

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 201, 206 and 2803 of the Public Health Law and sections 461 and 461-e of the Social Services Law, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended by adding a new Subpart 66-4, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Subpart 66-4, titled COVID-19 Nursing Home and Adult Care Facility Vaccination Program, is added to read as follows:

66-4.1. Requirements for Nursing Homes

- (a) Every nursing home regulated pursuant to Part 415 of this Title shall offer all consenting, unvaccinated existing personnel and residents an opportunity to receive the first or any recommended next or booster dose of the COVID-19 vaccine.
- (b) The operator and administrator of every nursing home regulated pursuant to Part 415 of this Title must ensure that all new personnel, including employees and contract staff, and every new resident and resident readmitted to the facility has an opportunity to receive the first or any recommended next or booster dose of the COVID-19 vaccine within fourteen days of having been hired by or admitted or readmitted to such facility, as applicable.
- (c) The requirement to ensure that all new and current personnel and residents have an opportunity to receive the COVID-19 vaccination, as set forth in subdivisions (a) and (b) of this section, shall include, but not be limited to:

- (1) Posting conspicuous signage throughout the facility reminding personnel and residents that the facility offers COVID-19 vaccination; and
 - (2) Providing all personnel and residents who decline to be vaccinated a written affirmation for their signature, which indicates that they were offered the opportunity for a COVID-19 vaccination but declined. Such affirmation must state that the signatory is aware that, if they later decide to be vaccinated for COVID-19, it is their responsibility to request vaccination from the facility. The facility shall maintain signed affirmations on file at the facility and make such forms available at the request of the Department.
- (d) Nursing homes must comply with the requirements for vaccination of personnel in 10 NYCRR § 415.19(a)(5).

66-4.2. Requirements for Adult Care Facilities

- (a) The operator and administrator of every adult care facility regulated pursuant to Parts 487, 488 and 490 of Title 18 of the NYCRR and Part 1001 of this Title shall make diligent efforts to arrange for all consenting, unvaccinated existing personnel and residents to register for a vaccine appointment and an appointment to receive any recommended booster, and shall document attempts to schedule and methods used to schedule the vaccine in the individual's personnel file or case management notes, as applicable.
- (b) The operator and administrator of every adult care facility regulated pursuant to Parts 487, 488 and 490 of Title 18 of the NYCRR and Part 1001 of this Title must arrange for the COVID-19 vaccination, including the first or any recommended next or booster dose, of all new personnel, including employees and contract staff, and every resident upon admission to the

facility. The requirement to arrange for COVID-19 vaccination of such personnel and residents shall include, but not be limited to:

(1) For residents:

(i) during the pre-admission screening process, and in no event after the first day of admission, the adult care facility shall screen the prospective or newly-admitted resident for COVID-19 vaccine eligibility, including whether any first doses of the vaccine were previously administered, and whether the resident is interested in obtaining the COVID-19 vaccine, including a recommended booster. Such information shall be documented with the resident's pre-admission screening information and, if admitted, retained in the resident's case management records; and

(ii) within seven days of admission, the facility shall make diligent efforts to schedule all consenting and eligible residents for the COVID-19 vaccination, including a recommended booster. The facility must document attempts to schedule and methods used to schedule the vaccine appointment in the resident's case management notes.

(2) For personnel:

(i) during the pre-employment screening process, the facility shall solicit information from the prospective personnel regarding their vaccination status, including whether any first doses of the vaccine were previously administered, and whether the prospective personnel is interested in obtaining the COVID-19 vaccine. Such information must be documented with the personnel's pre-employment screening information and, if hired, retained in the personnel file; provided, however, that nothing in this paragraph shall be construed to require an adult care facility to make any hiring determination based upon the prospective personnel's COVID-19 vaccination status, history, or interest in COVID-

19 vaccination; and

(ii) within seven days of hiring new personnel, the facility shall make diligent efforts to schedule all consenting and eligible new personnel for the COVID-19 vaccination. The facility must document attempts to schedule and methods used to schedule the vaccine appointment in the individual's personnel file.

(iii) Adult care facilities must comply with the requirements for vaccination of personnel in 18 NYCRR §§487.9(a)(18), 488.9(a)(14), 490.9(a)(15), and 10 NYCRR §1001.11(q)(5), as applicable.

(c) The facility shall further provide all current and new personnel and residents who decline to be vaccinated a written affirmation for their signature, which indicates that they were offered the opportunity for the facility to arrange for a COVID-19 vaccination, but declined. Such affirmation must state that the signatory is aware that, if they later decide to be vaccinated for COVID-19, it is their responsibility to request the facility arrange for their vaccination. The facility shall maintain signed affirmations on file at the facility and make such forms available at the request of the Department.

66-4.3. Penalties.

(a) A violation of any provision of this Subpart shall be subject to penalties in accordance with sections 12 and 12-b of the Public Health Law.

(b) For adult care facilities, failure to arrange for the vaccination of every facility resident and personnel as set forth in section 66-4.2 of this Part constitutes a "failure in systemic practices and procedures" under Social Services Law 460-d(7)(b)(2)(iii) and pursuant to 18 NYCRR 486.5(a)(4)(v).

(c) In addition to any monetary penalties or referral for criminal investigation to appropriate entities, the Department shall be empowered to immediately take custody and control of such vaccine at a nursing home and re-allocate to another provider.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under sections 201, 206, and 2803 of the Public Health Law (PHL) and sections 461 and 461-e of the Social Services Law (SSL).

PHL § 201 authorizes the New York State Department of Health (Department) to control and promote the control of communicable diseases to reduce their spread. Likewise, PHL § 206 authorizes the Commissioner of Health to take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law, including control of communicable diseases.

PHL § 2803 authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities.

SSL § 461 requires the Department to promulgate regulations establishing general standards applicable to Adult Care Facilities (ACF). SSL § 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 objectives of PHL §§ 201 and 206 are to protect the health and life of the people of the State of New York, including by controlling the spread of communicable diseases. The legislative objectives of PHL Article 28, including PHL § 2803, include the efficient provision and proper utilization of health services of the highest quality. The legislative objective of SSL § 461 is to promote the health and well-being of residents of adult care

facilities. Collectively, the legislative purpose of these statutes is to protect the residents of New York's long-term care facilities by providing safe, efficient, and adequate care.

Needs and Benefits:

These regulations are necessary to prevent the spread of COVID-19 in nursing homes and adult care facilities and to help ensure the health and life of residents of nursing homes and ACFs by requiring such congregate care facilities to offer or arrange for consenting residents and personnel to receive the COVID-19 vaccine. This requirement will help ensure residents are less likely to suffer a COVID-related death or severe illness and that fewer staff test positive for COVID-19. To date, there are an approximate 8,200 (9%) nursing home and 1,100 (4%) adult care facility residents that remain unvaccinated. As such, the potential for COVID-19 introduction or re-introduction to this vulnerable population remains a risk and the need for protecting their health and safety a top high priority.

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. Given the disproportionate adverse health impacts of COVID-19 for older adults and those with comorbidities, many of whom reside in New York's nursing homes and ACFs, it is imperative that nursing homes and ACFs facilitate the prompt vaccination of its residents. Moreover, in order to ensure that nursing home and ACF personnel can safely provide resident care, it is critically important that nursing homes offer continued COVID-19 vaccinations on-site for their current and new personnel and that ACFs arrange for

their current and new personnel to receive the COVID-19 vaccine at an off-site location, such as a pharmacy.

Based on the foregoing, the Department has made the determination that this emergency regulation is necessary to best protect the residents of New York's nursing homes and ACFs.

COSTS:

Costs to Regulated Parties:

The purpose of this regulation is to require nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. For nursing homes, costs are expected to be minimal given that the COVID-19 vaccine is provided free of charge, and Medicare reimbursement is available to help Medicare-enrolled nursing homes cover administrative costs; specifically, pursuant to April 2, 2021 guidance from the Centers for Medicare & Medicaid Services (CMS), "starting on March 15, 2021, for single dose COVID-19 vaccines, Medicare pays approximately \$40 for its administration. Starting on March 15, 2021, for COVID-19 vaccines requiring multiple doses, Medicare pays approximately \$40 for each dose in the series." Nursing homes will need in some circumstances to absorb the administrative costs associated with reporting doses of vaccine administered to the appropriate vaccine registry when not reported by an outside vendor or pharmacy provider.

For ACFs, costs to facilities are minimal to none, as ACFs will be responsible for arranging vaccinations at off-site locations, such as a local pharmacy. Many ACFs have vehicles which can be used for necessary transport, but there may be minimal costs associated with transportation, particularly if the distance to the vaccination site is great and/or if the ACF does not readily have access to a vehicle.

Costs to Local and State Governments:

This regulation will not impact local or State governments unless they operate a nursing home or ACF, in which case costs will be the same as costs for private entities. Currently, there are 21 nursing homes operated by local governments (counties and municipalities) and 6 nursing homes operated by the State. Additionally, there are currently two adult care facilities operated by county governments.

Costs to the Department of Health:

This regulation will not result in any additional operational costs to the Department of Health.

Paperwork:

This regulation imposes no additional paperwork. Although the regulation requires recordkeeping by facilities, including documentation in personnel files and resident clinical or case management records, these records must already be maintained by facilities.

Local Government Mandates:

Nursing homes and ACFs operated by local governments will be affected and will be subject to the same requirements as any other nursing home licensed under PHL Article 28 or ACF licensed under SSL Article 7, Title 2.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

The Department believes that promulgation of this regulation is the most effective means of ensuring that nursing homes and ACFs adequately ensure their residents and personnel are vaccinated against COVID-19. Accordingly, the alternative of not issuing these regulations was rejected.

Federal Standards:

No federal standards apply.

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a nursing home or ACF. Currently, there are 21 nursing homes operated by local governments (counties and municipalities) and 6 nursing homes operated by the State. Additionally, there are currently two ACFs operated by county governments (Chenango and Warren Counties).

Additionally, to date, 79 nursing homes in New York qualify as small businesses given that they have 100 or fewer employees. There are also 483 ACFs that have 100 or fewer employees and therefore qualify as small businesses.

Compliance Requirements:

This regulation primarily requires nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. Specifically, nursing homes will be required to offer ongoing COVID-19 vaccinations at the facility, and ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or a local pharmacy. The regulation also requires facilities to provide all current and new personnel and residents who decline to be vaccinated a written affirmation for their signature, which indicates that they were offered the opportunity for the facility to arrange for or offer, as applicable, a COVID-19 vaccination, but they declined. Further, nursing homes are required to post conspicuous signage throughout the facility reminding personnel and residents that the facility offers COVID-19 vaccinations.

Professional Services:

No professional services are required by this regulation. However, nursing homes may choose to partner with a pharmacy to offer COVID-19 vaccinations for personnel and residents of the facility, rather than receiving and administering the vaccine directly.

Compliance Costs:

This regulation requires nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. Specifically, nursing homes will be required to offer ongoing COVID-19 vaccinations at the facility, and ACFs will be responsible for arranging vaccinations at off-site locations, such as a local pharmacy. For nursing homes, costs are expected to be minimal given that the COVID-19 vaccine is provided free of charge, and Medicare reimbursement is available to help Medicare-enrolled nursing homes cover administrative costs; specifically, pursuant to April 2, 2021 guidance from the Centers for Medicare & Medicaid Services (CMS), “starting on March 15, 2021, for single dose COVID-19 vaccines, Medicare pays approximately \$40 for its administration. Starting on March 15, 2021, for COVID-19 vaccines requiring multiple doses, Medicare pays approximately \$40 for each dose in the series.” Nursing homes will need in some circumstances to absorb the administrative costs associated with reporting doses of vaccine administered to the appropriate vaccine registry when not reported by an outside vendor or pharmacy provider.

For ACFs, costs to facilities are minimal to none, as ACFs will be responsible for arranging vaccinations at off-site locations, such as a local pharmacy. Many ACFs have vehicles which can be used for necessary transport, but there may be minimal costs associated with

transportation particularly if the distance to the vaccination site is great and/or if the ACF does not readily have access to a vehicle.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is consistent with the existing responsibilities nursing homes and ACFs have to maintain the health and safety of residents, ensure sufficient staffing levels, and ensure staff are free from communicable diseases. Therefore, any adverse impacts are expected to be minimal and are outweighed by the regulation's health and safety benefits to residents and staff.

Small Business and Local Government Participation:

Due to the urgent need to ensure ACF and NH staff and residents are vaccinated as soon as possible given the seriousness of COVID-19 if contracted, particularly by older adults or persons with comorbidities, small business and local governments were not directly consulted. However, the Department will notify such entities of the existence of these regulations and the opportunity to submit comments or questions to the Department.

Cure Period:

This regulation does not include a cure period given the serious threat the COVID-19 virus causes to all New Yorkers, particularly those residing in nursing homes and adult care facilities, considering such residents' age and comorbidities. As detailed more fully within the

regulations, nursing homes and adult care facilities will have 14 and 7 days, respectively, to offer vaccinations to residents and staff. The Department finds these 14- and 7-day periods to comply with the regulatory requirements are sufficient to ensure facilities can establish or revise their vaccination policies and procedures, while balancing the urgent need to protect facility residents and personnel from this dangerous disease.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

Although 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 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

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 the United States Census estimated county populations for 2010:

Albany County
Broome County
Dutchess County
Erie County

Monroe County
Niagara County
Oneida County
Onondaga County

Orange County
Saratoga County
Suffolk County

Both licensed nursing homes and ACFs are located in these identified rural areas.

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

This regulation imposes no additional paperwork. Although the regulation requires recordkeeping by facilities, including documentation in personnel files and resident clinical or case management records, these records must already be maintained by facilities. Additionally, no professional services are required by this regulation. However, nursing homes may choose to partner with a pharmacy to offer COVID-19 vaccinations for personnel and residents of the facility, rather than receiving and administering the vaccine directly.

Compliance Costs:

This regulation requires nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. Specifically, nursing homes will be required to offer ongoing COVID-19 vaccinations at the facility, and ACFs will be responsible for arranging vaccinations at off-site locations, such as a local pharmacy. For nursing homes, costs are expected to be minimal given that the COVID-19 vaccine is provided free of charge, and Medicare reimbursement is available to help Medicare-enrolled nursing homes cover

administrative costs; specifically, pursuant to April 2, 2021 guidance from the Centers for Medicare & Medicaid Services (CMS), “starting on March 15, 2021, for single dose COVID-19 vaccines, Medicare pays approximately \$40 for its administration. Starting on March 15, 2021, for COVID-19 vaccines requiring multiple doses, Medicare pays approximately \$40 for each dose in the series.” Nursing homes will need in some circumstances to absorb the administrative costs associated with reporting doses of vaccine administered to the appropriate vaccine registry when not reported by an outside vendor or pharmacy provider.

For ACFs, costs to facilities are minimal to none, as ACFs will be responsible for arranging vaccinations at off-site locations, such as a local pharmacy. Many ACFs have vehicles which can be used for necessary transport, but there may be minimal costs associated with transportation particularly if the distance to the vaccination site is great and/or if the ACF does not readily have access to a vehicle.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is consistent with the existing responsibilities nursing homes and ACFs have to maintain the health and safety of residents, ensure sufficient staffing levels, and ensure staff are free from communicable diseases. Therefore, any adverse impacts are expected to be minimal and are outweighed by the regulation’s health and safety benefits to residents and staff.

Rural Area Participation:

Due to the urgent need to ensure ACF and NH staff and residents are vaccinated as soon as possible given the seriousness of the COVID-19 virus on this population, facilities located in rural areas were not directly consulted. However, the Department will notify covered entities located in rural areas of the existence of these regulations and the opportunity to submit comments or questions to the Department.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for these regulations is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health “Department” received comments regarding the addition of Subpart 66-4 to Part 66 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR). The comments received and the Department’s responses are summarized below.

Comment: The regulation should not apply when the COVID-19 vaccine is medically contraindicated for nursing home or adult care facility residents or staff. The Department should instead require that residents and staff be made to understand the requirements but be permitted to waive them if the individual has medical contraindications.

Response: This regulation requires nursing homes to offer COVID-19 vaccines to unvaccinated residents and personnel and to post conspicuous signage throughout the facility reminding personnel and residents that the facility offers COVID-19 vaccinations. This regulation also requires adult care facilities to arrange for unvaccinated residents and personnel to receive COVID-19 vaccinations outside of the facility (for example, at a pharmacy).

This regulation does not contain the requirement for personnel to be vaccinated. On June 22, 2022, the Department adopted and made final and permanent separate regulations in 10 NYCRR §§ 415.19(a)(5) and 1001.11(q)(5) and 18 NYCRR §§ 487.9(a)(18), 488.9(a)(14), and 490.9(a)(15) that contain personnel vaccination requirements. A medical exemption is available when the vaccine is medically contraindicated. No changes were made to the regulation in response to this comment.

Comment: This regulation closely mirrors the federal nursing home requirements already in place at 42 CFR § 483.80(d). However, the language in this State regulation differs slightly from the federal rule. This may cause confusion among surveyors and facility staff.

Response: The Department does not believe there is any conflict between the federal and State requirements, and the Department believes regulated facilities can comply with both regulations, where applicable. The Department acknowledges that the wording of the federal requirement is that “each resident and staff member is offered the COVID–19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized.”

Although worded differently, the federal and State requirements work the same in practice. All residents and personnel are offered the vaccine, but a medical exemption is available when the vaccine is medically contraindicated. Residents may refuse vaccination. The State regulation requires facilities to provide personnel and residents who decline to be vaccinated a written affirmation for their signature, which indicates that they were offered the opportunity to receive, or have arranged, a COVID-19 vaccination, but they declined. No changes to the regulation have been made in response to this comment.

Comment: There are federal and State penalties for non-compliance, and facilities are already financially stressed. This regulation has a punitive component at Section 66-4.3 which, when applicable, could further drain valuable financial resources. Moreover, adult care facility penalties are disproportionately severe in that failure to arrange for the vaccination of every resident and personnel constitutes a failure of systemic practices such that if one resident is not scheduled to receive the appropriate vaccine dose in the applicable timeframe, the facility will face harsh penalties.

Response: The penalty for non-compliance with this regulation underscores the importance of ensuring direct care staff are vaccinated and that residents have every opportunity to access to vaccination. It is important to understand that the purpose of a penalty is to compel compliance. As such, while we appreciate that some facilities are experiencing financial distress, however the language is appropriate. Regarding the characterization that failure to follow the requirements for one single resident or staff should not be considered a failure of systemic practices, the Department reminds the commenters that the nature of COVID-19 does not require multiple exposures for transmission. One single unvaccinated staff member or resident can be the precipitating factor in the death of a resident. Accordingly, one single case indeed represents a systemic failure. No change to the regulation was made in response to this comment.

Comment: The requirement to conspicuously post vaccine availability in nursing homes diminishes the homelike atmosphere of a facility. Moreover, required nursing home postings are increasing with lengthy and voluminous impersonal posters. We recommend the vaccine availability posting be limited to the staff break rooms and the facility entrance.

Response: The Department agrees with this comment, in that the homelike atmosphere of facilities can be muted by the posting of various materials. The Department believes that posting in the staff break rooms, staff locker rooms, activities rooms, and the facility's front entrance is sufficiently "conspicuous signage throughout the facility." In the Final Rule, the Department is deleting the words "including at points of entry and exit and each residential hallway" that was in Section 66-4.1(c)(1) of the Proposed Rule.

Comment: For purposes of clarity and consistency with mandates, the language at 66-4.2(b)(2)(i) should be updated to strike the following: “nothing in this paragraph shall be construed to require an adult care facility to make any hiring determination based upon the prospective personnel’s COVID-19 vaccination status, history, or interest in COVID-19 vaccination.”

Response: The Department believes that, as written, the regulation is clear and consistent. No changes to the regulation were made in response to this comment.

Comment: Adult care facility residents remain in “admitted” status even when they are not present at the facility, for example, when they are in a rehabilitation facility. When a resident is formally discharged and later wishes to return to the adult care facility from which they were discharged, such process is handled as a new admission. Accordingly, the regulation at Section 66-4.2 should remove the terms “readmission” and “readmitted,” as such term is not recognized in the adult care facility setting and such use will cause interpretive confusion.

Response: The Department agrees with this comment. The Final Rule deletes the terms “readmission” and “readmitted” from Section 66-4.2.