

Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda and Informational Announcements

*Thursday, July 29, 2021
10:15 AM*

Empire State Plaza, Concourse Level, Meeting Room 6, Albany

I. WELCOME AND INTRODUCTION

Angel Gutiérrez, Chair of the Committee on Codes, Regulations and Legislation

II. REGULATIONS

For Emergency Adoption

	Program Area	Unit Representative
20-22 Amendment of Sections 405.11 and 415.19 of Title 10 NYCRR (Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements)	Division of Legal Affairs	Jaclyn Sheltry
	Office of Primary Care and Health Systems Management	Laura Palmer
21-06 Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel)	Division of Legal Affairs	Jaclyn Sheltry
	Office of Primary Care and Health Systems Management	Laura Palmer
21-07 Amendment of Section 415.3 of Title 10 NYCRR and Addition of Section 485.18 to Title 18 NYCRR (Personal Caregiving and Compassionate Caregiving Visitors in Nursing Homes and Adult Care Facilities)	Division of Legal Affairs	Jacklyn Sheltry
	Office of Primary Care and Health Systems Management	Laura Palmer
20-24 Addition of Sections 1.2, 700.5 and Part 360 to Title 10 NYCRR; Amendment of Sections 400.1, 405.24 & 1001.6 of Title 10 NYCRR and Sections 487.3, 488.3 and 490.3 of Title 18 NYCRR (Surge and Flex Health Coordination System)	Division of Legal Affairs	Jonathan Karmel
	Office of Primary Care and Health Systems Management	Dr. Richard Becker
TO BE DISTRIBUTED UNDER SEPARATE COVER		
20-06 Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to Title 10 NYCRR (Investigation of Communicable Disease; Isolation and Quarantine)	Division of Legal Affairs	Vanessa Murphy
	Program Staff	TBD

20-07 Amendment of Part 66 of Title 10
NYCRR (Enforcement of Social Distancing
Measures)

Division of Legal
Affairs

Vanessa Murphy

Program Staff

TBD

20-27 Amendment of Section 405.11 and
Addition of New Sections 77.13, 77.14 and
415.33 to Title 10 NYCRR (COVID-19
Confirmatory Testing)

Division of Legal
Affairs

Vanessa Murphy

Program Staff

TBD

Pursuant to the authority vested in the Commissioner of Health by Section 2803 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by amending sections 405.11 and 415.19, to be effective upon filing with the Secretary of State, to read as follows:

Section 405.11 is amended by adding a new subdivision (g) as follows:

(g) (1) The hospital shall possess and maintain a supply of all necessary items of personal protective equipment (PPE) sufficient to protect health care personnel, consistent with federal Centers for Disease Control and Prevention guidance, for at least 60 days, by August 31, 2021.

(2) The 60-day stockpile requirement set forth in paragraph (1) of this subdivision shall be determined by the Department as follows for each type of required PPE:

(i) for single gloves, fifteen percent, multiplied by the number of the hospital's staffed beds as determined by the Department, multiplied by 550;

(ii) for gowns, fifteen percent, multiplied by the number of the hospital's staffed beds as determined by the Department, multiplied by 41;

(iii) for surgical masks, fifteen percent, multiplied by the number of the hospital's staffed beds as determined by the Department, multiplied by 21; and

(iv) for N95 respirator masks, fifteen percent, multiplied by the number of the hospital's staffed beds as determined by the Department, multiplied by 9.6.

(3) The Commissioner shall have discretion to increase the stockpile requirement set forth in paragraph (1) of this subdivision from 60 days to 90 days where there is a State or local public

health emergency declared pursuant to Section 24 or 28 of the Executive Law. Hospitals shall possess and maintain the necessary 90-day stockpile of PPE by the deadline set forth by the Commissioner.

(4) Failure to possess and maintain the required supply of PPE may result in the revocation, limitation, or suspension of the hospital's license; provided, however, that no such revocation, limitation, or suspension shall be ordered unless the Department has provided the hospital with a fourteen day grace period, solely for a hospital's first violation of this section, to achieve compliance with the requirement set forth herein.

Section 415.19 is amended by adding a new subdivision (f) as follows:

(f) (1) The nursing home shall possess and maintain a supply of all necessary items of personal protective equipment (PPE) sufficient to protect health care personnel, consistent with federal Centers for Disease Control and Prevention guidance, for at least 60 days, by August 31, 2021.

(2) The 60-day stockpile requirement set forth in paragraph (1) of this subdivision shall be determined by the Department as follows for each type of required PPE:

(i) for single gloves, the applicable positivity rate, multiplied by the number of certified nursing home beds as indicated on the nursing home's operating certificate, multiplied by 24;

(ii) for gowns, the applicable positivity rate, multiplied by the number of certified nursing home beds as indicated on the nursing home's operating certificate, multiplied by 3;

(iii) for surgical masks, the applicable positivity rate, multiplied by the number of certified nursing home beds as indicated on the nursing home's operating certificate, multiplied by 1.5; and

(iv) for N95 respirator masks, the applicable positivity rate, multiplied by the number of certified nursing home beds as indicated on the nursing home's operating certificate, multiplied by 1.4.

(v) For the purposes of this paragraph, the term "applicable positivity rate" shall mean the greater of the following positivity rates:

(a) The nursing home's average COVID-19 positivity rate, based on reports made to the Department, during the period April 26, 2020 through May 20, 2020; or

(b) The nursing home's average COVID-19 positivity rate, based on reports made to the Department, during the period January 3, 2021 through January 31, 2021; or

(c) 20.15 percent, representing the highest Regional Economic Development Council average COVID-19 positivity rate, as reported to the Department, during the periods April 26, 2020 through May 20, 2020 and January 3, 2021 through January 31, 2021.

(3) Failure to possess and maintain the required supply of PPE may result in the revocation, limitation, or suspension of the nursing home's license; provided, however, that no such revocation, limitation, or suspension shall be ordered unless the Department has provided the nursing home with a fourteen day grace period, solely for a nursing home's first violation of this section, to achieve compliance with the requirement set forth herein.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 2803 of the Public Health Law (PHL) 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, including hospitals and nursing homes.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection and promotion of the health of the residents of the State by requiring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

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.

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. Given New York's dramatic progress against COVID-19, with the success in vaccination rates, and declining hospitalization and positivity statewide, the declared state disaster emergency expired on June 24, 2021. Nevertheless, this does not mean that COVID-19 is gone, as the threat of COVID-19 still remains.

In order for hospital and nursing home staff to safely provide care for COVID-19 positive patients and residents, or patients and residents infected with another communicable disease, while ensuring that they themselves do not become infected with COVID-19 or any other communicable disease, it is critically important that personal protective equipment (PPE), including masks, gloves, respirators, face shields and gowns, is readily available and are used. Therefore, as a result of global PPE shortages at the outset of the State of Emergency, New York State provided general hospitals, nursing homes, and other medical facilities with PPE from the State's emergency stockpile from the beginning of the COVID-19 outbreak. However, hospitals and nursing homes must ensure sufficient PPE stockpiles exist for any future communicable disease outbreaks to ensure each facility is adequately prepared to protect its staff and patients or residents, without needing to rely on the State's emergency stockpile.

Based on the foregoing, the Department has made the determination that this emergency regulation is necessary to ensure that all general hospitals and nursing homes maintain a 60-day supply of PPE to ensure that sufficient PPE is available in the event of a continuation or resurgence of the COVID-19 outbreak or another communicable disease outbreak.

COSTS:

Costs to Regulated Parties:

The purpose of this regulation is to require general hospitals and nursing homes to maintain adequate stockpiles of PPE. The initial cost to facilities as they establish stockpiles of PPE will vary depending on the number of staff working at each facility. However, the Department anticipates that hospitals and nursing homes will routinely use stockpiled PPE as part of their routine operations; while facilities must maintain the requisite stockpile at all times in the event of an emergency need, facilities are expected to rotate through their stockpiles routinely to ensure the PPE does not expire and is replaced with new PPE, thereby helping to balance facility expenditures over time. Further, in the event of an emergency need, hospitals and nursing homes are expected to tap into their stockpiles; as such, hospitals and nursing homes will ultimately use equipment which would have been purchased had a stockpile not existed, thereby mitigating overall costs. Moreover, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). As such, this regulation imposes no long-term additional costs to regulated parties.

Costs to Local and State Governments:

This regulation will not impact local or State governments unless they operate a general hospital or nursing home, in which case costs will be the same as costs for private entities.

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 addition paperwork.

Local Government Mandates:

General hospitals and nursing homes operated by local governments will be affected and will be subject to the same requirements as any other general hospital licensed under PHL Article 28.

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 general hospitals and nursing homes have adequate stockpiles of PPE necessary to protect hospital staff from communicable diseases, compared to any alternate course of action.

Federal Standards:

No federal standards apply to stockpiling of such equipment at hospitals.

Compliance Schedule:

The regulations will become effective upon filing with the Department of State. These regulations are expected to be proposed for permanent adoption at a future meeting of the Public Health and Health Planning Council.

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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 general hospital or a nursing home. Currently there are five general hospitals in New York that employ less than 100 staff and qualify as small businesses, and there are 79 nursing homes in New York qualify as small businesses given that they employ less than 100 staff.

Compliance Requirements:

These regulations require all general hospitals and nursing homes to purchase and maintain adequate stockpiles of PPE, including but not limited to masks, respirators, face shields and gowns.

Professional Services:

It is not expected that any professional services will be needed to comply with this rule.

Compliance Costs:

The purpose of this regulation is to require general hospitals and nursing homes to maintain adequate stockpiles of PPE. The initial cost to facilities as they establish stockpiles of PPE will vary depending on the number of staff working at each covered facility. However, the Department anticipates that hospitals and nursing homes will routinely use stockpiled PPE as part of their routine operations; while facilities must maintain the requisite stockpile at all times in the event of an emergency need, facilities are expected to rotate through their stockpiles routinely to ensure the PPE does not expire and is replaced with new PPE, thereby helping to

balance facility expenditures over time. Further, in the event of an emergency need, hospitals and nursing homes are expected to tap into their stockpiles; as such, hospitals and nursing homes will ultimately use equipment which would have been purchased had a stockpile not existed, thereby mitigating overall costs. Moreover, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). As such, this regulation imposes no long-term additional costs to regulated parties.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

The Department anticipates that any adverse impacts will be minimal, as both hospitals and nursing homes have already mobilized their stockpiling efforts since early 2020, when the spread of the COVID-19 virus was first recognized in New York State, including through two surges of the COVID-19 pandemic. As such, the continuance of these stockpiling requirements is not expected to create any additional adverse impact on hospitals or nursing homes.

Moreover, for nursing homes, these PPE regulations are consistent with the existing directive in Public Health Law section 2803(12) to maintain a two-month PPE supply.

Small Business and Local Government Participation:

Small business and local governments were not directly consulted given the urgent need to ensure hospital patients and nursing home residents are adequately protected in the event of a resurgence of COVID-19 or another communicable disease outbreak. However, the Department

plans to issue an advisory to hospital CEOs and nursing home administrators alerting them to the anticipated proposed rulemaking on these regulations and opportunity to submit public comments.

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

There are 47 general hospitals located in rural areas as well as several licensed nursing homes.

Reporting, Recordkeeping, and Other Compliance Requirements; and Professional Services:

These regulations require all general hospitals and nursing homes, including those in rural areas, to purchase and maintain adequate stockpiles of PPE, including but not limited to masks, respirators, face shields and gowns.

Compliance Costs:

The purpose of this regulation is to require general hospitals and nursing homes to maintain adequate stockpiles of PPE. The initial cost to facilities as they establish stockpiles of PPE will vary depending on the number of staff working at each facility. However, the Department anticipates that hospitals and nursing homes will routinely use stockpiled PPE as

part of their routine operations; while facilities must maintain the requisite stockpile at all times in the event of an emergency need, facilities are expected to rotate through their stockpiles routinely to ensure the PPE does not expire and is replaced with new PPE, thereby helping to balance facility expenditures over time. Further, in the event of an emergency need, hospitals and nursing homes are expected to tap into their stockpiles; as such, hospitals and nursing homes will ultimately use equipment which would have been purchased had a stockpile not existed, thereby mitigating overall costs. Moreover, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). Therefore, this regulation imposes no long-term additional costs to regulated parties.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

The Department anticipates that any adverse impacts will be minimal, as both hospitals and nursing homes have already mobilized their stockpiling efforts since early 2020, when the spread of the COVID-19 virus was first recognized in New York State, including through two surges of the COVID-19 pandemic. As such, the continuance of these stockpiling requirements is not expected to create any additional adverse impact on hospitals or nursing homes.

Moreover, for nursing homes, these PPE regulations are consistent with the existing directive in Public Health Law section 2803(12) to maintain a two-month PPE supply.

Rural Area Participation:

Parties representing rural areas were not directly consulted given the urgent need to ensure hospital patients and nursing home residents are adequately protected in the event of a resurgence of COVID-19 or another communicable disease outbreak. However, the Department plans to issue an advisory to hospital CEOs and nursing home administrators alerting them to the anticipated proposed rulemaking and opportunity to submit public comments.

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.

EMERGENCY JUSTIFICATION

These regulations are needed on an emergency basis to ensure hospital and nursing home staff, as well as the patients and residents for whom they provide care, are adequately protected in the event of a resurgence of the 2019 Coronavirus (COVID-19) or another communicable disease outbreak. These regulations are specifically meant to address the lessons learned in New York State during the COVID-19 pandemic with respect to PPE.

Specifically, 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.

The federally-declared public health emergency was recently extended by the Secretary of Health and Human Services on April 15, 2021 and currently remains in effect through July 14, 2021. Likewise, on February 24, 2021, President Joseph R. Biden extended the national emergency pursuant to the National Emergencies Act (50 U.S.C. 1622(d)).

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. However, as a result of global PPE shortages, many hospitals and nursing homes in New York State had difficulty obtaining adequate PPE necessary to care for their patients and residents. New York State provided general hospitals, nursing homes, and

other medical facilities with PPE from the State's emergency stockpile from the beginning of the COVID-19 outbreak.

However, these regulations are needed on an emergency basis to ensure that hospitals and nursing homes Statewide do not again find themselves in need of PPE from the State's stockpile should another communicable disease outbreak occur, COVID-19 or otherwise. It is critically important that PPE, including masks, gloves, respirators, face shields and gowns, is readily available and used when needed, as hospital and nursing home staff must don all required PPE to safely provide care for patients and residents with communicable diseases, while ensuring that they themselves do not become infected with a communicable disease.

Based on the foregoing, the Department has made the determination that this emergency regulation is necessary to ensure that all general hospitals and nursing homes maintain a 60-day supply of PPE to ensure that sufficient PPE is available in the event of a resurgence of COVID-19 or another communicable disease outbreak.

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 filing with the Secretary of State, 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) Within fourteen days of the effective date of this regulation, 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 required next 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 required next 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, including at points of entry and exit and each residential hallway, reminding personnel and residents that the facility offers COVID-19 vaccination;
- (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; and
- (3) Certifying to the Department, in a manner and frequency prescribed by the Commissioner, but in no event more often than weekly, that the facility has proactively offered all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within fourteen days of being hired, admitted, or readmitted.

66-4.2. Requirements for Adult Care Facilities

- (a) Within seven days of the effective date of this regulation, 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 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 required next dose, of all new personnel, including employees and contract staff, and every new resident and resident readmitted 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 or readmission, the adult care facility shall screen the prospective or newly-admitted or readmitted 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. 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 or readmission, the facility shall make diligent efforts to schedule all consenting and eligible new or readmitted residents for the COVID-19 vaccination. 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; and

(3) Certifying to the Department, in a manner and frequency prescribed by the Commissioner, but in no event more often than weekly, that the facility has proactively arranged for all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within seven days of being hired, admitted, or readmitted.

(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 66-4.3 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.

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.”

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 filing with the Department of State.

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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. Additionally, nursing homes and ACFs will be required to certify to the Department that the facility has proactively arranged for or offered, as applicable, all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within the prescribed period of time. 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.”

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.”

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.

EMERGENCY JUSTIFICATION

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. According to Johns Hopkins' Coronavirus Resource Center, as of July 14, 2021, there have been over 188 million cases and over 4 million deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

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 local 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.

SUMMARY OF EXPRESS TERMS

These regulations are intended to implement section 2801-h of the Public Health Law (PHL) and section 461-u of the Social Services Law (SSL), as enacted by Chapter 108 of the Laws of 2021. These statutory amendments required the Commissioner of Health to promulgate regulations governing personal caregiving visitors in all licensed nursing homes and adult care facilities. According to the statute, a “personal caregiving visitor” means a family member, close friend, or legal guardian of a resident designated by such resident, or such resident’s lawful representative, to assist with personal caregiving or compassionate caregiving for the resident. Personal caregiving is defined as care and support of a resident to benefit such resident’s mental, physical, or social well-being, and compassionate caregiving is defined as personal caregiving provided in anticipation of the end of the resident’s life or in the instance of significant mental, physical or social decline or crisis (*see* PHL § 2801-h[1][a-c], SSL § 461-u[1][a-c]).

In accordance with the statutory directive, the new regulatory sections amend 10 NYCRR 415.3(d) to add new paragraphs (3), (4), and (5) concerning, respectively, personal caregiving visitation, additional provisions relating to compassionate caregiving, and authority for the Department of Health to review a nursing home’s personal caregiving visitation policies and procedures. Likewise, for adult care facilities, the regulation adds a new section 485.18 of 18 NYCRR to address general visitation rights in an adult care facility (section 485.18[b]), personal caregiving visitation (section 485.18[c]), additional provisions relating to compassionate caregiving (section 485.18[d]), and authority for the Department of Health to review an adult care facility’s personal caregiving visitation policies and procedures (section 485.18[e]).

More specifically, the regulatory amendments relating to personal caregiving visitation, as contained in the new 10 NYCRR 415.3(d)(3) and 18 NYCRR 485.18(c), provide that such

visitation shall be permitted in a nursing home and adult care facility during a public health emergency declared under section twenty-four or section twenty-eight of the Executive Law, notwithstanding general visitation restrictions in the facility, and subject to certain limitations, including the need to limit or temporarily suspend personal caregiving visitation due to an increase in local infection rates, temporary inadequate staff capacity, an acute emergency situation such as loss of an essential service, or because the personal caregiving visitor poses a threat to the safety and well-being of the resident or any resident or personnel in the facility. The regulations governing personal caregiving visitation further: (i) set forth procedures for residents or their lawful representatives to designate and change their designation of personal caregiving visitors; (ii) provide that a resident shall be entitled to designate at least two personal caregiving visitors; (iii) require that all personal caregiving visitors follow infection prevention safety protocols required for nursing home and adult care facility staff, such as communicable disease testing, health screenings, and donning appropriate personal protective equipment; and (iv) set forth standards for a facility to determine the maximum frequency and duration of personal caregiving visits and the total number of personal caregiving visitors allowed to visit the facility at any one time.

The new 10 NYCRR 415.3(d)(4) and 18 NYCRR 485.18(d) establish additional provisions for compassionate caregiving provided by personal caregiving visitors. These sections set forth the situations in which a resident is eligible for a compassionate caregiving visitor and the requirements for screening compassionate caregiving visitors prior to their entry into the facility.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2801-h and 2803 of the Public Health Law and sections 461, 461-e, and 461-u of the Social Services Law, Section 415.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended and a new Section 485.18 of Title 18 of the NYCRR is hereby added, to be effective upon filing with the Secretary of State, to read as follows:

Subparagraph (iv) of paragraph (2) of subdivision (d) of Section 415.3 of 10 NYCRR is amended to read as follows:

(iv) provide immediate access to any resident by the following:

* * *

(f) immediate family or other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time; [and]

(g) personal caregiving visitors, as defined in subdivision (1) of section 2801-h of the Public Health Law and pursuant to criteria specified in paragraph (3) of this subdivision, including those providing compassionate caregiving, as defined in subdivision (1) of section 2801-h of the Public Health Law and pursuant to criteria specified in paragraph (4) of this subdivision; and

[(g)] (h) others who are visiting with the consent of the resident, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time;

Subdivision (d) of Section 415.3 of 10 NYCRR is amended to add new paragraphs (3), (4), and (5) to read as follows:

(3) Personal caregiving visitors.

(i) During a public health emergency declared under section twenty-four or section twenty-eight of the executive law, the facility must continue to allow residents to access their designated personal caregiving visitors, notwithstanding any restrictions or prohibitions relating to residential health care visitation resulting from the declared public health emergency, subject to the following restrictions:

(a) If a facility has reasonable cause to believe that a resident will not benefit from accessing their designated personal caregiving visitors, and such reasoning has been documented in the resident's individualized comprehensive plan of care, a facility may require a health or mental health professional duly licensed or certified in New York State under the Education Law, and who need not be associated with the nursing home, including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist, to provide a written statement that the personal caregiving will substantially benefit the resident's quality of life, including a statement from such medical provider that the personal caregiving visitation will enhance the resident's mental, physical, or psychosocial well-being, or any additional criteria evidencing a benefit to quality of life as determined by the Department. Such written statements from the medical provider shall be maintained in the resident's individualized comprehensive plan of care.

(b) Notwithstanding any provision of this subparagraph (i), a facility may temporarily suspend or limit personal caregiving visitors to protect the health, safety and welfare of residents if: the declared public health emergency is related to a communicable disease and the Department determines that local infection rates are at a level that presents a serious risk of transmission of such communicable disease within local facilities; the

facility is experiencing temporary inadequate staffing and has reported such staffing shortage to the Department of Health and any other State or federal agencies as required by law, regulation, or other directive; or an acute emergency situation exists at the facility, including loss of heat, loss of elevator service, or other temporary loss of an essential service. Provided, however, that in the event a facility suspends or limits personal caregiving visitation pursuant to this clause, the facility shall notify residents, all designated personal caregiving visitors, and the applicable Department regional office of such suspension or limitation and the duration thereof within twenty-four hours of implementing the visitation suspension or limitation. Additionally, for each day of the suspension or limitation, the facility shall document the specific reason for the suspension or limitation in their administrative records. The facility shall further provide a means for all residents to engage in remote visitation with their designated personal caregiving visitor(s), including but not limited to phone or video calls, until such time that the suspension or limitation on personal caregiving visitation has ended.

(c) Notwithstanding any provision of this subparagraph (i), a facility may prohibit a personal caregiving visitor from entering if the facility has reasonable cause to believe that permitting the personal caregiving visitor to meet with the resident is likely to pose a threat of serious physical, mental, or psychological harm to such resident. In the event the facility determines that denying such personal caregiving visitor access to the resident is in the resident's best interests pursuant to this subparagraph, the facility must document the date of and reason for visitation refusal in the resident's individualized comprehensive plan of care, and on the same date of the refusal the facility shall communicate its decision to the resident and their designated representative. Further, a

facility may refuse access to or remove from the premises any personal caregiving visitor who is causing or reasonably likely to cause physical injury to any facility resident or personnel.

(ii) The facility shall develop written policies and procedures to ask residents, or their designated representatives in the event the resident lacks capacity, at time of admission or readmission, or for existing residents within fourteen days of the effective date of this paragraph, which individuals the resident elects to serve as their personal caregiving visitor during declared public health emergencies. A resident shall be entitled to designate at least two personal caregiving visitors at one time.

(iii) The facility shall maintain a written record of the resident's designated personal caregiving visitors in the resident's individualized comprehensive plan of care, and shall document when personal caregiving and compassionate caregiving is provided in the resident's individualized comprehensive plan of care.

(iv) As part of its ongoing review of a resident's comprehensive plan of care, the facility shall regularly inquire of all current residents, or their designated representative if the resident lacks capacity, whether the facility's current record of designated personal caregiving visitors remains accurate, or whether the resident, or their designated representative if the resident lacks capacity, wishes to make any changes to their personal caregiving visitor designations. The facility shall update the resident's individualized comprehensive plan of care with the date the facility sought updates from the resident and indicate any changes to the resident's personal caregiving visitor designations therein. Such inquiries shall be made no less frequently than quarterly and upon a change in the resident's condition; upon review of a facility's visitation policies and procedures,

the Department may also require the facility inquire of any resident whether the facility's current record of designated personal caregiving visitors remains accurate.

(v) The facility shall require all personal caregiving visitors to adhere to infection control measures established by the facility and consistent with any guidelines from the Department, or in the absence of applicable Department guidance, consistent with long term care facility infection control guidelines from the U.S. Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services. Such infection control measures may include, but need not be limited to:

(a) testing all personal caregiving visitors for any communicable disease that is the subject of the declared public health emergency, which may include rapid on-site testing or requiring the visitor to present a negative test result dated no more than seven days prior to the visit;

(b) checking the personal caregiving visitor's body temperature upon entry to the facility, and denying access to any visitor with a temperature above 100 degrees Fahrenheit;

(c) conducting health screenings of all personal caregiving visitors upon entry to the facility, including screenings for signs and symptoms of any communicable disease that is the subject of the declared public health emergency or any other communicable disease which is prevalent in the facility's geographic area, and recording the results of such screenings;

(d) requiring all personal caregiving visitors to don all necessary personal protective equipment appropriately, and providing such personal protective equipment to all personal caregiving visitors; and

(e) enforcing social distancing between persons during visitation, including personal caregiving visitation, except as necessary to provide personal caregiving by the personal caregiving visitor for the resident.

(vi) The facility shall establish policies and procedures regarding the frequency and duration of personal caregiving visits and limitations on the total number of personal caregiving visitors allowed to visit the resident and the facility at any one time. Such policies shall not be construed to limit access by other visitors that would otherwise be permitted under state or federal law or regulation. The facility shall ensure its policies and procedures respect resident privacy and take into account visitation protocols in the event a resident occupies a shared room. In establishing frequency and duration limits, the facility policy shall ensure that residents are able to receive their designated personal caregiving visitors for the resident's desired frequency and length of time, and any restrictions on that desired frequency and duration must be:

(a) attributable to the resident's clinical or personal care needs;

(b) necessary to ensure the resident's roommate has adequate privacy and space to receive their own designated personal caregiving visitors; or

(c) because the desired visitation frequency or duration would impair the effective implementation of applicable infection control measures, including social distancing of at least six feet between the visitors and others in the facility, having sufficient staff to effectively screen all personal caregiving visitors and monitor visits to ensure infection control protocols are being followed throughout, and having a sufficient supply of necessary personal protective equipment for all personal caregiving visitors.

(4) Compassionate caregiving.

(i) In the event a resident experiences a long-term or acute physical, mental, or psychosocial health condition for which, in the opinion of the resident, their representative, or a health care professional (including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist), a compassionate caregiving visitor would improve the resident's quality of life, the resident or their representative shall designate at least two compassionate caregiving visitors at one time, and the facility shall record such designation in the resident's individualized comprehensive plan of care. A resident's designated personal caregiving visitors may also provide compassionate caregiving.

(ii) Situations in which a resident is eligible for a compassionate caregiving visitor include but are not limited to the following:

(a) end of life;

(b) the resident, who was living with their family before recently being admitted to an adult care facility, is struggling with the change in environment and lack of physical family support;

(c) the resident is grieving after a friend or family member recently passed away;

(d) the resident needs cueing and encouragement with eating or drinking, and such cueing was previously provided by family and/or caregiver(s), and the resident is now experiencing weight loss or dehydration; and

(e) the resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

(iii) Compassionate caregiving visitation shall be permitted at all times, regardless of any general visitation restrictions or personal caregiving visitation restrictions in effect in the facility.

Provided, however, that the facility shall require compassionate caregiving visitors to be screened for communicable diseases prior to entering the facility and visits must be conducted using appropriate social distancing between the resident and visitor if applicable based on guidance from the Department or the U.S. Centers for Disease Control and Prevention; if, however, personal contact would be beneficial for the resident's mental or psychosocial well-being, the facility shall establish policies and procedures to ensure that such necessary physical contact follows appropriate infection prevention guidelines, including the visitor's use of personal protective equipment and adhering to hand hygiene protocols before and after resident contact, and that the physical contact is limited in duration.

(5) The Department shall have discretion to review and require modifications to a facility's personal caregiving visitation and compassionate caregiving visitation policies and procedures to ensure conformity with paragraphs (3) and (4) of this subdivision and any applicable visitation guidelines issued by the Department or the Centers for Medicare and Medicaid Services.

A new Section 485.18 of 18 NYCRR, titled Personal and Compassionate Caregiving Visitation, is added to read as follows:

(a) This section shall apply to all adult care facilities, including every adult care facility regulated pursuant to Parts 487, 488 and 490 of this Title and Part 1001 of Title 10 of the NYCRR.

(b) Subject to the resident's right to deny or withdraw consent at any time, all adult care facilities must provide immediate access to any resident of visitors of their choice, including but not limited to immediate family or other relatives of the resident and any others who are visiting with the consent of the resident. Provided, however, that the facility may establish policies and

procedures to establish reasonable restrictions on such visitation, including but not limited to: setting forth visitation hours; denying access to any visitor suffering from a communicable disease; terminating visitation with any visitor causing a threat to the health or safety of any resident; and setting a cap on the number of visitors allowed in the facility at any one time. Any such restrictions or limitations on visitation shall be communicated in writing to residents.

(c) Personal caregiving visitors.

(1) During a public health emergency declared under section twenty-four or section twenty-eight of the executive law, the facility must continue to allow residents to access their designated personal caregiving visitors, as defined in subdivision (1) of section 2801-h of the Public Health Law, notwithstanding any restrictions or prohibitions relating to residential health care facility visitation resulting from the declared public health emergency, subject to the following restrictions:

(i) If a facility has reasonable cause to believe that a resident will not benefit from accessing their designated personal caregiving visitors, and such reasoning has been documented in the resident's case management record, a facility may require a health or mental health professional duly licensed or certified in New York State under the Education Law, and who is not associated with the facility, including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist, to provide a written statement that the personal caregiving will substantially benefit the resident's quality of life, including a statement from such medical provider that the personal caregiving visitation will enhance the resident's mental, physical, or psychosocial well-being, or any additional criteria evidencing a benefit to quality of life

as determined by the Department. Such written statements shall be maintained in the resident's case management record.

(ii) Notwithstanding any provision of this paragraph, a facility may temporarily suspend or limit personal caregiving visitors to protect the health, safety and welfare of residents, if: the declared public health emergency is related to a communicable disease and the Department determines that local infection rates are at a level that presents a serious risk of transmission of such communicable disease within local facilities; the facility is experiencing temporary inadequate staffing and has reported such staffing shortage to the Department of Health any other State or federal agencies as required by law, regulation, or other directive; or an acute emergency situation exists at the facility, including loss of heat, loss of elevator service, or other temporary loss of an essential service. Provided, however, that in the event a facility suspends or limits personal caregiving visitation pursuant to this subparagraph, the facility shall notify residents, all designated personal caregiving visitors, and the applicable Department regional office of such suspension or limitation and the duration thereof within twenty-four hours of implementing the visitation suspension or limitation. Additionally, for each day of the suspension or limitation, the facility shall document the specific reason for the suspension or limitation in their administrative records. The facility shall further provide a means for all residents to engage in remote visitation with their designated personal caregiving visitor(s), including but not limited to phone or video calls, until such time that the suspension or limitation on personal caregiving visitation has ended.

(iii) Notwithstanding any provision of this paragraph, a facility may also prohibit a personal caregiving visitor from entering if the facility has reasonable cause to believe

that permitting the personal caregiving visitor to meet with the resident is likely to pose a threat of serious physical, mental, or psychological harm to such resident. In the event the facility determines that denying such personal caregiving visitor access to the resident is in the resident's best interests pursuant to this subparagraph, the facility must document the date of and reason for visitation refusal in the resident's case management record, and on the same date of the refusal the facility shall communicate its decision to the resident and their designated representative. Further, a facility may refuse access to or remove from the premises any personal caregiving visitor who is causing or reasonably likely to cause physical injury to any facility resident or personnel.

(2) The facility shall develop written policies and procedures to ask residents, or their designated representatives in the event the resident lacks capacity, at time of admission or readmission, or for existing residents within fourteen days of the effective date of this paragraph, which individuals the resident elects to serve as their personal caregiving visitor during declared local or state health emergencies. A resident shall be entitled to designate at least two personal caregiving visitors at one time.

(3) The facility shall maintain a written record of the resident's designated personal caregiving visitors in the resident's case management record, and shall document when personal caregiving and compassionate caregiving is provided in the case management record.

(4) As part of its ongoing review of a resident's case management needs, the facility shall regularly inquire of all current residents, or their designated representative if the resident lacks capacity, whether the facility's current record of designated personal caregiving visitors remains accurate, or whether the resident, or their designated representative if the resident lacks capacity, wishes to make any changes to their personal caregiving visitor designations. The facility shall

update the resident's case management record with the date the facility sought updates from the resident and indicate any changes to the resident's personal caregiving visitor designations therein. Such inquiries shall be made no less frequently than every six months and upon a change in the resident's condition; upon review of a facility's visitation policies and procedures, the Department may also require the facility inquire of any resident whether the facility's current record of designated personal caregiving visitors remains accurate.

(5) The facility shall require all personal caregiving visitors to adhere to infection control measures established by the facility and consistent with any guidelines from the Department, or in the absence of applicable Department guidance, consistent with long term care facility infection control guidelines from the U.S. Centers for Disease Control and Prevention. Such infection control measures may include, but need not be limited to:

- (i) testing all personal caregiving visitors for any communicable disease that is the subject of the declared public health emergency, which may include rapid on-site testing or requiring the visitor to present a negative test result from no more than seven days prior to the visit;
- (ii) checking the personal caregiving visitor's body temperature upon entry to the facility, and denying access to any visitor with a temperature above 100 degrees Fahrenheit;
- (iii) conducting health screenings of all personal caregiving visitors upon entry to the facility, including screenings for signs and symptoms of any communicable disease that is the subject of the declared public health emergency or any other communicable disease which is prevalent in the facility's geographic area, and recording the results of such screenings;

(iv) requiring all personal caregiving visitors to don all necessary personal protective equipment appropriately, and providing such personal protective equipment to all personal caregiving visitors; and

(v) enforcing social distancing between persons during visitation, including personal caregiving visitation, except as necessary to provide personal caregiving by the personal caregiving visitor for the resident.

(6) The facility shall establish policies and procedures regarding the frequency and duration of personal caregiving visits and limitations on the total number of personal caregiving visitors allowed to visit the resident and the facility at any one time. Such policies shall not be construed to limit access by other visitors that would otherwise be permitted under state or federal law or regulation. The facility shall ensure its policies and procedures respect resident privacy and take into account visitation protocols in the event a resident occupies a shared room. In establishing frequency and duration limits, the facility policy shall ensure that residents are able to receive their designated personal caregiving visitors for the resident's desired frequency and length of time, and any restrictions on that desired frequency and duration must be:

(i) attributable to the resident's clinical or personal care needs;

(ii) necessary to ensure the resident's roommate has adequate privacy and space to receive their own designated personal caregiving visitors; or

(iii) because the desired visitation frequency or duration would impair the effective implementation of applicable infection control measures, including social distancing of at least six feet between the visitors and others in the facility, having sufficient staff to effectively screen all personal caregiving visitors and monitor visits to ensure infection

control protocols are being followed throughout, and having a sufficient supply of necessary personal protective equipment for all personal caregiving visitors.

(d) Compassionate caregiving.

(1) In the event a resident experiences a long-term or acute physical, mental, or psychosocial health condition for which, in the opinion of the resident, their representative, or a health care professional (including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist), a compassionate caregiving visitor would improve the resident's quality of life, the resident or their representative shall designate at least two compassionate caregiving visitors at one time, and the facility shall record such designation in the resident's case management record. A resident's designated personal caregiving visitors may also provide compassionate caregiving.

(2) Situations in which a resident is eligible for a compassionate caregiving visitor include but are not limited to the following:

(i) end of life;

(ii) the resident, who was living with their family before recently being admitted to an adult care facility, is struggling with the change in environment and lack of physical family support;

(iii) the resident is grieving after a friend or family member recently passed away;

(iv) the resident needs cueing and encouragement with eating or drinking, and such cueing was previously provided by family and/or caregiver(s), and the resident is now experiencing weight loss or dehydration; and

(v) the resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

(3) Compassionate caregiving visitation shall be permitted at all times, regardless of any general visitation restrictions or personal caregiving visitation restrictions in effect in the facility.

Provided, however, that the facility shall require compassionate caregiving visitors to be screened for communicable diseases prior to entering the facility and visits must be conducted using appropriate social distancing between the resident and visitor if applicable based on guidance from the Department or the U.S. Centers for Disease Control and Prevention; if, however, personal contact would be beneficial for the resident's well-being, the facility shall establish policies and procedures to ensure such physical contact follows appropriate infection prevention guidelines, including the visitor's use of personal protective equipment and adhering to hand hygiene protocols before and after resident contact, and that physical contact is limited in duration.

(e) The Department shall have discretion to review and require modifications to a facility's personal caregiving visitation and compassionate caregiving visitation policies and procedures to ensure conformity with subdivisions (c) and (d) of this section and any applicable visitation guidelines issued by the Department or the Centers for Medicare and Medicaid Services.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under sections 2801-h and 2803 of the Public Health Law (PHL) and sections 461, 461-e, and 461-u of the Social Services Law (SSL).

PHL § 2801-h and SSL § 461-u specifically authorize the New York State Department of Health (Department) to promulgate regulations relating to personal caregiving visitors and compassionate caregiving visitors in nursing homes and adult care facilities (ACFs).

SSL § 461 requires the Department to promulgate regulations establishing general standards applicable to ACFs. SSL § 461-e authorizes the Department to promulgate regulations to require ACFs to maintain certain records with respect to the facilities' residents and the operation of the facility.

Legislative Objectives:

The legislative objective of PHL § 2801-h and SSL § 461-u is to ensure residents' rights to visitation are respected by allowing residents of nursing homes and ACFs to have access to their designated personal caregiving visitors and compassionate caregiving visitors during a declared State or local public health emergency. Further, the legislative objective of SSL § 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

These regulations are necessary pursuant to the statutory directives in PHL § 2801-h and SSL § 461-u, which direct the Commissioner of Health to promulgate regulations governing personal caregiving visitation and compassionate caregiving visitation in nursing homes and ACFs during a declared State or local public health emergency.

These regulations are beneficial insofar as they will provide clarity to facility operators and administrators, residents, and their family members regarding whether certain visitors are permitted to access a nursing home or ACF during a declared local or State health emergency, notwithstanding any visitation restrictions currently in effect within the facility.

COSTS:

Costs to Regulated Parties:

There are no anticipated costs to regulated parties. The regulations require facilities to establish policies and procedures regarding personal caregiving visitation and compassionate caregiving visitation that comply with these regulations and the governing statutes, PHL § 2801-h and SSL § 461-u. Insofar as facilities are obligated to establish policies and procedures for other facility operations, this responsibility should be managed using existing resources.

Costs to Local and State Governments:

There are no anticipated costs to any regulated parties, including nursing homes and ACFs operated by a local or State government.

Costs to the Department of Health:

This regulation will not result in any additional operational costs to the Department of Health. Any increased surveillance and enforcement activities relating to this regulation will be handled with existing resources.

Paperwork:

This regulation requires facilities to develop and maintain visitation policies relating to personal caregiving visitation and compassionate caregiving visitation. However, this requirement is expected to be of minimal burden to facilities, which are currently obligated to

develop and maintain other policies and procedures relating to facility operations, and the requirements for such visitation policies and procedures are thoroughly detailed in these regulations and the governing statutes, PHL § 2801-h and SSL § 461-u.

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. 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.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

There are no viable alternatives. The alternative of not issuing these regulations was rejected given the statutory directive to promulgate these regulations, pursuant to PHL § 2801-h and SSL § 461-u.

Federal Standards:

The federal Centers for Medicare & Medicaid Services (CMS) has issued visitation guidance applicable to Medicaid- and Medicare-enrolled nursing homes, titled “Nursing Home Visitation - COVID-19 (REVISED)” (QSO-20-39-NH), revised April 27, 2021. This visitation guidance discusses general visitation in nursing homes including compassionate care visitation. The Department has reviewed this CMS guidance and finds that the proposed regulations are consistent with the CMS guidance insofar as they both relate to compassionate care visitation in nursing homes. No other federal standards apply.

Compliance Schedule:

The regulations will become effective upon filing with the Secretary of State.

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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 adult care facility (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 requires nursing homes and ACFs to develop policies and procedures relating to compassionate caregiver visitation and personal caregiver visitation that are consistent with these regulations and the governing statutes, Public Health Law (PHL) § 2801-h and Social Services Law (SSL) § 461-u.

Professional Services:

No professional services are required by this regulation.

Compliance Costs:

There are no costs associated with this regulation.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is consistent with resident right standards and current CMS and Department visitation guidance. Therefore, the Department expects no adverse impact to facilities given that nursing homes and ACFs are currently required to comply with similar standards and are expected to have already developed policies and procedures in accordance with those existing standards. In any event, the Department is required by PHL § 2801-h and SSL § 461-u to promulgate these regulations; as such, any adverse impact on covered facilities cannot be avoided due to the statutory mandate.

Small Business and Local Government Participation:

Facilities were put on notice of the forthcoming promulgation of these regulations upon the enactment of PHL § 2801-h and SSL § 461-u, as enacted by Chapter 108 of the Laws of 2021. Additionally, the Department plans to advise all facilities, including those operated by small businesses and local governments, of the publication of these regulations and the opportunity to submit any questions relating to such regulations to the Department.

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 Executive Law § 481(7) (SAPA § 102(10)). Per Executive 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 have populations 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	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga 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.

Compliance Costs:

There are no costs associated with this regulation.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is consistent with resident right standards and current CMS and Department visitation guidance. Therefore, the Department expects no adverse impact to facilities given that nursing homes and ACFs are currently required to comply with similar standards and are expected to have already developed policies and procedures in accordance with those existing standards. In any event, the Department is required by PHL § 2801-h and SSL § 461-u to promulgate these regulations; as such, any adverse impact on covered facilities cannot be avoided due to the statutory mandate.

Rural Area Participation:

Facilities were put on notice of the forthcoming promulgation of these regulations upon the enactment of PHL § 2801-h and SSL § 461-u, as enacted by Chapter 108 of the Laws of 2021. Additionally, the Department plans to advise all facilities, including those located in rural areas, of the publication of these regulations and the opportunity to submit any questions relating to such regulations 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.

EMERGENCY JUSTIFICATION

Chapter 108 of the Laws of 2021, which amended Public Health Law (PHL) § 2801-h and Social Services Law (SSL) § 461-u, requires nursing homes and adult care facilities (ACFs) to permit personal and compassionate caregiving visitations. The new law became effective immediately and required that regulations be promulgated within forty-five days after enactment. Thus, the law authorized the promulgation of emergency regulations.

The purpose of the new law is to benefit the health and general well-being of nursing home and ACF residents. This emergency rulemaking is necessary to satisfy the statutory requirement, provide clarity to facility operators and administrators as well as residents and their families regarding the process for implementing personal caregiving requirements under the newly enacted law.

Furthermore, throughout the COVID-19 pandemic, visitation guidance for long-term care facilities has been issued by several authorities, including the Department and federal Centers for Medicare & Medicaid Services (CMS). Facility outreach to the Department and surveillance activities show that many nursing homes and adult care facilities have not appropriately adhered to these guidance documents or have implemented their own form of personal caregiving visitation policies. This emergency rulemaking will assist facilities in understanding their legal obligations with respect to visitation, for the purposes of preparing the facility's visitation policies and procedures in the event of a declared State or local public health emergency, by providing additional information as to who may access a facility during periods of visitation closure, and what, if any, restrictions can be implemented on personal caregiving and compassionate caregiving visitation.

20-24 Addition of Sections 1.2, 700.5 and Part 360 to Title 10 NYCRR; Amendment of Sections 400.1, 405.24 & 1001.6 of Title 10 NYCRR and Sections 487.3, 488.3 and 490.3 of Title 18 NYCRR (Surge and Flex Health Coordination System)

*******TO BE DISTRIBUTED UNDER SEPARATE
COVER*******

SUMMARY OF EXPRESS TERMS

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.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225, 576, and 2803 of the Public Health Law, Section 2.2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, Section 2.6 is repealed and a new Section 2.6 is added, a new Section 2.13 is added, Sections 2.25 through 2.30 are repealed, a new Section 58-1.14 is added, and Section 405.3 is amended, to be effective upon filing with the Secretary of State, to read as follows:

Subdivision (b) and (c) of Section 2.2 are amended, and new subdivisions (h) through (q) are added, to read as follows:

(b) [A *case* is defined as] Case shall mean a person who has been diagnosed [as likely to have] as having a particular disease or condition. The diagnosis may be based [solely] on clinical judgment, signs and symptoms combined with known exposure based on the best available evidence of transmissibility to a case or suspected case, [solely] and/or on laboratory evidence, [or on both criteria] as applicable.

(c) [A *suspected case* is defined as] Suspected case shall mean a person who has been [diagnosed] determined as [likely to have] possibly having a particular disease or condition. [The suspected diagnosis] A suspected case may be based [solely] on signs and symptoms, signs and symptoms combined with known exposure based on the best available evidence of transmissibility to a case or suspected case, [or solely] and/or on laboratory evidence, [or on both criteria] as applicable. The term “suspected case” shall include persons under

investigation, consistent with any guidance that the Commissioner of Health may issue with respect to a particular disease.

* * *

- (h) Contact shall mean any person known to have been sufficiently associated with a case or suspected case that, based on the best available evidence of transmissibility, such person has had the opportunity to contract a particular disease or condition.

- (i) Isolation shall mean the physical separation and confinement of an individual or group of individuals who are infected or reasonably determined by the State Commissioner of Health or local health authority to be infected with a highly contagious disease or organism, for such time as will prevent or limit the transmission of the reportable disease or organism to non-isolated individuals, in the clinical judgment of the State Commissioner of Health, or of the local health authority and consistent with any direction that the State Commissioner of Health may issue.

- (j) Quarantine shall mean the physical separation and confinement of an individual or groups of individuals who are reasonably determined by the State Commissioner of Health or local health authority to have been exposed to a highly contagious communicable disease, but who do not show signs or symptoms of such disease, for such time as will prevent transmission of the disease, in the clinical judgment of the State Commissioner of Health, or of the local

health authority and consistent with any direction that the State Commissioner of Health may issue.

- (k) Home quarantine or home isolation shall mean quarantine or isolation in a person's home, consistent with this Part and any direction that the State Commissioner of Health may issue;
- (l) Congregate quarantine shall mean quarantine at a location operated or contracted by the State or local health authority, consistent with this Part and any direction that the State Commissioner of Health may issue, where multiple persons are quarantined;
- (m) Highly contagious communicable disease shall mean a communicable disease or unusual disease that the State Commissioner of Health determines may present a serious risk of harm to the public health, for which isolation or quarantine may be required to prevent its spread.
- (n) Monitor shall mean contacting a person who is the subject of an isolation or quarantine order by the State Department of Health or local health authority, to ensure compliance with the order and to determine whether such person requires a higher level of medical care, consistent with any direction that the State Commissioner of Health may issue.
- (o) Mandatory quarantine shall mean quarantine pursuant to a legal order consistent with this Part.
- (p) Voluntary quarantine shall mean quarantine pursuant to a voluntary agreement with a public health authority.
- (q) Confinement shall mean enforcement of an isolation or quarantine order through the use or possible use of law enforcement personnel.

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

(a) Except where other procedures are specifically provided in law, every local health authority, either personally or through a qualified representative, shall immediately upon receiving a report of a case, suspected case, outbreak, or unusual disease, investigate the circumstances of such report at any and all public and private places in which the local health authority has reason to believe, based on epidemiological or other relevant information available, that such places are associated with such disease. Such investigations shall, consistent with any direction that the State Commissioner of Health may issue:

- (1) Verify the existence of a disease or condition;
- (2) Ascertain the source of the disease-causing agent or condition;
- (3) Identify unreported cases;
- (4) Locate and evaluate contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;
- (5) Collect and submit, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the source of disease, or to assist with diagnosis; and furnish or cause to be furnished with such specimens pertinent data on forms prescribed by the State Commissioner of Health, including but not limited to the history of cases, physical findings and details of the epidemiological investigation;
- (6) Examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;

- (7) Instruct a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and
- (8) Take any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

(b) When a case or suspected case of a disease, condition, outbreak, or unusual disease occurs in any business, organization, institution, or private home, the person in charge of the business, organization, institution or the home owner, as well as any individuals or entities required to report pursuant to sections 2.10 and 2.12 of this Part, shall cooperate with the State Department of Health and local health authorities in the investigation of such disease, condition, outbreak, or unusual disease.

(c) Investigation Updates and Reports.

- (1) Upon request of the State Department of Health, the local health authority shall submit updates and reports on outbreak investigations to the State Department of Health. The content, timeframe, and manner of submission of such updates shall be determined by the State Department of Health.
- (2) The local health authority shall complete investigation reports of outbreaks within 30 days of the conclusion of the investigation in a manner prescribed by the State Commissioner of Health, unless the State Commissioner of Health prescribes a different time period.

(d) Commissioner authority to lead investigation activities.

(1) The State Commissioner of Health may elect to lead investigation activities where:

(i) Residents of multiple jurisdictions within the State are affected by an outbreak of a reportable disease, condition, or unusual disease; or

(ii) Residents in a jurisdiction or jurisdictions within the State and in other state are affected by an outbreak of a reportable disease, condition, or unusual disease; or

(iii) An outbreak of an unusual disease or a reportable disease or condition involves a single jurisdiction with the high potential for statewide impact.

(2) Where the State Commissioner of Health elects to lead investigation activities pursuant to paragraph (1) of this subdivision, the State Commissioner of Health shall lead such investigation, but local health authorities shall take all reasonable steps to assist in such investigation, including supply of personnel, equipment or information. Provided further that the local health authority shall take any such action as the State Commissioner of Health deems appropriate and that is within the jurisdiction of the local health authority. Any continued investigation by the local health authority shall be solely pursuant to the direction of the State Commissioner of Health, and the State Commissioner of Health shall have access to any investigative materials which were heretofore created by the local health authority.

New section 2.13 is added to read as follows:

2.13 Isolation and Quarantine Procedures

(a) Duty to issue isolation and quarantine orders

- (1) Whenever appropriate to control the spread of a highly contagious communicable disease, the State Commissioner of Health may issue and/or may direct the local health authority to issue isolation and/or quarantine orders, consistent with due process of law, to all such persons as the State Commissioner of Health shall determine appropriate.
- (2) Paragraph (1) of this subdivision shall not be construed as relieving the authority and duty of local health authorities to issue isolation and quarantine orders to control the spread of a highly contagious communicable disease, consistent with due process of law, in the absence of such direction from the State Commissioner of Health.
- (3) For the purposes of isolation orders, isolation locations may include home isolation or such other residential or temporary housing location that the public health authority issuing the order determines appropriate, where symptoms or conditions indicate that medical care in a general hospital is not expected to be required, and consistent with any direction that the State Commissioner of Health may issue. Where symptoms or conditions indicate that medical care in a general hospital is expected to be required, the isolation location shall be a general hospital.
- (4) For the purposes of quarantine orders, quarantine locations may include home quarantine, other residential or temporary housing quarantine, or quarantine at such other locations as the public health authority issuing the order deems appropriate, consistent with any direction that the State Commissioner of Health may issue.

(b) Any isolation or quarantine order shall specify:

- (1) The basis for the order;
- (2) The location where the person shall remain in isolation or quarantine, unless travel is authorized by the State or local health authority, such as for medical care;
- (3) The duration of the order;
- (4) Instructions for traveling to the isolation or quarantine location, if appropriate;
- (5) Instructions for maintaining appropriate distance and taking such other actions as to prevent transmission to other persons living or working at the isolation or quarantine location, consistent with any direction that the State Commissioner of Health may issue;
- (6) If the location of isolation or quarantine is not in a general hospital, instructions for contacting the State and/or local health authority to report the subject person's health condition, consistent with any direction that the State Commissioner of Health may issue;
- (7) If the location of isolation or quarantine is a multiple dwelling structure, that the person shall remain in their specific dwelling and in no instance come within 6 feet of any other person, and consistent with any direction that the State Commissioner of Health may issue;
- (8) If the location of isolation or quarantine is a detached structure, that the person may go outside while remaining on the premise, but shall not leave the premise or come within 6 feet of any person who does not reside at the premise, or such other distance as may be appropriate for the specific disease, and consistent with any direction that the State Commissioner of Health may issue;
- (9) Such other limitations on interactions with other persons as are appropriate, consistent with any direction that the State Commissioner of Health may issue;

(10) Notification of the right to request that the public health authority issuing the order inform a reasonable number of persons of the conditions of the isolation or quarantine order;

(11) A statement that the person has the right to seek judicial review of the order;

(12) A statement that the person has the right to legal counsel, and that if the person is unable to afford legal counsel, counsel will be appointed upon request.

(c) Whenever a person is subject to an isolation or quarantine order, the State Department of Health or local health authority, or the local health authority at the State Department of Health's direction shall, consistent with any direction issued by the State Commissioner of Health:

(1) monitor such person to ensure compliance with the order and determine whether such person requires a higher level of medical care;

(2) whenever appropriate, coordinate with local law enforcement to ensure that such person comply with the order; and

(3) the extent such items and services are not available to such person, provide or arrange for the provision of appropriate supports, supplies and services, including, but not limited to: food, laundry, medical care, and medications.

(d) If the location of an isolation or quarantine order is owned by a landlord, hotel, motel or other person or entity, no such landlord or person associated with such hotel, motel or other person or entity shall enter the isolation or quarantine location without permission of the

local health authority, and consistent with any direction that the State Commissioner of Health may issue.

(e) No article that is likely to be contaminated with infective material may be removed from a premise where a person is isolated or quarantined unless the local health authority determines that such article has been properly disinfected or protected from spreading infection, or unless the quarantine period expires and there is no risk of contamination. Such determinations shall be made pursuant to any direction that the State Commissioner of Health may issue.

(f) Any person who violates a public health order shall be subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each day that the order is violated shall constitute a separate violation of this Part.

(g) Duty of attending physician

(1) Every attending physician shall immediately, upon discovering a case or suspected case of a highly contagious reportable communicable disease, cause the patient to be appropriately isolated and contact the State Department of Health and the local health authority where the patient is isolated and, if different, the local health authority where the patient resides.

(2) Such physician shall advise other members of the household regarding precautions to be taken to prevent further spread of the disease, consistent with any direction that the State Commissioner of Health may issue.

(3) Such physician shall furnish the patient, or caregiver of such patient where applicable, with detailed instructions regarding the disinfection and disposal of any contaminated articles, consistent with any direction that the State Commissioner of Health may issue.

Sections 2.25, 2.26, 2.27, 2.28, 2.29, and 2.30 are repealed.

Paragraph (11) of subdivision (d) of section 405.3 is amended, paragraph (12) is renumbered paragraph (13), and a new paragraph (12) is added, to read as follows:

(11) written minutes of each committee's proceedings. These minutes shall include at least the following:

- (i) attendance;
- (ii) date and duration of the meeting;
- (iii) synopsis of issues discussed and actions or recommendations made; [and]

(12) whenever the commissioner determines that there exists an outbreak of a highly contagious communicable disease pursuant to Part 2 of this Title or other public health emergency, such syndromic surveillance data as the commissioner deems appropriate, which the hospital shall submit in the manner and form determined by the commissioner; and

(13) any record required to be kept by the provisions of this Part.

* * *

Section 58-1.14 Reporting of certain communicable diseases

(a) The commissioner shall designate those communicable diseases, as defined by section 2.1 of the Sanitary Code, that require prompt action, and shall make available on the Department's website a list of such communicable diseases.

(b) Laboratories performing tests for screening, diagnosis or monitoring of communicable diseases requiring prompt action pursuant to subdivision (a) of this section, for New York State residents and/or New York State health care providers, shall:

(i) immediately report to the commissioner all positive results for such communicable diseases in a manner and format as prescribed by the commissioner; and

(ii) report all results, including positive, negative and indeterminate results, to the commissioner in a time and manner consistent with Public Health Law § 576-c.

* * *

Section 405.3 is amended by adding a new subdivision (g) as follows:

(g) Whenever the commissioner determines that there exists an outbreak of a highly contagious communicable disease pursuant to Part 2 of this Title or other public health emergency, the commissioner may direct general hospitals, as defined in Article 28 of the public health law, and consistent with the federal Emergency Medical Treatment and Labor Act (EMTALA), to accept patients pursuant to such procedures and conditions as the commissioner may determine appropriate.

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 PPHPC, 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.

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. Given New York's dramatic progress against COVID-19, with the success in vaccination rates, and declining hospitalization and positivity statewide, the declared state disaster emergency expired on June 24, 2021. Nevertheless, this does not mean that COVID-19 is gone, as the threat of COVID-19 still remains, especially for those who are not vaccinated.

In light of this situation, these regulations update, clarify and strengthen the Department's authority as well as that of local health departments to take specific actions to control the spread of disease, including actions related to investigation and response to a disease outbreak, as well as the issuance of isolation and quarantine orders.

The following is a summary of the amendments to the Department's regulations:

Part 2 Amendments:

- Relocate and update definitions, and add new definitions
- Repeal and replace current section 2.6, related to investigations, to make existing clarify local health department authority.

- Sets forth specific actions that local health departments must take to investigate a case, suspect case, outbreak, or unusual disease.
- Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.
- Clarifies authority for the Commissioner to lead investigation activities.
- Codifies in regulation the requirement that local health departments send reports the Department during an outbreak.
- New section 2.13 added to clarify isolation and quarantine procedures.
 - Clarify that the State Department of Health has the authority to issue isolation and quarantine orders, as do local departments of health.
 - Clarifies locations where isolation or quarantine may be appropriate.
 - Sets forth requirements for the content of isolation and quarantine orders.
 - Specifies other procedures that apply when a person is isolated or quarantined.
 - Explicitly states that violation of an order constitutes grounds for civil and/or criminal penalties
 - Relocates and updates existing regulatory requirements that require the attending physician to report cases and suspected cases to the local health authority, and to requires physicians to provide instructions concerning how to protect others.

Part 58 Amendments

- New section 58-1.14 added clarifying reporting requirements for certain communicable diseases

- Requires the Commissioner to designate those communicable disease that require prompt action, and to make available a list of such disease on the State Department of Health website.
- Requires clinical laboratories to immediately report positive test results for communicable diseases identified as requiring prompt attention, in a manner and format identified by the Commissioner.
- Requires clinical laboratories to report all test result, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

Part 405 Amendments

- Mandates hospitals to report syndromic surveillance data during an outbreak of a highly contagious communicable disease.
- Permits the Commissioner to direct hospitals to take patients during an outbreak of a highly contagious communicable disease, which is consistent with the federal Emergency Medical Treatment and Labor Act (EMTALA).

COSTS:

Costs to Regulated Parties:

The requirement that hospital submit syndromic surveillance reports when request during an outbreak is not expected to result in any substantial costs. Hospitals are already regularly and voluntarily submitting data to the Department, and nearly all of them submit such reports electronically. With regard to the Commissioner directing general hospitals to accept patients during an outbreak of a highly contagious communicable disease, hospitals are already required

to adhere to the federal Emergency Medical Treatment and Labor Act (EMTALA).

Accordingly, both of these proposed amendments will not impose any substantial additional cost to hospitals.

Clinical laboratories must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102. The regulation simply clarifies existing requirements and is not anticipated to impose any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

Although there are costs associated with disease investigation and response for any outbreak, these regulations clarify and strengthen the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations.

Costs to Local and State Governments:

Although there are costs associated with disease investigation and response for any outbreak, these regulations clarify and strengthen the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations. Further, making explicit the Department's authority to lead investigation activities will result in increased coordination of resources, likely resulting in a cost-savings for State and local governments.

Any clinical laboratories operated by a local government must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102. The regulation simply clarifies existing

requirements and is not anticipated to impose any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

To the extent that the State Department of Health and local health departments issue isolation and quarantine orders in response to COVID-19, such actions will impose costs upon the state. As the scope of any outbreak is difficult to predict, the cost to the State of issuing such orders cannot be predicted at this time.

Paperwork:

Some hospitals may be required to make additional syndromic surveillance reports that they are not already making. Otherwise, these regulations do not require any additional paperwork.

Local Government Mandates:

Under existing regulation, local health departments already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties.

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

The alternative would be to leave in place the current regulations on disease investigation and isolation and quarantine. However, many of these regulatory provisions have not been updated in fifty years and should be modernized to ensure appropriate response to a disease outbreak, such as COVID-19.

Federal Standards:

States and local governments have primary authority for controlling disease within their respective jurisdictions. Accordingly, there are no federal statutes or regulations that apply to disease control within NYS.

Compliance Schedule:

The regulations will become effective upon filing with the Department of State.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

Under existing regulation, local health departments already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties.

Compliance Requirements:

Under existing regulation, local health departments already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties. 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. 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. The regulation simply clarifies existing requirements and is not anticipated to impose any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

Professional Services:

It is not expected that any professional services will be needed to comply with this rule.

Compliance Costs:

Although there are costs associated with disease investigation and response for any outbreak, these regulations clarify and strengthen the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations.

Further, making explicit the Department's authority to lead investigation activities will result in increased coordination of resources, likely resulting in a cost-savings for State and local governments.

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 regulated entities to ensure they are aware of the new regulations and have the information necessary to comply.

Small Business and Local Government Participation:

Due to the emergent nature of COVID-19, small business and local governments 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.

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 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

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 JUSTIFICATION

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. On March 7, 2020, with widespread transmission rapidly

increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. Given New York's dramatic progress against COVID-19, with the success in vaccination rates, and declining hospitalization and positivity statewide, the declared state disaster emergency expired on June 24, 2021. Nevertheless, this does not mean that COVID-19 is gone, as the threat of COVID-19 still remains, especially for those who are not vaccinated.

In light of this situation, these emergency regulations are necessary to clarify and strengthen the Department's authority and that of the local health departments to take specific actions to continue to control the spread of disease, including actions related to investigation and response to a disease outbreak, as well as the issuance of isolation and quarantine orders.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 201, 206, and 225 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by renaming Part 66 and adding a new Subpart 66-3, and adding a new Section 2.60, to be effective upon filing with the Secretary of State, to read as follows:

The title of Part 66 is amended as follows:

Immunizations and Communicable Diseases

A new Subpart 66-3, titled COVID-19 Emergency Regulations, is added to read as follows:

66-3.1 Face-Coverings

(a) As determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread, any person who is over age two and able to medically tolerate a face-covering may be required to cover their nose and mouth with a mask or face-covering when: (1) in a public place and unable to maintain, or when not maintaining, social distance; or (2) in certain settings as determined by the Commissioner, which may include schools, public transit, homeless shelters, correctional facilities, nursing homes, and health care settings, and which may distinguish between individuals who are vaccinated against COVID-19 and those that are not vaccinated. The Commissioner shall issue findings regarding the necessity of face-covering requirements at the time such requirements are announced.

(b) Businesses must provide, at their expense, face-coverings for their employees required to wear a mask or face-covering pursuant to subdivision (a) of this section.

(c) large-scale indoor event venues with more than five thousand attendees shall require patrons to wear face coverings consistent with subdivision (a) of this section; may require all patrons to wear a face covering irrespective of vaccination status; and may deny admittance to any person who fails to comply. This regulation shall be applied in a manner consistent with the federal American with Disabilities Act, New York State or New York City Human Rights Law, and any other applicable provision of law.

(d) No business owner shall deny employment or services to or discriminate against any person on the basis that such person elects to wear a face-covering that is designed to inhibit the transmission of COVID-19, but that is not designed to otherwise obscure the identity of the individual.

(e) For purposes of this section face-coverings shall include, but are not limited to, cloth masks, surgical masks, and N-95 respirators that are worn to completely cover a person's nose and mouth.

66-3.2 Penalties

A violation of any provision of this Subpart is subject to all civil and criminal penalties as provided for by law. Individuals or entities that violate this Subpart are subject to a maximum fine of \$1,000 for each violation. For purposes of civil penalties, each day that an entity operates in a manner inconsistent with the Subpart shall constitute a separate violation under this Subpart.

A new section 2.60 is added to read as follows

2.60. Enforcement of Social Distancing Measures.

For purposes of civil enforcement, the provisions of Subpart 66-3 of this Title are incorporated herein, and a violation of the provisions of Subpart 66-3 shall be deemed a violation of this Chapter. All local health officers shall take such steps as may be necessary to enforce the provisions of Subpart 66-3 in accordance with the Public Health Law and this Chapter.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for adding a new Subpart 66-3 is sections 201 and 206 of the Public Health Law. The statutory authority for adding new section 2.60 is section 225 of the Public Health Law.

Legislative Objectives:

The legislative objective of PHL § 201 includes authorizing the New York State Department of Health (“Department”) to control and promote the control of communicable diseases to reduce their spread. Likewise, the legislative objective of PHL § 206 includes authorizing 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. The legislative objective of Public Health Law § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to amend the State Sanitary Code to address public health issues related to communicable disease.

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.

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. Given New York's dramatic progress against COVID-19, with the success in vaccination rates, and declining hospitalization and positivity statewide, the declared state disaster emergency expired on June 24, 2021. Nevertheless, this does not mean that COVID-19 is gone, as the threat of COVID-19 still remains, especially for those who are not vaccinated.

These regulations update previously filed emergency regulations to provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread.

COSTS:

Costs to Regulated Parties:

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 state since March of 2020. Accordingly, this regulation does not impose additional costs to regulated parties.

Costs to Local and State Governments:

State and local government are authorized to enforce civil and criminal penalties related to the violation of these regulations, and there may be some cost of enforcement, however such costs are anticipated to be minimal as these provisions continue existing enforcement requirements.

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

As part of ongoing efforts to address the COVID-19 pandemic, local governments have been a partner in implementing and enforcing measures to limit the spread and/or mitigate the impact of COVID-19 within their jurisdictions since March of 2020. Further, local governments have separate authority and responsibilities to control disease within their jurisdictions pursuant to PHL sec. 2100 and Part 2 of the State Sanitary Code.

Duplication:

There is no duplication of federal law.

Alternatives:

The alternative would be to not promulgate these emergency regulations. However, this alternative was rejected, as the Department believes this regulation will facilitate the Department's ability to respond to the evolving nature of this serious and ongoing communicable disease outbreak.

Federal Standards:

States and local governments have primary authority for controlling disease within their respective jurisdictions. Accordingly, there are no federal statutes or regulations that apply to disease control within NYS.

Compliance Schedule:

The regulations will become effective upon filing with the Department of State.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

As part of ongoing efforts to address the COVID-19 pandemic, businesses and local government have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Accordingly, this regulation will not have a significant impact on or cost to small business and local government.

Compliance Requirements:

These regulations update previously filed emergency regulations to provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread.

Professional Services:

It is not expected that any professional services will be needed to comply with this rule.

Compliance Costs:

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 state since March of 2020. Accordingly, this regulation will not have a significant impact..

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 state since March of 2020. Accordingly, any adverse impacts are expected to be minimal.

Small Business and Local Government Participation:

Due to the emergent nature of COVID-19, small business and local governments were not consulted.

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

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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	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:

These regulations update previously filed emergency regulations to provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread.

Compliance Costs:

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 state since March of 2020. Accordingly, this regulation does not impose additional costs to regulated parties.

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 state since March of 2020. Accordingly, adverse impacts are expected to be minimal.

Rural Area Participation:

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted.

JOB IMPACT STATEMENT

The Department of Health has determined that this regulatory change is necessary to prevent further complete closure of the businesses impacted, and therefore, while there may be lost revenue for many businesses, the public health impacts of continued spread of COVID-19 are much greater.

EMERGENCY JUSTIFICATION

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. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. Given New York's dramatic progress against COVID-19, with the success in vaccination rates, and declining hospitalization and positivity statewide, the declared state disaster emergency expired on June 24, 2021.

Nevertheless, this does not mean that COVID-19 is gone, as the threat of COVID-19 still remains, especially for those who are not vaccinated.

These regulations update previously filed emergency regulations to provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 2800 and 2803 of the Public Health Law, and in the Commissioner of Health by Section 3401 of the Public Health Law, 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 Secretary of State, to read as follows:

Section 405.11 of 10 NYCRR is amended by adding a new subdivision (h) to read as follows:

(h) *COVID-19 Confirmatory Testing.*

(1) Any patient with symptoms of COVID-19 or who has been exposed to COVID-19 shall be tested for the COVID-19 virus, along with any other clinically appropriate testing.

(2) Whenever a person expires while in the hospital, or while enroute to the hospital, and in the professional judgment of the attending clinician there is a clinical suspicion that COVID-19 was a cause of death, but no such test was performed in the 14 days before death, the hospital shall administer a COVID-19 test within 48 hours after death, along with any other clinically appropriate testing. Such COVID-19 test shall be performed using rapid testing methodologies to the extent available. The facility shall report the death to the Department immediately after and only upon receipt of such test results through the Health Emergency Response Data System (HERDS). Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the hospital lack the ability to perform such testing expeditiously, the hospital should request assistance from the State Department of Health.

A new section 415.33 of 10 NYCRR is added to read as follows:

415.33 COVID-19 Confirmatory Testing

(1) Any resident with symptoms of COVID-19 or who has been exposed to COVID-19 shall be tested for the COVID-19 virus, along with any other clinically appropriate testing.

(2) Whenever a person expires while in a nursing home, where in the professional judgment of the nursing home clinician there is a clinical suspicion that COVID-19 was a cause of death, but no such test was performed in the 14 days before death, the nursing home shall administer a COVID-19 test within 48 hours after death, along with any other clinically appropriate testing.

Such COVID-19 test shall be performed using rapid testing methodologies to the extent available. The facility shall report the death to the Department immediately after and only upon receipt of such test results through the Health Emergency Response Data System (HERDS).

Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the nursing home lack the ability to perform such testing expeditiously, the nursing home should request assistance from the State Department of Health.

A new section 77.13 of 10 NYCRR is added to read as follows:

77.13 COVID-19 Confirmatory Testing – Funeral Directors.

Whenever the funeral director has been advised by an attending health care practitioner (whether the death was in hospice, an adult care facility, or any another setting where a positive diagnosis was not made) and there is a clinical suspicion that COVID-19 was a cause of death, but no such test was performed within 14 days prior to death in a nursing home or hospital, or by the hospice

agency, coroner, or medical examiner, the funeral director shall administer a COVID-19 test within 48 hours after death, whenever the body is received within 48 hours after death. Such test shall be performed using rapid testing methodologies to the extent available. The funeral director shall report the death to the Department immediately after and only upon receipt of such test results, through a means determined by the Department. Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the funeral director lack the ability to perform such testing expeditiously, the funeral director should request assistance from the State Department of Health.

A new section 77.14 of 10 NYCRR is added to read as follows:

77.14 COVID-19 Confirmatory Testing – Coroners and Medical Examiners.

Whenever a coroner or medical examiner has a reasonable suspicion that COVID-19 was a cause of death, but no such test was performed within 14 days prior to death in a nursing home or hospital, or by the hospice agency, the coroner or medical examiner shall administer a COVID-19 test within 48 hours after death, whenever the body is received within 48 hours after death. Such test shall be performed using rapid testing methodologies to the extent available. The coroner or medical examiner shall report the death to the Department immediately after and only upon receipt of such test results, through a means determined by the Department.

Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the coroner or medical examiner lack the ability to perform such testing expeditiously, the coroner or medical examiner may request assistance from the State Department of Health.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations with respect to facilities subject to Article 28 of the Public Health Law (PHL) is contained in PHL sections 2800 and 2803(2). PHL Article 28 (Hospitals), section 2800, specifies: “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 2801 defines the term “hospital” as also including residential health care facilities, which are commonly referred to as nursing homes. 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 such health care facilities. PHL 3401 authorizes the Commissioner to issue regulations pertaining to the business of funeral directing.

Legislative Objectives:

The objectives of PHL Article 28 include protecting the health of New York State residents by ensuring that they have access to safe, high-quality health services in medical facilities, while also protecting the health and safety of healthcare workers. The objective of PHL Section 3401 is to authorize the Commissioner to regulate the business of funeral directing.

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.

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive

Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. Given New York's dramatic progress against COVID-19, with the success in vaccination rates, and declining hospitalization and positivity statewide, the declared state disaster emergency expired on June 24, 2021. Nevertheless, this does not mean that COVID-19 is gone, as the threat of COVID-19 still remains, especially for those who are not vaccinated.

Contact tracing is particularly important for cases of COVID-19 as the State continues its highly effective containment and mitigation strategies to ensure that the spread of COVID-19 remains at a level that the hospital system can accommodate. In order for New York State to more fully assess the number of COVID-19 cases and conduct contact tracing, testing of hospital patients and nursing home residents must be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19. Patients or residents without symptoms, but who have had an exposure to COVID-19 must also be tested for COVID-19, and any other clinically appropriate testing. Further, in the event of an unattended death, in those instances where such testing was not already performed, the coroner, medical examiner, or funeral director must perform the test, depending on who first receives the deceased.

Costs:

Costs to Regulated Parties:

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected but not known to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCR) test ranges from \$100-150 per sample. However, where testing is conducted on a deceased person, rapid testing

methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID-19 testing technologies have been advertised at as low as \$5 per test.

Costs to Local Governments:

For those local governments that operate a general hospital or nursing home, the costs will be the same as those described above.

Cost to State Government:

The administration and oversight of these planning and response activities will be managed within the Department's existing resources.

Paperwork:

It is not anticipated that the proposed regulatory amendments will impose any significant paperwork requirements. Although this regulation will require hospitals and nursing homes to test persons for COVID-19, the Department does not anticipate that such additional tests will be burdensome given that these facilities are already testing patients and residents for these diseases in many instances.

Local Government Mandates:

Facilities operated by local governments will be subject to the same requirements as any other regulated facility, as described above.

Duplication:

These proposed regulatory amendments do not duplicate state or federal rules.

Alternatives:

The alternative would be to not promulgate the regulation, and to allow deaths to be reported as “presumed” deaths of COVID-19. However, this alternative was rejected on two grounds. First, a lack of the regulation would translate to a lack of accuracy in case statistics and delays or inadequate contact tracing, which would allow COVID-19 to spread indefinitely. Second, the regulations would encourage hospitals, nursing homes and hospices to test patients early for COVID-19, which will increase safety of patients and residents.

Federal Standards:

No federal standards apply.

Compliance Schedule:

These regulatory amendments will become effective upon filing with the Department of State.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

For those local governments or small businesses that operate a general hospital or nursing home, testing of hospital patients and nursing home residents will be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19. Significantly, this includes testing after a resident or patient is deceased, in those instances where such testing was not performed in the 14 days preceding death.

Compliance Requirements:

As discussed above, testing of hospital patients and nursing home residents will be mandatory, where such patients or residents are or were suspected, but not known, to have been suffering from COVID-19. Significantly, this includes testing after a resident or patient is deceased, in those instances where such testing was not performed in the 14 days preceding death.

Professional Services:

It is not expected that any new professional services will be needed to comply with this rule. Where testing must be conducted on a deceased person, rapid testing technology may be used when available.

Compliance Costs:

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected but not known to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCR) test ranges from \$100-150 per sample. However, where testing is conducted on a deceased person, rapid testing methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID testing technologies have been advertised at as low as \$5 per test.

Economic and Technological Feasibility:

This proposal will not impose any economic or technological compliance burdens, other than the costs described above.

Minimizing Adverse Impact:

Many facilities covered under this regulation, including those owned and operated by a local government or small business, currently test patients or residents for COVID-19. Given that such facilities are actively testing persons within their facility, the Department anticipates that any adverse impacts will be minimal.

Small Business and Local Government Participation:

Due to the emergent nature of COVID-19, small business and local governments were not consulted. However, parties representing local governments and small businesses may

submit comments during the notice and comment period in the event the Department promulgates proposed regulations.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Number 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 have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

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:

It is not expected that any new professional services will be needed to comply with this rule. Where testing must be conducted on a deceased person, rapid testing technology may be used.

Compliance Costs:

The regulation requires regulated entities to perform confirmatory COVID-19 testing on persons suspected, but not known, to be suffering or to have suffered from COVID-19. The cost for testing for SARS-CoV-2 using a general polymerase chain reaction (PCR) test ranges from \$100-150 per sample. However, where testing is conducted on a deceased person, rapid testing

methodology may be used; the Department understands that only some hospitals and nursing homes may have this capability at this time. Newer rapid COVID testing technologies have been advertised at as low as \$5 per test. Lastly, per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas.

Economic and Technological Feasibility:

This proposal will not impose any economic or technological compliance burdens, other than the costs described above.

Minimizing Adverse Impact:

Many facilities covered under this regulation, including those owned and operated by a local government or small business, currently test patients or residents for COVID-19. Given that such facilities are actively testing persons within their facility, the Department anticipates that any adverse impacts will be minimal.

Rural Area Participation

Due to the emergency nature of COVID-19, parties representing rural areas were not consulted in the initial draft. However, parties representing rural may submit comments during the notice and comment period in the event the Department promulgates proposed regulations.

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

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Nevertheless, this does not mean that COVID-19 is gone, as the threat of COVID-19 still remains, especially for those who are not vaccinated.

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Consistent with CDC guidance and the end of the influenza season, the Department is removing the general requirement that hospitals and nursing homes test patients and residents for influenza, and the general requirement that funeral directors, coroners and medical examiners to test deceased persons for influenza, as influenza is not prevalent in the state and COVID-19 protocols require face coverings in healthcare settings.

Given the foregoing, the Department has determined that these regulations should be issued on an emergency basis.