

**Public Health and Health Planning Council**  
*Special Codes, Regulations and Legislation Committee Meeting*  
*Agenda and Informational Announcements*

*October 26, 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**

20-22 Amendment of Sections 405.11 and 415.19 of Title 10 NYCRR (Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements)

21-06 Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel)

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)

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)

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 additional 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 July 19, 2021, and currently remains in effect.

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; and

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

#### 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.

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

#### 66-4.3. Penalties.

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

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

486.5(a)(4)(v).

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

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

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

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

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

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

### **Legislative Objectives:**

The legislative objectives of PHL §§ 201 and 206 are to protect the health and life of the people of the State of New York, including by controlling the spread of communicable diseases. The legislative objectives of PHL Article 28, including PHL § 2803, include the efficient provision and proper utilization of health services of the highest quality. The legislative objective of SSL § 461 is to promote the health and well-being of residents of adult care



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

**Needs and Benefits:**

These regulations are necessary to prevent the spread of COVID-19 in nursing homes and adult care facilities and to help ensure the health and life of residents of nursing homes and ACFs by requiring such congregate care facilities to offer or arrange for consenting residents and personnel to receive the COVID-19 vaccine. This requirement will help ensure residents are less likely to suffer a COVID-related death or severe illness and that fewer staff test positive for COVID-19.

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. 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

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions or modifications. The proposed regulatory amendments would permit the State Commissioner of Health or designee to take specific actions, as well as to temporarily suspend or modify certain regulatory provisions (or parts thereof) in Titles 10 and 18 of the NYCRR during a state disaster emergency, where such provisions are not required by statute or federal law. These proposed amendments would also permit the Commissioner to take certain actions, where consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. Examples include issuing directives to authorize and require clinical laboratories or hospitals to take certain actions consistent with any such EOs, as well as the temporary suspension or modification of additional regulatory provisions when the Governor temporarily suspends or modifies a controlling state statute.

The proposed regulatory amendments would also require hospitals to: develop disaster emergency response plans; maintain a 60-day supply of personal protective equipment (PPE); ensure that staff capable of working remotely are equipped and trained to do so; and report data as requested by the Commissioner.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225, 2800, and 2803 of the Public Health Law; and in the Commissioner of Health by Sections 576 and 4662 of the Public Health Law and Section 461 of the Social Services Law, Title 10 (Health) and Title 18 (Social Services) 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:

A new Part 360 is added to Title 10, to read as follows:

Part 360 Surge and Flex Health Coordination System Activation During a State Disaster

Emergency Declaration

Part 360. Surge and Flex System

Section 360.1. Administrative Purpose, Application and Scope

(a) Administrative purpose.

Hospitals across New York State, prior to the COVID-19 pandemic, rarely worked together or coordinated as a unified healthcare system. But a pandemic on the scale of the COVID-19 crisis demonstrated that our health care facilities could not meet the demand of the moment unless a new and innovative system was put into place requiring unprecedented coordination, cooperation, and agility. The New York State Department of Health takes note of the successful implementation of the Surge and Flex System by New York State's hospitals and offers these regulations as an additional way to strengthen the pandemic response. Surge and Flex Health Coordination System Activation has helped hospitals respond to the COVID-19 state



disaster emergency, and New York's hospitals have made commendable efforts to coordinate their response to the pandemic, to direct patients to the hospitals with the capacity to treat them, and to increase capacity as needed, during each wave of the pandemic.

The COVID-19 crisis demanded a new coordinated approach to ensure no one hospital was overwhelmed by COVID-19 patients or needed more ventilators, while a hospital nearby had capacity for more patients and excess equipment. It was imperative for government to coordinate and organize all hospitals under the umbrella of one unified system, and efficiently use all the resources available in the state to attempt to meet the significant demands of the crisis.

The "Surge and Flex" system is designed to create a single, coordinated statewide public healthcare system to prevent a disaster from overwhelming any one hospital in the state. The purpose of this NYSDOH regulation is to institutionalize Surge and Flex operation, giving hospitals the time and guidance to adequately prepare for a potential future activation of Surge and Flex. This regulation provides the Department of Health with the necessary tools to enact Surge and Flex operation during another wave of COVID-19, or a future public health emergency. Further, this regulation is designed to help each hospital and healthcare system prepare for this contingency in order to ensure a straightforward transition from standard operating procedures to "Surge and Flex."

(b) Application and Scope. In the event of a State disaster emergency declared pursuant to section 28 of the Executive Law, the Commissioner may exercise the authorities granted in this Part, thereby maximizing the efficiency and effectiveness of the State's health care delivery systems and mitigating the threat to the health of the people of New York. Further, this Part

establishes certain ongoing emergency planning requirements, called the Surge and Flex Health Care Coordination System, for facilities and agencies regulated by the Department.

To the extent that any provision of this Part conflicts with any other regulation of the Department, this Part shall take precedence. All authorities granted to the Commissioner shall be subject to any conditions and limitations that the Commissioner may deem appropriate. The Commissioner may delegate activation of the authorities provided by this Part to appropriate executive staff within the Department. In the event that there are inconsistent statutes, which would preclude effectiveness of such regulation, such regulation shall be effective upon the suspension of such inconsistent statute by the Governor pursuant to authority in Article 2-B of the Executive Law, and such regulation shall immediately be effective.

#### Section 360.2. Surge and Flex Health Care Coordination System Requirements.

(a) In the event of a declared State disaster emergency, the Commissioner shall have all necessary authority and procedures to activate the Surge and Flex Health Care Coordination System (hereinafter “Surge and Flex System”), including the following:

(1) Increase Bed Capacity. At the Commissioner’s direction, which shall be incremental and geographically targeted, health care facilities shall increase by up to 50% the number of acute care beds and/or change the service categories of beds certified or otherwise approved in any entity regulated by the Department. At the Commissioner’s direction, health care facilities shall postpone up to 100% of non-essential elective procedures or allow such procedures only pursuant to such conditions as the Commissioner may determine. The Department shall establish procedures to approve temporary changes at regulated health care facilities to physical plants, to facilitate the increased capacity and shall expedite review of construction applications related to

temporary locations, provided that schematics are filed with the Department and patient safety is maintained.

(2) Enhanced Staffing Capacity. Health care facilities shall establish plans to meet enhanced staffing levels sufficient to ensure that the increased bed capacity has adequate staffing. The Commissioner may further expand or modify criteria for staffing. Health care facilities shall have access to a State-run portal for staffing needs identifying both volunteers and available staff; whether licensed or registered in New York State, or authorized or licensed to practice in any other state or Canada.

(3) Availability of Supplies and PPE. Health care facilities shall maintain and actively manage a supply of personal protective equipment (PPE) appropriate for use during a declared health emergency that could last at least 60-days pursuant to Section 405.11(g) of this Title. The Commissioner shall have all necessary authority to re-distribute the resources of a regulated entity if there is a determination that such resources are limited and in order to preserve the health and safety of New Yorkers, including:

(i) Requiring that any medical or other equipment that is held in inventory by any entity in the State, or otherwise located in the State, be reported to the Department, in a form and with such frequency as the Commissioner may determine.

(ii) Requiring that the patient census be reported to the Department, in a form and with such frequency as the Commissioner may determine.

(iii) For any infectious and communicable disease, ensuring that testing results are reported immediately if positive, and as determined by the Commissioner if such testing results are negative, via the electronic clinical laboratory reporting system or as the Commissioner may determine.

(iv) Suspending or restricting visitation, in accordance with the need to conserve PPE, and subject to such conditions or limitations as the Commissioner may determine.

(4) Statewide Coordination.

(i) Discharging, transfer, and receiving of patients. Health care facilities regulated by the Department shall, if directed to do so by the Commissioner, rapidly discharge, transfer, or receive patients, while protecting the health and safety of such patients and residents, and consistent with the Emergency Medical Treatment and Active Labor Act (EMTALA). The Department shall coordinate with health care facilities to balance individual facility patient load, and may promulgate further directives to specify the method and manner of transfer or discharge.

(ii) Designating Health Care Facilities as Trauma Centers. The Department is authorized to designate an entity as a trauma center; extend or modify the period for which an entity may be designated as a trauma center; or modify the review team for assessment of a trauma center; or change the level of acuity designation or health services of a facility or other determination about patient care as appropriate, including restricting admission or treatment to patients with a particular diagnosis.

(iii) Maintaining a Statewide Health Care Data Management System. Health care facilities or health systems shall report as directed by the Department any information necessary to implement the Surge and Flex System (e.g. available hospital beds, equipment available and in use) and the Department shall use that health facility or health system data in order to monitor, coordinate, and manage during the emergency.

Section 360.3. Hospital emergency Surge and Flex Response Plans.

(a) Every general hospital (hereinafter, “hospital”) shall adopt a detailed emergency Surge and Flex Response Plan (hereinafter, “plan”) that, at a minimum, includes the following elements:

- (1) Bed surge plan. The plan shall explain how the hospital will increase the number of current staffed acute care operational beds to a number set by the Commissioner, which shall be up to a 50% increase of such beds within seven days from the date of the declaration of the state disaster emergency. For the purposes of this Part, an “acute care operational bed” means a bed that is staffed and equipped with appropriate infrastructure such that it can be used to deliver health care services to a patient. The Commissioner may further define the type of acute care operational beds for a given state disaster emergency, which may include isolation beds, intensive care (ICU) beds, pediatric and/or acute care beds. The plan shall contain scenarios for increases of current staffed acute care operational beds in phased increments, detailing the associated considerations for PPE, staffing, and other supplies and equipment, including whether the hospital can meet those requirements using internal resources and capabilities, as well as intra-system load balancing and postponement of some or all non-essential elective procedures. These plans shall inform the Commissioner’s directives, which shall be incremental and geographically tailored at the Statewide, regional, or community level, as dictated by infection rate data.
- (2) PPE surge plan. The plan shall explain how the hospital will increase its supply of personal protective equipment (PPE) appropriate for use in a pandemic to achieve continuous maintenance of its required 60-day supply of PPE, pursuant to section 405.11(g) of this Title. The plan shall list the contracted entities or other supply chain

- agreements executed by the hospital. Such plan shall further include, as appropriate, how the hospital will repurpose existing equipment, replenish the inventory from other areas of the health system, and establish cooperative agreements to obtain PPE to accommodate supply chain interruptions. A PPE surge plan may provide for hospital utilization of some, but not all, of the stockpile reserves during a State disaster emergency, provided that within 30 days of the end of the State disaster emergency, the stockpile reserve is fully restored.
- (3) Mass casualty plan. The plan shall explain how the hospital will receive and treat mass casualty victims, in the event of a secondary disaster arising from the interruption of normal services resulting from an epidemic, earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences, while addressing the continued need for surge capacity for the underlying state disaster emergency declaration.
- (4) Staffing plan. The plan shall explain how the hospital will: identify and train backups for employees who may be unable to report to work during a pandemic; institute employee overtime protocols; and increase staffing by inter- and intra-system loan, cross-training, and volunteer programs, which would be operational on seven days' notice.
- (5) Capital plan. The plan shall explain how the hospital shall ensure continuous operation of facilities and access to utilities, materials, electronic devices, machinery and equipment, vehicles, and communication systems. The plan shall ensure that the hospital routinely performs all required maintenance and peak load testing of its

infrastructure systems, including: electrical, heating, ventilation and air conditioning (HVAC), and oxygen supply.

(b) The Chief Executive Officer (CEO) of the hospital, or system if authorized by the Commissioner to report on a system-wide basis, shall certify to the review and approval of the plan, including an attestation that it can be implemented and achieved in the event of a declared disaster emergency. The CEO shall be responsible for ensuring that the plan is reviewed and updated, as necessary, periodically as specified by the Commissioner and shall re-certify that it is able to be implemented and achieved upon each review.

(c) The Department may require the hospital to submit its disaster emergency response plan and history of semi-annual certifications for review, and may require the hospital to make such amendments to the plan as the Commissioner deems appropriate, to ensure that the plan will achieve the requirements established in subdivision (a) of this section, including increases in bed capacity.

(d) In the event of a declared state disaster emergency, any or all hospitals shall execute their plans immediately upon the direction of the Commissioner.

(e) Additional preparedness requirements.

(1) PPE. Every hospital shall, at all times, continue to maintain the required 60-day supply of PPE appropriate for use in a disaster emergency including a pandemic, pursuant to section 405.11(g) of this Title.

(2) Information technology. Every hospital shall ensure that non-essential staff who are capable of working remotely in the event of an emergency are equipped and trained to do so, and that infrastructure is in place to allow for the repurposing of existing workspaces as needed when activating the Surge and Flex System.

(f) Reporting requirements during the activation of the Surge and Flex System.

(1) In the event of a declared state disaster emergency, upon the Commissioner's direction, hospitals or health systems shall report to the Department all data requested by the Commissioner, in a manner determined by the Commissioner under Section 306.2.

Such data may include, but shall not be limited to:

- (i) Bed availability, both in total and by designated service.
- (ii) Bed capacity, meaning acute care operational beds as defined in paragraph (a)(1) of this Section.
- (iii) Patient demographics.
- (iv) Other health statistics, including deaths.
- (v) PPE and other supplies, in stock and ordered.
- (vi) PPE and other supply usage rates.

(2) Such reports shall be submitted periodically as determined by the Commissioner, except and unless otherwise directed by the Department.

#### Section 360.4 Clinical laboratory testing

(a) In the event of a declared state disaster emergency, the Commissioner shall have all necessary authority to:

(1) Authorize clinical laboratories to operate temporary collecting stations to collect specimens from individuals.

(b) In addition, and to the extent consistent with any Executive Order issued by the Governor, the Commissioner shall have all necessary authority to:



- (1) Waive permit requirements for clinical laboratories and establish minimum qualifications to allow non-permitted clinical laboratories to accept and test specimens from New York State, provided that such laboratories must meet any federal requirements.
  - (2) Establish minimum qualifications of individuals that may perform clinical laboratory tests, provided that such persons meet federal requirements.
  - (3) Allow clinical laboratories to accept specimens without an order, subject to a plan approved by Commissioner to ensure the result of any tests are reported to the patient or the patient's personal representative and there will be appropriate follow up with the patient based on the results.
  - (4) Authorize licensed pharmacists to order clinical laboratory tests, consistent with federal law, including certificate of waiver requirements.
  - (5) Permit licensed pharmacists to be designated as qualified healthcare professionals for the purpose of directing a limited service laboratory, pursuant to Section 579 of the Public Health Law.
  - (6) Permit licensed pharmacists to order and administer clinical tests.
- (c) Prioritization of clinical laboratory tests. In the event the declared state disaster emergency requires utilization of clinical laboratory testing at a rate that exceeds available capacity, no laboratory shall perform such test unless the test has been ordered consistent with the testing prioritization published by the Commissioner.
- (d) Reporting of results of any communicable disease during a Surge and Flex period shall be made immediately via the Electronic Clinical Laboratory Reporting system, if positive, and on a schedule as determined by the Commissioner if negative.

Subdivision (g) of section 405.24 of 10 NYCRR is amended to read as follows:

Emergency and disaster preparedness. The hospital shall have a written plan, rehearsed and updated at least twice a year, with procedures to be followed for the proper care of patients and personnel, including but not limited to the reception and treatment of mass casualty victims, in the event of an internal or external emergency or disaster arising from the interruption of normal services resulting from earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences. Personnel responsible for the hospital's accommodation to extraordinary events shall be trained in all aspects of preparedness for any interruption of services and for any disaster. This shall be in addition to the Surge and Flex Plan that is required pursuant to Part 360 of the Title.

Section 400.1 of 10 NYCRR is amended to read as follows:

(a) This Subchapter shall be known and may be cited as "Medical Facilities--Minimum Standards," and shall apply to medical facilities defined as hospitals within article 28 of the Public Health Law. The standards within a particular article shall constitute the minimum standards for the identified medical facility in addition to those standards that may apply to such facilities as set forth in Articles 1 and 3 of this Subchapter as applicable.

(b) During the period of a state disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay

action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to his authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 700.5 of 10 NYCRR is added to read as follow:

700.5 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority

under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (8) is added to subdivision (e) of section 1001.6 of 10 NYCRR, to read as follows:

(8) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 1.2 of 10 NYCRR is added to read as follows.

1.2 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Title, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (4) subdivision (g) of section 487.3 of 18 NYCRR is added to read as follows:

(4) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the

Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (6) subdivision (f) of section 488.3 of 18 NYCRR is added to read as follows:

(6) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (5) subdivision (g) of section 490.3 of 18 NYCRR is added to read as follows:

(5) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

## 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 (nursing homes) and diagnostic and treatment centers (D&TCs). 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 section 4662 authorizes the Commissioner to issue regulations governing assisted living residences. Social Services Law (SSL) section 461(1) authorizes the Commissioner to promulgate regulations establishing standards applicable to adult care facilities. PHL section 576 authorizes the Commissioner to regulate clinical laboratories.



PHL section 225 authorizes the Public Health and Health Planning Council (PHHPC) and the 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.

Upon the future declaration of any disaster emergency, any further authorization by the Governor pursuant to article 2-B of the Executive Law, if it should suspend any statutes which otherwise conflict with these regulations, will establish the immediate effectiveness of these provisions.

**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. Similarly, PHL Articles 36 and 40 ensure that the Department has the tools needed to achieve these goals in the home care and hospice spaces, and PHL section 4662 and SSL section 461 likewise ensure that the Department has appropriate regulatory authority with respect to assisted living residences and adult care facilities. PHL section 576 ensures that the Commissioner has appropriate regulatory authority over clinical laboratories. Finally, PHL section 225 ensures that the State Sanitary Code includes appropriate regulations in the areas of communicable disease control and environmental health, among others.

By permitting the Commissioner to temporarily suspend or modify regulatory provisions in each these areas, where not required by state statute or federal law, or where he is authorized

by a gubernatorial Executive Order, these amendments provide crucial flexibility for this and future emergency response efforts.

**Needs and Benefits:**

During a state disaster emergency, Section 29-a of the Executive Law permits the Governor to, among other things, “temporarily suspend specific provisions of any statute, local law, ordinance, or orders, rules or regulations, or parts thereof, of any agency during a state disaster emergency, if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the disaster.”

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions or modifications. The proposed regulatory amendments would permit the State Commissioner of Health or designee to take specific actions, as well as to temporarily suspend or modify certain regulatory provisions (or parts thereof) in Titles 10 and 18 of the NYCRR during a state disaster emergency, where such provisions are not required by statute or federal law. These proposed amendments would also permit the Commissioner to take certain actions, where consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. Examples include issuing directives to authorize and require clinical laboratories or hospitals to take certain actions consistent with any such EOs, as well as the temporary suspension or modification of additional regulatory provisions when the Governor temporarily suspends or modifies a controlling state statute.

The proposed regulatory amendments would also require hospitals to: develop disaster emergency response plans; maintain a 60-day supply of personal protective equipment (PPE); ensure that staff capable of working remotely are equipped and trained to do so; and report data as requested by the Commissioner.

During a state disaster emergency with significant public health impact, and where compliance with certain regulations may prevent, hinder or delay action necessary to cope with the disaster, as is the case with COVID-19, this authority will ensure that the State has the most efficient regulatory tools to facilitate the State's and regulated parties' response efforts to Surge and Flex the healthcare system statewide. Additionally, this authority will also ensure that the Department has the flexibility to impose additional requirements, where necessary, to ensure effective response to a declared state disaster emergency. Accordingly, these tools will help ensure the health and safety of patients and residents in New York State.

**Costs:**

**Costs to Regulated Parties:**

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within, and as part of, a coordinated response to a specific situation.

To the extent that additional requirements are imposed on regulated parties by these proposed regulatory amendments, most requirements would be in effect only for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible.

**Costs to Local Governments:**

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within and as part of a coordinated response to a specific situation.

To the extent additional requirements are imposed on local governments that operate facilities regulated by the Department, most requirements would be in effect only for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible.

**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 these proposed amendments require additional reporting,

these reports can be submitted electronically using the current platforms that facilities are already using. Moreover, such reporting requirements would only be activated during a declared state disaster emergency, thereby limiting the burden.

**Local Government Mandates:**

Facilities operated by local governments will 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. However, this alternative was rejected, as the Department believes that these regulatory amendments are necessary to facilitate response to a state disaster emergency.

**Federal Standards:**

42 CFR 482.15 establishes emergency preparedness minimum standards in four core areas including emergency planning, development of applicable policies and procedures, communications plan, and training and testing. These proposed amendments would complement the federal regulation and further strengthen hospitals' emergency preparedness and response programs.

**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:**

The proposed regulatory amendments would primarily affect health care professionals, licensed health care facilities, permitted clinical laboratories, emergency medical service personnel, providers, and agencies, and pharmacies.

### **Compliance Requirements:**

A significant portion of these regulatory amendments are designed to provide regulatory relief during a declared state disaster emergency. Where the regulatory amendments would impose requirements, most of them would only be applicable when there is a declared state disaster emergency. An example of a requirement that may be implemented during a declared state disaster emergency is reporting of data and inventory as requested by the Commissioner (i.e. medical supplies and equipment, as well as hospital bed capacity, bed utilization, patient demographics, etc.). There are certain ongoing requirements proposed by this regulatory amendments, which would apply regardless of whether there is a declared state disaster emergency, in which hospitals would be required to: (1) maintain minimum levels of PPE; (2) ensure work from home capabilities; and (3) develop disaster emergency response plans.

### **Professional Services:**

It is not expected that any professional services will be required to comply with the proposed regulatory amendments.

**Compliance Costs:**

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within and as part of a coordinated response to a specific situation.

To the extent additional requirements are imposed on small businesses and local governments by these proposed regulatory amendments, most requirements would only be in effect for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible. Ongoing costs requiring hospitals to maintain a minimum PPE supply and ensure work from home capabilities should have been addressed throughout the ongoing COVID-19 pandemic, thereby limiting costs of continued implementation. Ongoing costs related to hospital development of disaster emergency response plan will complement and build upon existing planning documents that hospitals are already required to have, which also limits costs.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the proposed regulatory amendments.

**Minimizing Adverse Impact:**

Although the proposed regulatory amendments impose some additional requirements on regulated parties, most of these requirements are only triggered during a declared state disaster



emergency. Proposed amendments that would impose ongoing requirements would only apply to hospitals, and as noted above, will largely be a continuation of the efforts already being employed by these entities.

**Small Business and Local Government Participation:**

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

## 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:**

A significant portion of these regulatory amendments are designed to provide regulatory relief during a declared state disaster emergency. Where the regulatory amendments would impose requirements, most of them would only be applicable when there is a declared state disaster emergency. An example of a requirement that may be implemented during a declared state disaster emergency is reporting of data and inventory as requested by the Commissioner (i.e. medical supplies and equipment, hospital bed capacity, bed utilization, patient demographics, etc.). There are certain ongoing requirements proposed by this regulatory amendments, regardless of whether there is a declared state disaster emergency, in which hospitals would be required to: (1) maintain minimum levels of PPE; (2) ensure work from home capabilities; and (3) develop disaster emergency response plans. This regulation provides that the Commissioner's directives shall be incremental and geographically tailored and targeted at the Statewide, regional, or community level, as dictated by infection rate data.

It is not expected that any professional services will be required to comply with the proposed regulatory amendments.

### **Compliance Costs:**

As a large part of these regulatory amendments would give the State Commissioner of Health authority to temporarily suspend or modify certain regulations within Titles 10 and 18 during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to public and private entities in rural areas.

To the extent additional requirements are imposed on public and private entities in rural areas by these proposed regulatory amendments, such requirements would only be in effect for the duration of a declared state disaster emergency.

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**

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

### **Minimizing Adverse Impact**

Although the proposed regulatory amendments impose additional requirements on regulated parties, including those in rural areas, most of these requirements are only triggered during a declared state disaster emergency. Proposed amendments that would require disaster emergency preparedness planning on the part of regulated parties will complement and build upon existing state and federal planning requirements.

## **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 for the 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**

During a state disaster emergency with significant public health impact, and where compliance with certain regulations may prevent, hinder or delay action necessary to cope with the disaster, as is the case with COVID-19, these proposed regulations will ensure that the State has the most efficient regulatory tools to facilitate the State's and regulated parties' response efforts to Surge and Flex the healthcare system statewide. Additionally, this authority will also ensure that the Department has the flexibility to impose additional requirements, where necessary, to ensure effective response to a declared state disaster emergency. Accordingly, these tools will help ensure the health and safety of patients and residents in New York State.

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, an Executive Order was issued 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. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed rule making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

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## **REGULATORY FLEXIBILITY ANALYSIS**

### **Effect on Small Business and Local Government:**

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

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

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

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

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

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

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**

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, an Executive Order was issued 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.

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.

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