

# Public Health and Health Planning Council

## *Codes, Regulations and Legislation Committee Meeting Agenda and Informational Announcements*

*Thursday, June 3, 2021  
9:30 AM*

*Via Live Webcasting*

### **I. WELCOME AND INTRODUCTION**

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

### **II. REGULATIONS**

<b>For Discussion</b>	<b>Program Area</b>	<b>Unit Representative</b>
20-22 Amendment of Section 405.11 of Title 10 NYCRR (Hospital Personal Protective Equipment (PPE) Requirements)	Division of Legal Affairs	Vanessa Murphy
20-23 Amendment of Section 415.19 of Title 10 NYCRR (Nursing Home Personal Protective Equipment (PPE) Requirements)	Division of Legal Affairs	Jaclyn Sheltry
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)	Office of Primary Care and Health Systems Management	Dr. Richard Becker
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)		TBD
20-06 Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to Title 10 NYCRR (Investigation of Communicable Disease; Isolation and Quarantine)	Division of Legal Affairs	Vanessa Murphy
21-06 Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel)	Division of Legal Affairs	Jaclyn Sheltry

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 section 405.11, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

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

(g) (i) 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 guidance, for at least 60 days by August 31, 2020, and at least 90 days by September 30, 2020, at rate of usage equal the average daily rate that PPE was used between April 13, 2020 and April 27, 2020; provided, however, that upon request the Department may grant an extension of the deadline to October 30, 2020, at its sole and exclusive discretion for having at least a 90 day supply of PPE where the hospital demonstrates, to the Commissioner's satisfaction, that:

(A) the hospital's inability to meet this deadline is solely attributable to supply chain issues that are beyond the hospital's control and purchasing PPE at market rates would facilitate price gouging by PPE vendors; or

(B) the seven-day rolling average of new COVID-19 infections in New York State remains below one and a half percent (1.5%) of the total seven-day rolling average of COVID-19 tests performed over the same period; and there are ten or less states in the United States that have a seven-day rolling average of new COVID-19 infections exceeding five thousand cases.

(ii) Failure to possess and maintain such a supply of PPE may result in the revocation or suspension of the hospital's license; provided, however, that no such revocation 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.

## **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.

### **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. According to Johns Hopkins' Coronavirus Resource Center, as of May 25, 2021, there have been over 167 million cases and over 3.4 million deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. Since then, the situation has 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.

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. Subsequently, on March 13, 2020, former President Donald J. Trump declared a national emergency in response to COVID-19, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

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.

In order for hospital staff to safely provide care for COVID-19 positive patients who require hospitalization, 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. As a result of global PPE shortages at the outset of the State of Emergency, New York State provided general hospitals and other medical facilities with PPE from the State's emergency stockpile from the beginning of the COVID-19 outbreak.

Based on the foregoing, the Department has made the determination that this regulation is necessary to ensure that all general hospitals maintain a 90-day supply of PPE, at a usage rate

equal to the highest average rate of usage during the COVID-19 emergency, such that sufficient PPE is available in the event of a continuation or resurgence of the COVID-19 outbreak.

## **COSTS:**

### **Costs to Regulated Parties:**

The purpose of this regulation is to require general hospitals to maintain adequate stockpiles of PPE. General hospitals have already experienced the initial cost of establishing stockpiles of PPE. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, 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, in which case costs will be the same as costs for private entities.

### **Costs to the Department of Health:**

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

### **Paperwork:**

This regulation imposes no addition paperwork.

**Local Government Mandates:**

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

**Federal Standards:**

Part 1910 of Title 29 of the Code of Federal Regulations requires general hospitals to provide adequate PPE to hospital staff. However, no federal standards apply to stockpiling of such equipment.

**Compliance Schedule:**

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register. These regulations are expected to be proposed for permanent adoption at the next meeting of the Public Health and Health Planning Council following the termination of the COVID-19 emergency.

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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. Currently there are five general hospitals in New York that employ less than 100 staff and qualify as small businesses.

### **Compliance Requirements:**

These regulations require all general hospitals 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 to maintain adequate stockpiles of PPE. General hospitals have already experienced the initial cost of establishing stockpiles of PPE. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, 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:**

As these regulations require general hospitals to maintain stockpiles of PPE, which they are already obligated to provide to staff under existing federal regulations, any adverse impacts are expected to be minimal.

**Small Business and Local Government Participation:**

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

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Estimated Numbers of Rural Areas:

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.

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

These regulations require all general hospitals, 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 to maintain adequate stockpiles of PPE. General hospitals have already experienced the initial cost of establishing stockpiles of PPE. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, 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:**

As these regulations simply require general hospitals to maintain stockpiles of PPE, that they are already obligated to provide to staff under existing federal regulations, any adverse impacts are expected to be minimal.

**Rural Area Participation:**

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

## **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.

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 section 415.19, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

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

(f) (i) The facility shall possess and maintain a supply of all necessary items of personal protective equipment (PPE) sufficient to protect facility personnel, consistent with federal Centers for Disease Control guidance, for at least 30 days at rate of usage equal to the average daily rate that PPE was used between April 19, 2020 and April 27, 2020 by August 31, 2020, and for at least 60 days at a rate of usage equal to the average daily rate that PPE was used between April 19, 2020 and April 27, 2020 by September 30, 2020; provided, however, that upon request the Department may grant an extension of the deadline to have such sixty day supply to October 30, 2020, at its sole and exclusive discretion, to meet this requirement where the facility demonstrates, to the Commissioner's satisfaction, that:

(A) the facility's inability to meet this deadline is solely attributable to supply chain issues that are beyond the facility's control and purchasing PPE at market rates would facilitate price gouging by PPE vendors; or

(B) the seven-day rolling average of new COVID-19 infections in New York State remains below one and a half percent (1.5%) of the total seven-day rolling average of COVID-19 tests performed over the same period; and there are ten or less states in the United States that have a seven-day rolling average of new COVID-19 infections exceeding five thousand cases.

(ii) Failure to possess and maintain such a supply of PPE may result in the revocation or suspension of the facility's license; provided, however, that no such revocation or suspension shall be ordered unless the Department has provided the facility with a fourteen day grace period, solely for a facility'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.

### **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. According to Johns Hopkins' Coronavirus Resource Center, as of May 25, 2021, there have been over 167 million cases and over 3.4 million deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. Since then, the situation has 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.

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. Subsequently, on March 13, 2020, former President Donald J. Trump declared a national emergency in response to COVID-19, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

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.

In order for a nursing home's staff to safely provide care for residents, 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. As a result of global PPE shortages at the outset of the State of Emergency, New York State provided nursing homes and other health care facilities with PPE from the State's emergency stockpile from the beginning of the COVID-19 outbreak.

Based on the foregoing, the Department has made the determination that this regulation is necessary to ensure that all nursing homes maintain a 60-day supply of PPE, at rate of usage

equal the average daily rate that PPE was used between April 19, 2020 and April 27, 2020, such that sufficient PPE is available in the event of a continuation or resurgence of the COVID-19 outbreak.

## **COSTS:**

### **Costs to Regulated Parties:**

The purpose of this regulation is to require nursing homes to maintain adequate stockpiles of PPE. Nursing homes have already experienced the initial cost associated with establishing stockpiles of PPE. Further, 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). Additionally, the federal Occupational Health and Safety Administration (OSHA) has recommended that nursing homes ensure that staff have access to sufficient PPE to perform their jobs safely, and employers are currently obligated to pay for personnel PPE pursuant to OSHA regulations at 29 CFR 1910.132(h). Therefore, 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 nursing home, in which case costs will be the same as costs for private entities.

### **Costs to the Department of Health:**

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

**Paperwork:**

This regulation imposes no addition paperwork.

**Local Government Mandates:**

Nursing homes 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.

**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 have adequate stockpiles of PPE necessary to protect nursing home staff from communicable diseases, compared to any alternate course of action.

**Federal Standards:**

No federal standards apply to stockpiling of such equipment at nursing homes.

**Compliance Schedule:**

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register. These regulations are expected to be proposed for permanent adoption at the next meeting of the Public Health and Health Planning Council following the termination of the COVID-19 emergency.

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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. To date, 79 nursing homes in New York qualify as small businesses given that they employ less than 100 staff.

### **Compliance Requirements:**

These regulations require all 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 nursing homes to maintain adequate stockpiles of PPE. Nursing homes have already experienced the initial cost associated with establishing stockpiles of PPE. Further, 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). Additionally, the federal Occupational Health and Safety Administration (OSHA) has recommended that nursing homes ensure that staff have access to sufficient PPE to perform their jobs safely, and employers are currently obligated to pay for personnel PPE pursuant to OSHA regulations at 29 CFR 1910.132(h). 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:**

As these regulations require nursing homes to maintain stockpiles of PPE, consistent with the directive in Public Health Law section 2803(12) for nursing homes to maintain or contract to have at least a two-month supply of PPE, as well as OSHA regulations and recommendations regarding the payment for and provision of PPE, any adverse impacts are expected to be minimal.

**Small Business and Local Government Participation:**

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

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Estimated Numbers of Rural Areas:

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	

Licensed nursing homes are located in these identified rural areas.

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

These regulations require all 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 nursing homes to maintain adequate stockpiles of PPE. Nursing homes have already experienced the initial cost associated with establishing stockpiles of PPE. Further, 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). Additionally, the federal Occupational Health and Safety Administration (OSHA) has recommended that nursing homes ensure that staff have access to sufficient PPE to perform their jobs safely, and employers are currently obligated to pay for personnel PPE pursuant to OSHA regulations at 29 CFR 1910.132(h). 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:**

As these regulations simply require nursing homes to maintain stockpiles of PPE, which is consistent with the directive in Public Health Law section 2803(12) for nursing homes to maintain or contract to have at least a two-month supply of PPE, as well as OSHA regulations and recommendations regarding the payment for and provision of PPE any adverse impacts are expected to be minimal.

**Rural Area Participation:**

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

## **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.

## SUMMARY OF EXPRESS TERMS

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations and issue directives pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions, modifications, and directives. 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 90-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 publication of a Notice of Adoption in the New York State Register, 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.

As of July 2020, there are 213 hospitals - public, private, and independent - across New York State, each operating as essentially a private entity in a highly competitive environment. Prior to the COVID-19 pandemic, these individual institutions and hospital networks 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.

No one situation best encapsulates this lack of coordination than what transpired at Elmhurst Hospital, a facility in the New York City-operated Health & Hospitals (H&H) system, during the third week of March. Elmhurst Hospital was overwhelmed with patients at a time when there were just 4,000 total COVID-19 hospitalizations statewide, nearly 900 available beds across the eleven hospitals in the H&H system, and more than 3,500 open beds across all public and private hospitals in New York City. In other words, the problem the Elmhurst situation exposed was not one of hospital capacity, but one of patient load management across all hospitals and hospital systems.

As the Elmhurst situation demonstrated, 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. There was an immediate realization that if peak projections actually materialized in New York, 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.

This approach was operationalized in late March when Governor Andrew M. Cuomo directed the New York State Department of Health (NYSDOH) to create a new and innovative “Surge and Flex” system, designed to create for the first time one singular coordinated statewide public healthcare system to prevent the virus from overwhelming any one hospital in the state. The approach was literally a life-saver—it helped New York at our peak of hospitalizations in April to facilitate the transfer of thousands of patients. The purpose of this NYSDOH regulation is to institutionalize the Surge and Flex operation to both allow the state to quickly activate Surge

and Flex in the event of a resurgence of coronavirus, while also giving hospitals the time and guidance to adequately prepare for a potential future activation of Surge and Flex.

The Surge and Flex system operation launched in March 2020 included four key elements which this regulation will institutionalize, as detailed below.

**First, the State quickly built unprecedented hospital capacity.**

Health experts modeled that New York State could potentially need as many as 140,000 COVID-only hospital beds when there were only 53,000 hospital beds total in the entire state. As a result, New York State had to quickly build unprecedented bed capacity including requiring all hospitals to delay non-life-threatening elective procedures and increase their number of beds by at least 50 percent (by turning single rooms into doubles and freeing meeting rooms and other areas for patient care among other measures) and preferably 100 percent. In addition, the State worked with local and federal government partners to deploy and stand up temporary hospitals and create contingency plans with large-scale venue operators, hotels, and college dormitory operators, to ensure we were prepared for a worst-case scenario - a projected need for as many as 140,000 COVID patients hospitalized at one time. In total, this approach enabled New York State in a matter of weeks to expand hospital capacity from 53,000 total beds to more than 90,000.

**Second, more beds require more staff.**

Staffing was a major issue. In many cases, health care staff were becoming sick with COVID and unable to work. This put tremendous strain on the system. To address staffing shortages, New York State established a web portal to recruit and connect health care professionals from across the nation willing to serve, an effort that enlisted the support of nearly 100,000 health care workers. New York State connected these healthcare heroes with housing as

needed and provided support to hospital human resource offices to expedite the onboarding process. Further, New York State facilitated transfers of healthcare staff from upstate hospitals that had few COVID-19 patients to hospitals in New York City in need of staffing support. In the case of another wave of COVID-19 or another infectious disease it is critical that extra staffing capacity be available to meet the emergency.

**Third, more beds require more supplies and equipment.**

Access to life-saving supplies and materials was a scramble for every state in the nation because our country is reliant on an international supply chain. There was a dire need for ventilators and there was a literal hunger games scenario among states and nations to purchase enough to meet the demand under the crisis. But purchasing alone wasn't enough. There simply weren't enough supplies. To address any potential supply and equipment shortages, New York State used data and a daily reporting system to build a statewide inventory of personal protective equipment (PPE), ventilators, medications and other critical items. Using a reporting system, New York State could take limited resources and distribute them to the hospitals and other institutions that needed them the most. For example, a hospital in New York City may have had only a few ventilators while other facilities nearby had more than 100. The Surge and Flex system allowed for the overburdened hospital to get unused ventilators from a nearby facility. New York State distributed more than 13,000,000 pieces of PPE and other equipment, including thousands of ventilators. To ensure no hospital lacked supplies and equipment while others had excess, the state built an operational system that could quickly transport supplies and equipment from a hospital with excess to a hospital in need.



**Fourth, the State had to coordinate all aspects of the Surge and Flex operation.**

For this operational undertaking, the State convened a Hospital Capacity Coordination Committee (HCCC), an around the clock command center with representatives from each of the State's hospital systems to serve as the central hub for operations related to patient transfers, supply and equipment deployment, and staffing support. Guided by online data dashboards that tracked hospital capacity, equipment use, and supply stockpiles by institution in real time, and provided a 24/7 hotline accessible to every hospital in the state, the HCCC had a dedicated desk and assigned leader for every aspect of the operation: patient management, supply & equipment deployment, staffing deployment, and for each supporting function including transportation, legal, and intergovernmental relations.

Taken together, the "Surge and Flex" strategy enabled New York during our apex in late March and through the month of April to save lives and avoid the type of catastrophic failure of the healthcare system that Italy and other nations experienced. This regulation provides the Department of Health with the necessary tools to enact each of these four critical parts of NYS Surge and Flex operation during a second 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 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, health care facilities shall increase by at least 50% and up to 100% 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 all non-essential elective procedures or allow such procedures only pursuant to such conditions as the Commissioner may determine. The Department shall 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 90-days pursuant to Sections 360.2 and 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, but at minimum every 24 hours.
- (ii) Requiring that the patient census be reported to the Department, in a form and with such frequency as the Commissioner may determine, but at minimum every 24 hours.
- (iii) For any infectious and communicable disease, ensuring that testing results are reported immediately if positive, and four times per day if such testing results are

negative via the electronic clinical laboratory reporting system, or any other form and frequency 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 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 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, and up to a 100% increase within 30 days. 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.
- (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 90-day supply of PPE within 30 days, based on a usage rate determined by the Commissioner, 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.

(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 and 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, every six months 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 90-day supply of PPE appropriate for use in a disaster emergency including a pandemic, based on a usage rate and determined by the Commissioner, and 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 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 every 24 hours, 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 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 Chapter, 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.

**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.

Each of these areas has been impacted by COVID-19. 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 the Commissioner 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 any statute, local law, ordinance, orders, rules, or regulations, or parts thereof, of any agency . . . if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the state disaster emergency.” To that end, on March 7, 2020 and in response to the COVID-19 pandemic, Governor Andrew M. Cuomo issued Executive Order No. 202, declaring a state disaster emergency, thereby enabling additional State action that aided in addressing the threat COVID-19 presents to the health and welfare of New York State residents and visitors.

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations and issue directives pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions, modifications, and directives. 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 90-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 a significant portion of these regulatory amendments would give the State Commissioner of Health authority to temporarily suspend or modify certain regulations within Titles 10 and 18 of the NYCRR during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to regulated parties.

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, thereby limiting costs. The ongoing cost to hospitals of requiring a minimum PPE supply have already been realized through Executive Orders.

**Costs to Local Governments:**

As a significant portion of these regulatory amendments would give the Commissioner authority to temporarily suspend or modify certain regulations within Titles 10 and 18 of the NYCRR during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to regulated parties, including facilities operated by local governments.

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, thereby limiting costs. The ongoing cost to hospitals of requiring a minimum PPE supply have already been realized through Executive Orders.

**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 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. 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 publication of a Notice of Adoption in the New York State Register.

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## **REGULATORY FLEXIBILITY ANALYSIS**

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

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 a significant portion 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 small businesses and local governments.

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, thereby limiting costs. 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.

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.

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 Sections 3401 and 4143 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 publication of a Notice of Adoption in the New York State Register, 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 section 3401 authorizes the Commissioner to issue regulations pertaining to the business of funeral directing, and section 4143 authorized the Commissioner to collect information from coroners and medical examiners related to cause of death.

**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, and the objective of section 4143 is to authorize the Commissioner to collect such information related to cause of death from coroners and medical examiners as the Commissioner may require.

**Needs and Benefits:**

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.

**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 publication of a Notice of Adoption in the New York State Register.

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## **REGULATORY FLEXIBILITY ANALYSIS**

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

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. In the case of nursing homes, facilities are required to test personnel for COVID-19 pursuant to New York State Executive Order 202.30, as modified by Executive Order 202.88. Given that such facilities are actively testing persons within their facility, the Department anticipates that any adverse impacts will be minimal. Moreover, the Department will work to promptly issue guidance documents to covered parties to clarify these regulatory requirements, thus helping to minimize any adverse impacts.



**Small Business and Local Government Participation:**

Due to the emergent nature of COVID-19, small business and local governments were not consulted. However, parties representing local governments and small businesses may submit comments during the notice and comment period in the event the Department promulgates proposed regulations.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Number of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.” The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

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

Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

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

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

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

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

**Compliance Costs:**

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

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

**Economic and Technological Feasibility:**

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

**Minimizing Adverse Impact:**

Many facilities covered under this regulation, including those owned and operated by a local government or small business, currently test patients or residents for COVID-19. In the case of nursing homes, facilities are required to test personnel for COVID-19 pursuant to New York State Executive Order 202.30, as modified by Executive Order 202.88. Given that such facilities are actively testing persons within their facility, the Department anticipates that any adverse impacts will be minimal. Moreover, the Department will work to promptly issue guidance documents to covered parties to clarify these regulatory requirements, thus helping to minimize any adverse impacts.

**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.

## **SUMMARY OF EXPRESS TERMS**

These regulations clarify the authority and duty of the New York State Department of Health (“Department”) and local health departments to protect the public in the event of an outbreak of communicable disease, through appropriate public health orders issued to persons diagnosed with or exposed to a communicable disease. These regulations also require hospitals to report syndromic surveillance data to the Department upon direction from the Commissioner and clarify reporting requirements for clinical laboratories with respect to communicable diseases.

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

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

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

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



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

\* \* \*

- (h) Contact shall mean any person known to have been sufficiently associated with a case or suspected case that, based on the best available evidence of transmissibility, such person has had the opportunity to contract a particular disease or condition.
  
- (i) Isolation shall mean the physical separation and confinement of an individual or group of individuals who are infected or reasonably determined by the State Commissioner of Health or local health authority to be infected with a highly contagious disease or organism, for such time as will prevent or limit the transmission of the reportable disease or organism to non-isolated individuals, in the clinical judgment of the State Commissioner of Health, or of the local health authority and consistent with any direction that the State Commissioner of Health may issue.
  
- (j) Quarantine shall mean the physical separation and confinement of an individual or groups of individuals who are reasonably determined by the State Commissioner of Health or local health authority to have been exposed to a highly contagious communicable disease, but who do not show signs or symptoms of such disease, for such time as will prevent transmission of the disease, in the clinical judgment of the State Commissioner of Health, or of the local

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

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

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

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

- (1) Verifying the existence of a disease or condition;
- (2) Ascertaining the source of the disease-causing agent or condition;
- (3) Identifying unreported cases;
- (4) Locating and evaluating contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;
- (5) Collecting and submitting, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the source of disease, or to assist with diagnosis; and furnish or cause to be furnished with such specimens pertinent data on forms prescribed by the State Commissioner of Health, including but not limited to the history of cases, physical findings and details of the epidemiological investigation;

- (6) Examining the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;
- (7) Instructing a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and
- (8) Taking any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

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

(c) Investigation Updates and Reports.

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

Commissioner of Health, unless the State Commissioner of Health prescribes a different time period.

(d) Commissioner authority to lead investigation activities.

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

- (i) Residents of multiple jurisdictions within the State are affected by an outbreak of a reportable disease, condition, or unusual disease; or
- (ii) Residents in a jurisdiction or jurisdictions within the State and in other state are affected by an outbreak of a reportable disease, condition, or unusual disease; or
- (iii) An outbreak of an unusual disease or a reportable disease or condition involves a single jurisdiction with the high potential for statewide impact.

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

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

New section 2.13 is added to read as follows:

2.13 Isolation and Quarantine Procedures

(a) Duty to issue isolation and quarantine orders

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

(4) For the purposes of quarantine orders, quarantine locations may include home quarantine, other residential or temporary housing quarantine, or quarantine at such other locations as the public health authority issuing the order deems appropriate, consistent with any direction that the State Commissioner of Health may issue.

(b) Any isolation or quarantine order shall specify:

(1) The basis for the order;

(2) The location where the person shall remain in isolation or quarantine, unless travel is authorized by the State or local health authority, such as for medical care;

(3) The duration of the order;

(4) Instructions for traveling to the isolation or quarantine location, if appropriate;

(5) Instructions for maintaining appropriate distance and taking such other actions as to prevent transmission to other persons living or working at the isolation or quarantine location, consistent with any direction that the State Commissioner of Health may issue;

(6) If the location of isolation or quarantine is not in a general hospital, instructions for contacting the State and/or local health authority to report the subject person's health condition, consistent with any direction that the State Commissioner of Health may issue;

(7) If the location of isolation or quarantine is a multiple dwelling structure, that the person shall remain in their specific dwelling and in no instance come within 6 feet of any other person, and consistent with any direction that the State Commissioner of Health may issue;

- (8) If the location of isolation or quarantine is a detached structure, that the person may go outside while remaining on the premise, but shall not leave the premise or come within 6 feet of any person who does not reside at the premise, or such other distance as may be appropriate for the specific disease, and consistent with any direction that the State Commissioner of Health may issue;
- (9) Such other limitations on interactions with other persons as are appropriate, consistent with any direction that the State Commissioner of Health may issue;
- (10) Notification of the right to request that the public health authority issuing the order inform a reasonable number of persons of the conditions of the isolation or quarantine order;
- (11) A statement that the person has the right to seek judicial review of the order;
- (12) A statement that the person has the right to legal counsel, and that if the person is unable to afford legal counsel, counsel will be appointed upon request.

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

- (1) monitor such person to ensure compliance with the order and determine whether such person requires a higher level of medical care;
- (2) whenever appropriate, coordinate with local law enforcement to ensure that such person comply with the order; and



- (3) the extent such items and services are not available to such person, provide or arrange for the provision of appropriate supports, supplies and services, including, but not limited to: food, laundry, medical care, and medications.
- (d) If the location of an isolation or quarantine order is owned by a landlord, hotel, motel or other person or entity, no such landlord or person associated with such hotel, motel or other person or entity shall enter the isolation or quarantine location without permission of the local health authority, and consistent with any direction that the State Commissioner of Health may issue.
- (e) No article that is likely to be contaminated with infective material may be removed from a premise where a person is isolated or quarantined unless the local health authority determines that such article has been properly disinfected or protected from spreading infection, or unless the quarantine period expires and there is no risk of contamination. Such determinations shall be made pursuant to any direction that the State Commissioner of Health may issue.
- (f) Any person who violates a public health order issued pursuant to this section shall be subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each day that the order is violated shall constitute a separate violation of this Part.
- (g) Duty of attending physician
- (1) Every attending physician shall immediately, upon discovering a case or suspected case of a highly contagious reportable communicable disease, cause the patient to be

appropriately isolated and contact the State Department of Health and the local health authority where the patient is isolated and, if different, the local health authority where the patient resides.

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

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

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

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

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

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

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

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

\* \* \*

Section 58-1.14 Reporting of certain communicable diseases

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

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

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

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

\* \* \*

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

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

## REGULATORY IMPACT STATEMENT

### **Statutory Authority:**

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

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

The statutory authority for the proposed amendments to section 405.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is section 2803 of the PHL, which authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

**Legislative Objectives:**

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

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

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

**Needs and Benefits:**

The 2019 Coronavirus (COVID-19) is a disease that has caused 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 hospital and can be fatal.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. A short time later, on January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On January 31, 2020, the Secretary of Health and Human Services determined that as a result of confirmed cases of COVID-19 in the United States, a public health emergency exists and has existed since January 27, 2020, nationwide.

Thereafter, the United States quickly progressed from identifying travel-associated cases and person-to-person transmission of COVID-19 among close contacts of travel-associated cases, to the identification of community spread of the disease throughout the country.

The Department proposes to adopt these regulations, originally proposed as emergency regulations, that update, clarify and strengthen the Department's authority as well as that of local health departments to take specific actions to control the spread of disease, including actions related to investigation and response to a disease outbreak, as well as the issuance of isolation and quarantine orders.

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

*Part 2 Amendments:*

- Relocate and update definitions, and add new definitions
- Repeal and replace current section 2.6, related to investigations, to make existing clarify local health department authority.
  - Sets forth specific actions that local health departments must take to investigate a case, suspect case, outbreak, or unusual disease.
  - Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.
  - Clarifies authority for the Commissioner to lead investigation activities.
  - Codifies in regulation the requirement that local health departments send reports the Department during an outbreak.
- New section 2.13 added to clarify isolation and quarantine procedures.
  - Clarify that the State Department of Health has the authority to issue isolation and quarantine orders, as do local departments of health.

- Clarifies locations where isolation or quarantine may be appropriate.
- Sets forth requirements for the content of isolation and quarantine orders.
- Specifies other procedures that apply when a person is isolated or quarantined.
- Explicitly states that violation of an order constitutes grounds for civil and/or criminal penalties
- Relocates and updates existing regulatory requirements that require the attending physician to report cases and suspected cases to the local health authority, and to requires physicians to provide instructions concerning how to protect others.

*Part 58 Amendments*

- New section 58-1.14 added clarifying reporting requirements for certain communicable diseases
  - Requires the Commissioner to designate those communicable disease that require prompt action, and to make available a list of such disease on the State Department of Health website.
  - Requires clinical laboratories to immediately report positive test results for communicable diseases identified as requiring prompt attention, in a manner and format identified by the Commissioner.
  - Requires clinical laboratories to report all test result, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

*Part 405 Amendments*



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

## **COSTS:**

### **Costs to Regulated Parties:**

The requirement that hospital submit syndromic surveillance reports when request during an outbreak is not expected to result in any substantial costs. Hospitals are already regularly and voluntarily submitting data to the Department, and nearly all of them submit such reports electronically. With regard to the Commissioner directing general hospitals to accept patients during an outbreak of a highly contagious communicable disease, hospitals are already required to adhere to the federal Emergency Medical Treatment and Labor Act (EMTALA). Accordingly, both of these proposed amendments will not impose any substantial additional cost to hospitals.

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

Although there are costs associated with disease investigation and response for any outbreak, these regulations clarify and strengthen the existing authorities and responsibilities of

local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations.

**Costs to Local and State Governments:**

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

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

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

**Paperwork:**

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

**Local Government Mandates:**

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

**Duplication:**

There is no duplication in existing State or federal law.

**Alternatives:**

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

**Federal Standards:**

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

**Compliance Schedule:**

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

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## **REGULATORY FLEXIBILITY ANALYSIS**

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

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

### **Compliance Requirements:**

Under existing regulation, local health departments already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties. With respect to mandating syndromic surveillance reporting during an outbreak of a highly infectious communicable disease, hospitals are already reporting syndromic surveillance data regularly and voluntarily. With respect to clinical laboratories, they must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102. The regulation simply clarifies existing requirements and is not anticipated to impose any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

### **Professional Services:**

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

**Compliance Costs:**

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

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

**Economic and Technological Feasibility:**

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

**Minimizing Adverse Impact:**

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

**Small Business and Local Government Participation:**

Due to the emergent nature of COVID-19, small business and local governments were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity provided comments during the notice and comment period.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Estimated Numbers of Rural Areas:

While this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.”

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

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

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

Census estimated county populations for 2010:

Albany County  
Broome County  
Dutchess County  
Erie County

Monroe County  
Niagara County  
Oneida County  
Onondaga County

Orange County  
Saratoga County  
Suffolk County

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

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

**Compliance Costs:**

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



**Economic and Technological Feasibility:**

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

**Minimizing Adverse Impact:**

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

**Rural Area Participation:**

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity provided comments during the notice and comment period.

## **JOB IMPACT STATEMENT**

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

Pursuant to the authority vested in the Commissioner of Health by sections 201, 206 and 2803 of the Public Health Law, sections 461 and 461-e of the Social Services Law, and Executive Orders 202, 202.86 and 202.88, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended by adding a new Subpart 66-4, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

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

#### 66-4.1. Duration and Applicability

The provisions of this Subpart shall apply to all nursing homes and adult care facilities. To the extent any provision of this Subpart becomes inconsistent with any Executive Order, the remainder of the provisions in the Subpart shall remain in effect and shall be interpreted to the maximum extent possible as consistent with such Executive Orders.

#### 66-4.2 Requirements for Nursing Homes

(a) Within fourteen days of the effective date of this regulation, every nursing home regulated pursuant to Part 415 of this Title shall offer all consenting, unvaccinated existing personnel and residents an opportunity to receive the first or any required next dose of the COVID-19 vaccine.

(b) The operator and administrator of every nursing home regulated pursuant to Part 415 of this Title must ensure that all new personnel, including employees and contract staff, and every new resident and resident readmitted to the facility has an opportunity to receive the first or any

required next dose of the COVID-19 vaccine within fourteen days of having been hired by or admitted or readmitted to such facility, as applicable.

(c) The requirement to ensure that all new and current personnel and residents have an opportunity to receive the COVID-19 vaccination, as set forth in subdivisions (a) and (b) of this section, shall include, but not be limited to:

(1) Posting conspicuous signage throughout the facility, including at points of entry and exit and each residential hallway, reminding personnel and residents that the facility offers COVID-19 vaccination;

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

(3) Certifying to the Department, on a weekly basis, that the facility has proactively offered all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within fourteen days of being hired, admitted, or readmitted.

#### 66-4.3. Requirements for Adult Care Facilities

(a) Within seven days of the effective date of this regulation, the operator and administrator of every adult care facility regulated pursuant to Parts 487, 488 and 490 of Title 18 of the NYCRR and Part 1001 of this Title shall make diligent efforts to arrange for all consenting, unvaccinated existing personnel and residents to register for a vaccine appointment, and shall document

attempts to schedule and methods used to schedule the vaccine in the individual's personnel file or case management notes, as applicable.

(b) The operator and administrator of every adult care facility regulated pursuant to Parts 487, 488 and 490 of Title 18 of the NYCRR and Part 1001 of this Title must arrange for the COVID-19 vaccination, including the first or any required next dose, of all new personnel, including employees and contract staff, and every new resident and resident readmitted to the facility. The requirement to arrange for COVID-19 vaccination of such personnel and residents shall include, but not be limited to:

(1) For residents:

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

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

(2) For personnel:

(i) during the pre-employment screening process, the facility shall solicit information from the prospective personnel regarding their vaccination status, including whether any

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

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

(3) Certifying to the Department, on a weekly basis, that the facility has proactively arranged for all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within seven days of being hired, admitted, or readmitted.

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

66-4.4. Penalties.

(a) A violation of any provision of this Subpart is subject to all civil and criminal penalties provided for by law. To the extent any Executive Order is inconsistent with the penalties prescribed herein, the penalties in the Executive Order shall apply.

(b) All other violations of this Subpart shall be subject to penalties in accordance with sections 12 and 12-b of the Public Health Law.

(c) For adult care facilities, failure to arrange for the vaccination of every facility resident and personnel as set forth in section 66-4.3 of this Part constitutes a “failure in systemic practices and procedures” under Social Services Law 460-d(7)(b)(2)(iii) and pursuant to 18 NYCRR 486.5(a)(4)(v).

(d) 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 in accordance with the State’s Vaccination Plan.

## **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. SSL § 461-e authorizes the Department to promulgate regulations to require adult care facilities to maintain certain records with respect to the facility's 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. According to Johns Hopkins' Coronavirus Resource Center, as of May 25, 2021, there have been over 167 million cases and over 3.4 million deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

New York State first identified cases on March 1, 2020 and thereafter become 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 Executive Order No. 202, 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. With over 2 million confirmed

cases and almost 42,000 deaths as of May 25, 2021, New York State has been immensely affected by COVID-19.

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 State-operated vaccination site or a pharmacy.

Based on the foregoing, the Department has made the determination that this 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 State-run vaccination sites or a local pharmacy. Many ACFs have vehicles which can be used for necessary transport, but there may be minimal costs associated with transportation, particularly if the distance to the vaccination site is great and/or if the ACF does not readily have access to a vehicle.

**Costs to Local and State Governments:**

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

**Costs to the Department of Health:**

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

**Paperwork:**

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

**Local Government Mandates:**

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

**Duplication:**

These regulations do not duplicate any State or federal rules.

**Alternatives:**

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

**Federal Standards:**

No federal standards apply.

**Compliance Schedule:**

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

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## **REGULATORY FLEXIBILITY ANALYSIS**

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

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

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

### **Compliance Requirements:**

This regulation primarily requires nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. Specifically, nursing homes will be required to offer ongoing COVID-19 vaccinations at the facility, and ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or a local pharmacy. Additionally, nursing homes and ACFs will be required to certify to the Department that the facility has proactively arranged for or offered, as applicable, all new unvaccinated residents and personnel an opportunity to obtain the COVID-19 vaccine within the prescribed period of time. The regulation also requires facilities to provide all current and new personnel and residents who decline to be vaccinated a written affirmation for their signature, which indicates that they were offered the opportunity for the facility to arrange for or offer, as

applicable, a COVID-19 vaccination, but they declined. Further, nursing homes are required to post conspicuous signage throughout the facility reminding personnel and residents that the facility offers COVID-19 vaccinations.

**Professional Services:**

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

**Compliance Costs:**

This regulation requires nursing homes and ACFs to promptly coordinate the COVID-19 vaccination of their residents and personnel. Specifically, nursing homes will be required to offer ongoing COVID-19 vaccinations at the facility, and ACFs will be responsible for arranging vaccinations at off-site locations, such as State-run vaccination sites or 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 State-run vaccination sites or 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 emergent nature of COVID-19, small business and local governments were not directly consulted.

**Cure Period:**

This regulation does not include a cure period given the emergent nature of COVID-19 and the serious threat the 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 emergent nature of COVID-19 and 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 State-run vaccination sites or 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 State-run vaccination sites or 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 emergent nature of COVID-19, parties representing rural areas were not directly consulted.

## **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.