 2021
– the 30-day period expires on October 15, 2021

KATHY HOCHUL
GOVERNOR

ROSSANA ROSADO
SECRETARY OF STATE

NEW YORK STATE DEPARTMENT OF STATE

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

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

As the proposed regulations largely clarify existing responsibilities and duties among regulated entities and individuals, no additional recordkeeping, compliance requirements, or professional services are expected. With respect to mandating syndromic surveillance reporting during an outbreak of a highly infectious communicable disease, hospitals are already reporting syndromic surveillance data regularly and voluntarily. Additionally, the requirement for local health departments to continually report to the Department during an outbreak is historically a practice that already occurs. With respect to clinical laboratories, they must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102.

Compliance Costs:

As the proposed regulations largely clarify existing responsibility and duties among regulated entities and individuals, no initial or annual capital costs of compliance are expected above and beyond the cost of compliance for the requirements currently in Parts 2, 58 and 405.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

As the proposed regulations largely clarify existing responsibility and duties among regulated entities and individuals, any adverse impacts are expected to be minimal. The Department, however, will work with local health departments to ensure they are aware of the new regulations and have the information necessary to comply.

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 provided comments during the notice and comment period.

Job Impact Statement

The Department of Health has determined that this regulatory change will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

EMERGENCY RULE MAKING

Prevention of COVID-19 Transmission by Covered Entities

I.D. No. HLT-37-21-00003-E
Filing No. 946
Filing Date: 2021-08-26
Effective Date: 2021-08-26

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of section 2.61; amendment of sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 and 1001.11 of Title 10 NYCRR; amendment of sections 487.9, 488.9 and 490.9 of Title 18 NYCRR.

Statutory authority: Public Health Law, sections 225, 2800, 2803, 3612, 4010; Social Services Law, sections 461 and 461-e

Finding of necessity for emergency rule: Preservation of public health and general welfare.

Specific reasons underlying the finding of necessity: 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 10-fold, and 95 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 11 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 emergency 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.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19 in the identified regulated facilities or entities. As described above, current circumstances and the risk of spread to vulnerable resident and patient populations by unvaccinated personnel in these settings necessitate immediate action and, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Subject: Prevention of COVID-19 Transmission by Covered Entities.

Purpose: To require covered entities to ensure their personnel are fully vaccinated against COVID-19 subject to certain exemptions.

Text of emergency rule: 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, with the first dose for current personnel received by September 27, 2021 for general hospitals and nursing homes, and by October 7, 2021 for all other covered entities absent receipt of an exemption as allowed below. 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 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 a ddressing 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.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt this emergency rule as a permanent rule and will publish a notice of proposed rule making in the *State Register* at some future date. The emergency rule will expire November 23, 2021.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

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 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 10-fold, and 95 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 11 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 emergency 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:

These emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed rule making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

Regulatory Flexibility Analysis

Effect of Rule:

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

Types 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 42 counties have an estimated population of less than 200,000 based upon 2019 United States Census projections:

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren 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	Monroe County	Orange County
Niagara County	Saratoga County	Oneida County
Suffolk County	Erie County	Onondaga 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.

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Frequently Asked Questions (FAQs) Regarding the August 26, 2021 – Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation

1. **Q: When did this regulation go into effect?**
   A: The emergency regulation was effective on August 26, 2021, when it was filed with the Department of State. Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021, for general hospitals and nursing homes, and by October 7, 2021, for all other covered entities absent receipt of a medical exemption.

2. **Q: Does this emergency regulation supersede the Section 16 Commissioner's Order that was issued on August 18, 2021?**
   A: Yes. This regulation supersedes the Section 16 Order dated August 18, 2021. The Section 16 Order was vacated, and general hospitals and nursing homes that were subject to that Section 16 Order must now comply with this emergency regulation.

COVERED ENTITIES

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

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

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

   - Private medical and therapist practices
   - Entities certified under Article 44 of the Public Health Law, such as Managed Long Term Care plans; however, the regulation does apply to covered entities (e.g.,

certified home health agencies or licensed home care services agencies) that are owned or operated by or in conjunction with an Article 44 entity.
- Mental/behavioral health facilities regulated by Article 31 of the Mental Hygiene Law; however, the regulation does apply to mental/behavioral health units of healthcare facilities that are also regulated under Article 28
- Fiscal Intermediaries and Personal Assistants under the Consumer Directed Personal Assistant Program (CDPAP).

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

5. **Q: Is a University Faculty Practice a "covered entity"?**
A: One type of private practice is a university faculty practice corporation under Not-for-Profit Corporation law §1412. Such practices may be affiliated with a medical school or affiliated with a teaching hospital. Private practices are not "covered entities" under the regulation.

COVERED PERSONNEL

6. **Q: What personnel are covered?**
A: Covered entities that are subject to the Prevention of influenza transmission by healthcare and residential facility and agency personnel regulation ("flu mask reg") should begin by identifying the personnel covered by the flu mask reg, because such personnel are personnel under the Prevention of COVID-19 Transmission by Covered Entities regulation as well.

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

7. **Q: What personnel "could potentially expose other covered personnel"?**
A: This regulation is intended to reduce exposure by personnel who are not vaccinated against COVID-19 and do not have a medical exemption, to other covered personnel, in addition to reducing exposure to patients and residents of facilities, agencies, and programs. Personnel may include members of the workforce who have no direct patient or resident contact if the personnel engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel. Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of Section 2.61.

8. **Q: Which contractors are covered personnel?**
   A: Contractors must comply with this regulation if they (1) function as employees or staff of the regulated facility, agency, or program; or (2) are under the covered entity's direct control. This includes, but is not limited to, nurses and other healthcare professionals contracted to provide care to patients or residents. Contractors who do not meet this definition are considered visitors and are NOT subject to this regulation. Examples of contractors who are NOT subject to this regulation include, but are not limited to:
   - contracted construction/plumbing/electrical workers hired for a specific job(s)
   - medical equipment vendors
   - vending machine service personnel
   - one-time or sporadically occasional entertainers hired by contract
   - EMS, ambulette, or other transportation services personnel in a contract relationship with a covered entity, but who do not meet the definition of functioning as employees or staff of the facility, agency, or program, or being under the entity's direct control
   - Laboratory and radiology technicians who provide services to a covered entity by contract (e.g., enter a nursing home intermittently to draw blood or perform medical imaging procedures), but who do not function as employees or staff of the covered entity and are not under the covered entity's direct control, are not personnel of the contracting covered entity.
   - Law enforcement officers entering the facility in their official capacity.

9. **Q: Which volunteers are covered personnel?**
   A: Volunteers who have a formal relationship with the covered entity and who provide regularly scheduled volunteer services must comply with the regulation. Examples of individuals who are NOT subject to this regulation include:
   - One-time or sporadically visiting volunteers
   - Participants in the NYS Long Term Care Ombudsman Program

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

11. **Q: Are covered entities responsible for vaccination of government employees or contractors engaged in health care oversight or similar assessment activities?**
    A: No, healthcare oversight agencies are responsible for ensuring their own employees or contractors are vaccinated. For example, the Department has a contract to conduct Conflict-Free Evaluation and Enrollment Center activities, including evaluations to determine if a consumer is eligible for Community Based Long Term Care (CBLTC) for more than 120 days. Covered entities are not responsible for requiring such contract staff to be vaccinated. Likewise, covered entities are not responsible for "settlement providers" working with the Department's Office of Community Transitions, such as housing contractors and peer bridger agencies under 18 NYCRR Section 487.13 who are "settlement providers."

COMPLIANCE DATES

12. **Q: What are the dates for initial compliance?**
A: Nursing homes and hospitals must ensure personnel have documentation of COVID-19 vaccination or a valid medical exemption by September 27, 2021. All other covered facilities must ensure such compliance by October 7, 2021.

13. **Q: After the initial dates for compliance, how long do covered facilities have to document COVID-19 vaccination or a valid medical exemption for new hires?**
A: Documentation must occur continuously, as needed, following the dates for initial compliance, including documentation of any reasonable accommodation therefor.

14. **Q: Does this regulation change the requirements under** the COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel regulation that became effective on July 30, 2021?
A: No, this regulation does not alter the requirements, including the compliance dates, under 10 NYCRR Subpart 66-4 that were added on July 30, 2021.

EXEMPTIONS

15. **Q: Does the regulation include a medical exemption?**
A: Yes, there is a medical exemption.

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

16. **Q: What are the applicable ACIP COVID-19 vaccination contraindications and precautions at the time of the publication of this guidance?**
A: Current COVID-19 vaccine contraindications and precautions are posted on the CDC's website at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications.
At the time of publication of this guidance, the CDC considers the following to be contraindications to vaccination with COVID-19 vaccines:

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

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

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

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

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

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

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

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

17. **Q: May personnel with medical exemptions continue normal job responsibilities?**
A: Yes, provided that they comply with all applicable requirements for personal protective equipment, including masking.

18. **Q: Do personnel with medical exemptions need to undergo COVID-19 testing?**
A: This regulation does not require personnel with medical exemptions to undergo COVID-19 testing; however, COVID-19 testing may nevertheless be required under existing regulations and guidance, including NH 21-17 *Revised* Nursing Home COVID-19 Testing Requirements.

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

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

DOCUMENTATION

21. Q: Are there any specific vaccines that are excluded when determining whether personnel are "fully vaccinated"?
A: According to the CDC, only people who have received a complete series of a COVID-19 vaccine that is either approved or authorized for emergency use by the U.S. Food and Drug Administration (FDA) or the World Health Organization (WHO) are "fully vaccinated." People who received a COVID-19 vaccine that has neither been authorized by the FDA or the WHO are not fully vaccinated. Current lists of vaccine authorized by the FDA and WHO are available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines and https://covid19.trackvaccines.org/agency/who/.

22. Q: How can a covered entity determine whether a record from a foreign nation is an "official record"?
A: Covered entities must develop and implement a policy and procedure to ensure compliance with the provisions of the regulation. Such policies and procedures should prevent fraudulent documentation to the extent reasonably practicable.

23. Q: Is documentation that personnel has already had COVID-19 acceptable in lieu of vaccination?
A: No. The COVID-19 vaccination requirement is still applicable to personnel who have already had COVID-19.

24. Q: Is there a standard medical exemption form that covered entities can use?
A: The standard medical exemptions forms used by schools to document medical exemptions for students can be found here (State DOH form) and here (NYC Dept of Education form). These forms can be adapted for use by covered entities.

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DEPARTMENT OF STATE
Division of Administrative Rules

NEW YORK STATE REGISTER

INSIDE THIS ISSUE:

Opinions of the Attorney General

State agencies must specify in each notice which proposes a rule the last date on which they will accept public comment. Agencies must always accept public comment: for a minimum of 60 days following publication in the *Register* of a Notice of Proposed Rule Making, or a Notice of Emergency Adoption and Proposed Rule Making; and for 45 days after publication of a Notice of Revised Rule Making, or a Notice of Emergency Adoption and Revised Rule Making in the *Register*. When a public hearing is required by statute, the hearing cannot be held until 60 days after publication of the notice, and comments must be accepted for at least 5 days after the last required hearing. When the public comment period ends on a Saturday, Sunday or legal holiday, agencies must accept comment through the close of business on the next succeeding workday.

For notices published in this issue:

– the 60-day period expires on February 13, 2022
– the 45-day period expires on January 29, 2022
– the 30-day period expires on January 14, 2022

KATHY HOCHUL
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ACTING SECRETARY OF STATE

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No local government will need professional services to comply with this rule because the rule does not apply to any local government.

4. Compliance Costs: As noted above, new recordkeeping requirements may impose limited compliance costs on debt collectors if they must modify their standard notices or implement new policies.

No local government will incur any costs to comply with this amendment because the amendment does not apply to any local government.

5. Economic and Technological Feasibility: The rulemaking should not impose technological burdens on small businesses. Debt collectors already must comply with similar requirements. To a large extent, small businesses have already taken action to prepare for compliance with the recently adopted federal Regulation F, which also covers debt collectors. The proposed rule follows but also builds upon Regulation F and therefore may produce some compliance costs.

This rule does not apply to any local government; therefore, no local government should experience any economic or technological impact as a result of the rule.

6. Minimizing Adverse Impact: The Department has taken steps to ensure that debt collectors' preparation for compliance with Regulation F will be applicable to compliance with the proposed rule. No local government should be adversely impacted by this rule because the rule does not apply to any local government.

7. Small Business and Local Government Participation: The Department complied with SAPA § 202-b(6) by posting the proposed rule on its website for informal outreach and notifying trade organizations that represent the interests of small businesses that the proposed rule had been posted. The Department also will comply with SAPA § 202-b(6) by publishing the proposed amendment in the State Register and posting the proposed amendment on its website again.

Rural Area Flexibility Analysis

The Department of Financial Services ("Department") finds that the rule will not have any adverse impact on rural areas or impose new substantial reporting, recordkeeping or other compliance requirements on public or private entities in rural areas in New York State. The rule does not impose any reporting requirements on debt collectors and does not change existing recordkeeping requirements to require the creation and maintenance of new records, though it does change the period of time for which records must be maintained. The rule applies to all debt collectors in the State, whether they operate in rural or non-rural areas and should not impact them differently based on location.

Job Impact Statement

The Department of Financial Services ("Department") does not expect compliance with amended Part 1 to have an adverse effect on jobs or employment opportunities in the debt collection and debt buying industry. The proposed amendment clarifies and modifies the rule that sets forth standards for debt collection practices in New York, including establishing disclosure and recordkeeping requirements with which debt collectors and debt buyers already must comply. Debt collectors and debt buyers currently are also subject to federal laws and regulations of a similar type.

Department of Health

EMERGENCY/PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Prevention of COVID-19 Transmission by Covered Entities

I.D. No. HLT-50-21-00001-EP

Filing No. 1176

Filing Date: 2021-11-24

Effective Date: 2021-11-24

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Proposed Action: Addition of section 2.61; amendment of sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 and 1001.11 of Title 10 NYCRR; amendment of sections 487.9, 488.9 and 490.9 of Title 18 NYCRR.

Statutory authority: Public Health Law, sections 225, 2800, 2803, 3612, 4010; Social Services Law, sections 461 and 461-e

Finding of necessity for emergency rule: Preservation of public health.

Specific reasons underlying the finding of necessity: 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 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 11 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 emergency 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.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19 in the identified regulated facilities or entities. As described above, current circumstances and the risk of spread to vulnerable resident and patient populations by unvaccinated personnel in these settings necessitate immediate action and, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Subject: Prevention of COVID-19 Transmission by Covered Entities.

Purpose: To require covered entities to ensure their personnel are fully vaccinated against COVID-19 subject to certain exemptions.

Text of emergency/proposed rule: 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.

This notice is intended: to serve as both a notice of emergency adoption and a notice of proposed rule making. The emergency rule will expire February 21, 2022.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 60 days after publication of this notice.

This rule was not under consideration at the time this agency submitted its Regulatory Agenda for publication in the Register.

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 emergency 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:

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.

Alternatives:

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:

These emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed rule making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

Regulatory Flexibility Analysis

Effect of Rule:

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 vac-

cinated 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

Types 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
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren 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	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga 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.

EMERGENCY/PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Investigation of Communicable Disease; Isolation and Quarantine

I.D. No. HLT-50-21-00002-EP

Filing No. 1177

Filing Date: 2021-11-24

Effective Date: 2021-11-24

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Proposed Action: Amendment of Part 2 and section 405.3; addition of section 58-1.14 to Title 10 NYCRR.

Statutory authority: Public Health Law, sections 225, 576 and 2803

Finding of necessity for emergency rule: Preservation of public health.

Specific reasons underlying the finding of necessity: Where compliance with routine administrative procedures would be contrary to public interest, the State Administrative Procedure Act (SAPA) § 202(6) empowers state agencies to adopt emergency regulations necessary for the preservation of public health, safety, or general welfare. In this case, compliance with SAPA for filing of this regulation on a non-emergency basis, including the requirement for a period of time for public comment, cannot be met because to do so would be detrimental to the health and safety of the general public.

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak.

Now, over a year and half after the first cases were identified in the United States, 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.

Based on the foregoing, the Department has determined that these regulations, while applicable to several diseases, are necessary to promulgate on an emergency basis to control the spread of COVID-19 in New York State. Accordingly, current circumstances necessitate immediate action, and pursuant to the State Administrative Procedure Act Section 206(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Subject: Investigation of Communicable Disease; Isolation and Quarantine.

Purpose: Control of communicable disease.

Substance of emergency/proposed rule (Full text is posted at the following State website: https://regs.health.ny.gov/regulations/emergency): These regulations clarify the authority and duty of the New York State Department of Health ("Department") and local health departments to protect the public in the event of an outbreak of communicable disease, through appropriate public health orders issued to persons diagnosed with or exposed to a communicable disease. These regulations also require hospitals to report syndromic surveillance data to the Department upon direction from the Commissioner and clarify reporting requirements for clinical laboratories with respect to communicable diseases.

This notice is intended: to serve as both a notice of emergency adoption and a notice of proposed rule making. The emergency rule will expire February 21, 2022.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 60 days after publication of this notice.

This rule was not under consideration at the time this agency submitted its Regulatory Agenda for publication in the Register.

Regulatory Impact Statement

Statutory Authority:

The statutory authority for the regulatory amendments to Part 2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is Section 225 of the Public Health Law (PHL), which authorizes the Public Health and Health Planning Council (PHHPC), subject to the approval of the Commissioner of Health (Commissioner), to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York. Additionally, Section 2103 of the PHL requires all local health officers to report cases of communicable disease to the New York State Department of Health (Department).

The statutory authority for the proposed new section 58-1.14 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is section 576 of the PHL, which authorizes the Department to adopt regulations prescribing the requirements for the proper operation of a clinical laboratory, including the methods and the manner in which testing or analyses of samples shall be performed and reports submitted.

The statutory authority for the proposed amendments to section 405.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is section 2803 of the PHL, which 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.

Legislative Objectives:

The legislative objective of PHL § 225 is, in part, to protect the public health by authorizing PPHPC, with the approval of the Commissioner, to amend the SSC to address public health issues related to communicable disease.

The legislative objective of PHL § 576 is, in part, to promote public health by establishing minimum standards for clinical laboratory testing and reporting of test results, including to the Department for purposes of taking prompt action to address outbreaks of disease.

The legislative objective of PHL § 2803 includes among other objectives authorizing PHHPC, with the approval of the Commissioner, to adopt regulations concerning the operation of facilities licensed pursuant to Article 28 of the PHL, including general hospitals.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

Now, over a year and half after the first cases were identified in the United States, 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

Prevention of COVID-19 Transmission by Covered Entities

Effective date: 1/21/22

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 filing with the Department of State, 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, and to have received any booster or supplemental dose as recommended by the CDC, 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 emergency 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:

These emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed rule making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

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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:

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.

EMERGENCY JUSTIFICATION

The Centers for Disease Control and Prevention (CDC) and health authorities around the world have identified recent surges in the number of new cases since the emergence of the SARS-CoV-2 Omicron variant, which is known to be more easily transmissible than previous variants of SARS-CoV-2. The World Health Organization classified the Omicron variant as a Variant of Concern due to its increased transmissibility on November 26, 2021. The emergence of the Omicron variant follows concerning national trends of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, the number of new cases per 100,000 residents has risen from fewer than 2 to over 300 per 100,000 residents. Recent New York State data show that unvaccinated individuals continue to be more likely to be diagnosed with COVID-19 compared to vaccinated individuals, however the Omicron variant's spread corresponds with an increase in new infections among vaccinated individuals. Those who are unvaccinated have over 10 times the risk of being hospitalized with COVID-19 compared with vaccinated individuals. Recent data show that booster doses of the COVID-19 vaccine offer more protection against the Omicron variant compared with the primary series alone.

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 and Omicron variants, which is a critical component to protecting public health. Booster doses of the COVID-19 vaccine are important to maximize protection against infection. 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. Personnel in such settings who have not received all recommended doses of the COVID-19 vaccine 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 an unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel have received all doses of the COVID-19 recommended by ACIP, including boosters and supplemental doses, 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.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19 in the identified regulated facilities or entities. As described above, current circumstances and the risk of spread to vulnerable resident and patient populations by unvaccinated personnel in these settings necessitate immediate action and, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.