Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda
September 7, 2023
10:15 a.m.

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

I. WELCOME AND INTRODUCTION

Thomas Holt, Chair of the Committee on Codes, Regulations and Legislation

II. REGULATIONS

For Adoption

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

23-09 Repeal of Section 2.61 from Title 10, Amendment of Sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 & 1001.11 of Title 10 & Sections 487.9, 488.9 and 490.9 of Title 18 NYCRR
(Removal of the COVID-19 Vaccine Requirement for Personnel in Covered Entities)

20-06 Amendment of Part 2 and Section 405.3 of Title 10 NYCRR
(Investigation of Communicable Disease)

For Emergency Adoption

20-06 Amendment of Part 2 and Section 405.3 of Title 10 NYCRR
(Investigation of Communicable Disease)

23-07 Amendment of Section 405.45 of Title 10 NYCRR
(Trauma Centers – Resources for Optimal Care of the Injured Patient)

For Information

23-07 Amendment of Section 405.45 of Title 10 NYCRR
(Trauma Centers – Resources for Optimal Care of the Injured Patient)

23-18 Amendment of Section 2.1 of Title 10 NYCRR
(Communicable Diseases Reporting and Control - Adding Respiratory Syncytial Virus (RSV) and Varicella)

III. ADJOURNMENT

******Agenda items may be called in an order that differs from above******

Pursuant to the authority vested in the Commissioner of Health by Section 2803 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by amending sections 405.11 and 415.19, to be effective upon 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) (1) The hospital shall possess and maintain a supply of all necessary items of personal protective equipment (PPE) sufficient to protect health care personnel, consistent with federal Centers for Disease Control and Prevention guidance, for at least 60 days, by August 31, 2021.

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

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

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

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

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

(3) A hospital shall be considered to possess and maintain the required PPE if:

(i) it maintains all PPE on-site; or

(ii) it maintains PPE off-site, provided that the off-site storage location is within New York State, can be accessed by the hospital within at least 24 hours, and the hospital maintains at least a 10-day supply of all required PPE on-site, as determined by the calculations set forth in paragraph (2) of this subdivision. A hospital may enter into an agreement with a vendor to store off-site PPE, provided that such agreement requires the vendor to maintain unduplicated, facility-specific stockpiles; the vendor agrees to maintain at least a 60-day supply of all required PPE, or a 90-day supply in the event the Commissioner increases the required stockpile amount pursuant to this subdivision (less the amount that is stored on site at the facility); and the PPE is accessible by the facility 24 hours a day, 7 days a week, year round. In the event the Department finds a hospital has not maintained the required PPE stockpile, it shall not be a defense that the vendor failed to maintain the supply.

(iii) Any PPE stored outside of New York State shall not count toward the facility's required 60-day stockpile.

(4) The Commissioner shall have discretion to increase the stockpile requirement set forth in paragraph (1) of this subdivision from 60 days to 90 days where there is a State or local public health emergency declared pursuant to Section 24 or 28 of the Executive Law. Hospitals shall possess and maintain the necessary 90-day stockpile of PPE by the deadline set forth by the Commissioner.

(5) The Department shall periodically determine the number of staffed beds in each hospital. Hospitals shall have 90 days to come into compliance with the new PPE stockpile requirements, as set forth in paragraph (2) of this subdivision, following such determination by the Department. Provided further that the Commissioner shall have discretion to determine an applicable bed

calculation for a hospital which is different than the number of staffed beds, if circumstances so require.

(6) In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers, and providers are strongly encouraged to rotate inventory through regular usage and replace what has been used in order to ensure a consistent readiness level and reduce waste. Expired products should be disposed of when their expiration date has passed. Expired products shall not be used to comply with the stockpile requirement set forth in paragraph (1) of this subdivision.

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

(8) In the event a new methodology relating to PPE in hospitals is developed, including but not limited to a methodology by the U.S. Department of Health & Human Services, and the Commissioner determines that such alternative methodology is appropriate for New York hospitals and will adequately protect hospital staff and patients, the Commissioner shall amend this subdivision to reflect such new methodology.

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

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

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

(i) for single gloves, the applicable positivity rate, multiplied by the nursing home's average census as determined annually by the Department, multiplied by 24;

(ii) for gowns, the applicable positivity rate, multiplied by the nursing home's average census as determined annually by the Department, multiplied by 3;

(iii) for surgical masks, the applicable positivity rate, multiplied by the nursing home's average census as determined annually by the Department, multiplied by 1.5; and

(iv) for N95 respirator masks, the applicable positivity rate, multiplied by the nursing home's average census as determined annually by the Department, multiplied by 1.4.

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

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

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

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

(d) In the case of nursing homes previously designated by the Department as a COVID-positive only facility, the term "applicable positivity rate" shall be as defined in item *(c)* of this subparagraph.

(3) A nursing home shall be considered to possess and maintain the required PPE if:

(i) it maintains all PPE on-site; or

(ii) it maintains PPE off-site, provided that the off-site storage location is within New York State, can be accessed by the nursing home within at least 24 hours, and the nursing home maintains at least a 10-day supply of all required PPE on-site, as determined by the calculations set forth in paragraph (2) of this subdivision. A nursing home may enter into an agreement with a vendor to store off-site PPE, provided that such agreement requires the vendor to maintain unduplicated, facility-specific stockpiles, the vendor agrees to maintain at least a 60-day supply of all required PPE (less the amount that is stored on-site at the facility), and the PPE is accessible by the facility 24 hours a day, 7 days a week, year round. In the event the Department finds a nursing home has not maintained the required PPE stockpile, it shall not be a defense that the vendor failed to maintain the supply.

(iii) Any PPE stored outside of New York State shall not count toward the facility's required 60-day stockpile.

(4) The Department shall determine the nursing home's average census annually, by January 1st of each year, and shall communicate such determination to each facility. Nursing homes shall

have 90 days to come into compliance with the new PPE stockpile requirements, as set forth in paragraph (2) of this subdivision, following such determination by the Department.

(5) In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers, and providers are strongly encouraged to rotate inventory through regular usage and replace what has been used in order to ensure a consistent readiness level and reduce waste. Expired products should be disposed of when their expiration date has passed. Expired products shall not be used to comply with the stockpile requirement set forth in paragraph (1) of this subdivision.

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

(7) In the event a new methodology relating to PPE in Residential Health Care Facilities is developed, including but not limited to a methodology by the U.S. Department of Health & Human Services, and the Commissioner determines that such alternative methodology is appropriate for New York nursing homes and will adequately protect facility staff and patients, the Commissioner shall amend this subdivision to reflect such new methodology.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 2803 of the Public Health Law (PHL) authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities, including hospitals and nursing homes.

Legislative Objectives:

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

Needs and Benefits:

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

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout

the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

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

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

COSTS:

Costs to Regulated Parties:

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

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

Costs to Local and State Governments:

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

Costs to the Department of Health:

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

Paperwork:

This regulation imposes no addition paperwork.

Local Government Mandates:

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

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

The Department believes that promulgation of this regulation is the most effective means of ensuring that general hospitals and nursing homes have adequate stockpiles of PPE necessary to protect hospital staff from communicable diseases, compared to any alternate course of action.

Federal Standards:

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

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a general hospital or a nursing home. Currently there are five general hospitals in New York that employ less than 100 staff and qualify as small businesses, and there are 79 nursing homes in New York qualify as small businesses given that they employ less than 100 staff.

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

The Department anticipates that any adverse impacts will be minimal, as both hospitals and nursing homes have already mobilized their stockpiling efforts since early 2020, when the spread of the COVID-19 virus was first recognized in New York State, including through two surges of the COVID-19 pandemic. As such, the continuance of these stockpiling requirements is not expected to create any additional adverse impact on hospitals or nursing homes. Moreover, for nursing homes, these PPE regulations are consistent with the existing directive in Public Health Law section 2803(12) to maintain a two-month PPE supply.

Small Business and Local Government Participation:

The Department contacted hospital and nursing home associations, individual hospitals and health systems, and health care labor unions for input regarding these regulations and the

underlying methodology. Input from these stakeholders has been incorporated into the regulations.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

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

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

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

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

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

The Department anticipates that any adverse impacts will be minimal, as both hospitals and nursing homes have already mobilized their stockpiling efforts since early 2020, when the spread of the COVID-19 virus was first recognized in New York State, including through two surges of the COVID-19 pandemic. As such, the continuance of these stockpiling requirements is not expected to create any additional adverse impact on hospitals or nursing homes. Moreover, for nursing homes, these PPE regulations are consistent with the existing directive in Public Health Law section 2803(12) to maintain a two-month PPE supply.

Rural Area Participation:

The Department contacted hospital and nursing home associations, individual hospitals and health systems, and health care labor unions for input regarding these regulations and the underlying methodology, including associations representing facilities in rural areas of the State. Input from these stakeholders has been incorporated into the regulations.

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 Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) and Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 2.61 of Title 10 is repealed.

Subparagraph (vi) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 of Title 10 is repealed.

Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 of Title 10 is repealed.

Paragraph (7) of subdivision (d) of Section 751.6 of Title 10 is repealed.

Paragraph (6) of subdivision (c) of Section 763.13 of Title 10 is repealed.

Paragraph (7) of subdivision (d) of Section 766.11 of Title 10 is repealed.

Paragraph (8) of subdivision (d) of Section 794.3 of Title 10 is repealed.

Paragraph (5) of subdivision (q) of Section 1001.11 of Title 10 is repealed.

Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is repealed.

Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is repealed.

Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is repealed.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) Sections 225(5), 2800, 2803(2), 3612 and 4010(4) authorize the Public Health and Health Planning Council (PHHPC) and Commissioner to promulgate regulations: amending the State Sanitary Code; implementing the purposes and provisions of PHL Article 28; with respect to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies; and with respect to hospice organizations.

Social Service Law (SSL) Section 461 authorizes the Department of Health (Department) to promulgate regulations establishing general standards applicable to Adult Care Facilities (ACF).

Legislative Objectives:

The legislative objective of PHL Section 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL

Article 40 declares that hospice is a socially and financially beneficial alternative to conventional curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

COVID-19 vaccines are safe and effective, and COVID-19 vaccination offers the benefit of helping to reduce the number of COVID-19 infections. The State's regulation requiring covered entities to ensure that personnel are fully vaccinated against COVID-19, has increased the percentage of health care workers who are vaccinated against COVID-19.

However, federal recommendations for COVID-19 vaccination have changed and are expected to evolve as the future course of COVID-19 becomes more apparent. Additionally, there are now effective treatments for COVID-19, case rates appear to have steadily declined, and hospitalizations due to COVID-19 have substantially decreased.

In response to changes in federal recommendations for COVID-19 vaccination and the overall pandemic landscape, the proposed regulation would repeal the requirement that covered entities ensure that personnel are fully vaccinated against COVID-19, as well as repeal the requirement that covered entities document evidence thereof in appropriate records. In lieu of a regulation, covered entities may now individually consider how to implement their own internal policies regarding COVID-19 vaccination, provided they remain in compliance with other applicable state and federal laws and regulations.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

The proposed regulation does not impose any new costs to regulated entities.

Cost to State and Local Government:

The proposed regulation does not impose any new costs to the State or local governments.

Cost to the Department of Health:

There are no additional costs to the State or local government but there may be modest costs savings, since the State and local governments will no longer need to perform surveillance of regulated parties to monitor compliance with the requirement that personnel be fully vaccinated against COVID-19.

Local Government Mandates:

There is no impact on local government mandates associated with this proposed rule change.

Paperwork:

No new paperwork is necessitated by the proposed regulation.

Duplication:

This regulation will not conflict with any state or federal rules.

Alternative Approaches:

One alternative the Department considered was to amend the regulation to require personnel to be "up to date" on COVID-19 vaccinations, rather than "fully vaccinated." However, this option was not considered viable because of the likelihood of continued changes to federal COVID-19 vaccine recommendations and the language surrounding those recommendations. Another alternative that was considered was to allow personnel to wear a well-fitting face covering in lieu of being vaccinated. However, this option was ultimately not chosen because of unknowns surrounding future trends in COVID-19 case rates and because of the likely continuing evolution of federal vaccine recommendations.

Federal Requirements:

On November 5, 2021, the U.S. Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS) issued an interim final rule (CMS-3415-IFC) requiring Medicare and Medicaid-certified providers and suppliers to ensure that their staff were fully vaccinated for COVID-19 (i.e., obtain the primary vaccination series). On April 10, 2023, the President signed legislation that ended the COVID-19 national emergency and subsequently on May 11, 2023, the COVID-19 public health emergency expired. In light of these developments and comments received on the interim final rule, CMS has stated that it will soon end the requirement that covered providers and suppliers establish policies and procedures for staff vaccination, which would bring the state and federal requirements into alignment.

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register. Effective immediately the Department will cease citing providers for failing to comply with the requirements of 10 NCYRR Section 2.61 while the regulation is in the process of being repealed. The Department may, however, continue to seek sanctions against providers based on previously cited violations that allegedly occurred.

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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not required because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for these amendments is not necessary 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 Public Health and Health Planning Council and the Commissioner of Health by Sections 225 and 2803 of the Public Health Law, Sections 2.1 and 2.5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, Section 2.6 is repealed and a new Section 2.6 is added, and Section 405.3 is amended, to be effective upon filing with the Secretary of State, to read as follows:

Subdivision (a) of section 2.1 is amended to read as follows:

(a) When used in the Public Health Law and in this Chapter, the term infectious, contagious or communicable disease, shall be held to include the following diseases and any other disease which the commissioner, in the reasonable exercise of his or her medical judgment, determines to be communicable, rapidly emergent or a significant threat to public health, provided that the disease which is added to this list solely by the commissioner's authority shall remain on the list only if confirmed by the Public Health and Health Planning Council at its next scheduled meeting:

* * *

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* * *

Section 2.5 is amended to read as follows:

A physician in attendance on a person affected with or suspected of being affected with any of the diseases mentioned in this section shall submit to an approved laboratory, or to the laboratory of the State Department of Health, for examination of such specimens as may be designated by

the State Commissioner of Health, together with data concerning the history and clinical manifestations pertinent to the examination:

* * *

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* * *

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

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

(1) Verify the existence of a disease or condition;

(2) Ascertain the source of the disease-causing agent or condition;

(3) Identify unreported cases;

(4) Locate and evaluate contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;

(5) Collect and submit, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the source of disease, or to assist with diagnosis; and furnish or cause to be furnished with

such specimens pertinent data on forms prescribed by the State Commissioner of Health, including but not limited to the history of cases, physical findings and details of the epidemiological investigation;

(6) With the training or assistance of the State Department of Health, examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;

(7) Instruct a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and

(8) Take any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

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

(c) Investigation Updates and Reports.

(1) Upon request of the State Department of Health, the local health authority shall submit updates and reports on outbreak investigations to the State Department of Health. The content, timeframe, and manner of submission of such updates shall be determined by the State Department of Health.

(2) The local health authority shall complete investigation reports of outbreaks within 30 days of the conclusion of the investigation in a manner prescribed by the State Commissioner of Health, unless the State Commissioner of Health prescribes a different time period.

(d) Commissioner authority to lead investigation and response activities.

(1) The State Commissioner of Health may elect to lead investigation and response 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 another state or states 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 and response activities pursuant to paragraph (1) of this subdivision, local health authorities shall take all reasonable steps to assist in such investigation and response, 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 or response 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.

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:

(d) Records and reports. Any information, records or documents provided to the department shall be subject to the applicable provisions of the Public Health Law, Mental Hygiene Law, Education Law, and the Public Officers Law in relation to disclosure. The hospital shall maintain and furnish to the Department of Health, immediately upon written request, copies of all documents, including but not limited to:

* * *

(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 communicable disease of high public health consequence pursuant to Part 2 of this Title or other public health emergency, such syndromic and disease 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 405.3 is amended by adding a new subdivision (g) as follows:

(g) Whenever the commissioner determines that there exists an outbreak of a communicable disease of high public health consequence 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 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 PHHPC, with the approval of the Commissioner, to amend the SSC to address public health issues related to communicable disease.

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

Needs and Benefits:

These regulations update, clarify and strengthen the Department's authority as well as that of local health departments to take specific actions to monitor the spread of disease, including actions related to investigation and response to a disease outbreak.

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

Part 2 Amendments:

- Amend sections 2.1 and 2.5 to reflect The World Health Organization's (WHO) decision to change the name of "monkeypox" to "Mpox" in an effort to reduce the stigma that monkeypox comes with and deal with possible misinformation falsely suggesting that monkeys are the main source of spreading the virus.
- Repeal and replace current section 2.6, related to investigations, to clarify existing local health department authority.
    - Sets forth specific actions that local health departments must take to investigate a case, suspected case, outbreak, or unusual disease.
    - Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.
    - While the Department works collaboratively with local health departments on a variety of public health issues, including disease control, this regulation clarifies the authority for the Commissioner to lead disease investigation activities under certain circumstances (i.e., where there is potential for statewide impact, multiple jurisdictions impacted, or impact on one or more New York State jurisdictions and another state or states), while working collaboratively with impacted local health departments. In all other situations, local health

departments retain the primary authority and responsibility to control communicable disease within their respective jurisdictions, with the Department providing assistance as needed.

- Codify in regulation the requirement that local health departments send reports to the Department during an outbreak.

Part 405 Amendments

- Mandates hospitals to report syndromic surveillance data during an outbreak of a communicable disease of high public health consequence or other public health emergency.
- Permits the Commissioner to direct general hospitals to accept patients during an outbreak of a communicable disease of high public health consequence or other public health emergency, provided it's done consistent with the federal Emergency Medical Treatment and Labor Act (EMTALA).

COSTS:

Costs to Regulated Parties:

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.

The requirement that hospitals submit syndromic surveillance reports when requested 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 communicable disease of high public health consequence, 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.

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.

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. However, many of these regulatory provisions have not been updated in fifty years and should be modernized to ensure appropriate response to communicable disease outbreaks.

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:

These emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 60 days from the date of filing. The Department anticipates continuing these emergency regulations until such time as the regulation can be finalized for permanent adoption.

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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 communicable disease of high public health consequence, hospitals are already reporting syndromic surveillance data regularly and voluntarily.

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:

These regulations have been proposed for permanent adoption, so all parties have had an opportunity to provide comments during the notice and comment period.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

The following 44 counties have a population of less than 200,000 based upon 2020 United States Census data:

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

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

As the proposed regulations largely clarify existing responsibilities and duties among regulated entities and individuals, no additional recordkeeping, compliance requirements, or professional services are expected. With respect to mandating syndromic surveillance reporting during an outbreak of a communicable disease of high public health consequence, hospitals are already reporting syndromic surveillance data regularly and voluntarily. Additionally, the requirement for local health departments to continually report to the Department during such an outbreak is historically a practice that already occurs.

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 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:

These regulations have been proposed for permanent adoption, so all parties have had an opportunity to provide comments during the notice and comment period.

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

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

New York continues to experience significant community levels of COVID-19 disease. The levels of COVID-19 illness in hospitalized persons have been increasing since July 2023 (currently, 4.85 per 100,000 population) and is already higher than what would be typical for influenza pre- or early season. New York still has a 7-day average of over 900 reported cases per day, and statewide COVID-19 admissions are rising (up 23% compared to prior week). Regrettably, New York still averages about eight (8) deaths per day associated with COVID-19.

Severe acute respiratory syndrome coronavirus -2 (SARS-CoV-2) still mutates, and while the XBB subvariant group of Omicron is currently most prevalent, new variants continue to emerge. Potential threats from emerging variants include increased virulence affecting morbidity and mortality and decreased protection by existing vaccines or pharmacotherapeutics. Several monoclonal antibody treatments are no longer authorized for use by FDA, because they do not work against new Omicron strains.

In fall and early winter of 2022-23, New York experienced large increases in COVID-19, influenza, and respiratory syncytial virus (RSV) that taxed the healthcare system. While this "tripledemic" has since eased, COVID continues to cause significant morbidity and mortality to

New Yorkers, and the impact of the addition of influenza and RSV this coming winter is unknown.

New York is also uniquely subject to rare diseases due to its size, congestion, and status as a major international travel hub. Within the past year, as part of an Ebola virus outbreak in Uganda, travelers from the country were funneled to five airports in the US, with JFK and Newark airports being two of those. In the event that individuals with contacts to known cases were identified, measures would need to be taken to protect the public health.

Outbreaks of Marburg virus occurred during 2022 in Equatorial Guinea and Tanzania. Marburg is similar to Ebola, and outbreaks like this highlight the ongoing outsized roles that New York may have in international infectious disease cases and outbreaks. Outbreaks of Lassa fever, Crimean-Congo hemorrhagic fever, measles, Dengue fever, and Zika virus are also currently, or recently, taking place in various parts of the globe.

Furthermore, a confirmed case of paralytic poliomyelitis caused by Sabin type 2 poliovirus that reverted to become capable of causing paralysis was identified in July of 2022 in Rockland County, New York in an unvaccinated adult. Wastewater surveillance in Rockland, Orange, Nassau, and Sullivan Counties and New York City showed genetically related poliovirus circulating between April 2022 and February 2023, indicating other asymptomatic or non-paralytic polio cases in these counties. Poliovirus genetically related to the New York outbreak strain continues to circulate in Israel, with recent paralytic and non-paralytic cases. Additionally, polio is actively seen in several other countries around the world. Poliovirus can spread where vaccination rates are low. A single case of polio is considered an outbreak and, in conjunction with the ongoing detections of poliovirus in wastewater, constitutes a public health emergency.

When one paralytic case is identified, it typically means that there are many other unidentified, non-paralytic infections.

The emergency regulations are needed to ensure the continued coordination of communicable disease outbreaks between the NYS Department of Health and local health departments. In addition, the emergency regulations will ensure the continued reporting by hospitals of syndromic surveillance data and ensure that the Commissioner has express authority to direct hospitals to accept patients during an outbreak of a communicable disease of high public health consequence.

Based on the ongoing burden of multiple outbreaks seen across the state, the Department has determined that these regulations are necessary to promulgate on an emergency basis to control the spread of communicable diseases in New York State, especially those of high public health consequence. Accordingly, current circumstances necessitate immediate action, and pursuant to the SAPA § 206(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225 and 2803 of the Public Health Law, Sections 2.1 and 2.5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, Section 2.6 is repealed and a new Section 2.6 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 (a) of section 2.1 is amended to read as follows:

(a) When used in the Public Health Law and in this Chapter, the term infectious, contagious or communicable disease, shall be held to include the following diseases and any other disease which the commissioner, in the reasonable exercise of his or her medical judgment, determines to be communicable, rapidly emergent or a significant threat to public health, provided that the disease which is added to this list solely by the commissioner's authority shall remain on the list only if confirmed by the Public Health and Health Planning Council at its next scheduled meeting:

* * *

[Monkeypox] <u>Mpox</u>

* * *

Section 2.5 is amended to read as follows:

A physician in attendance on a person affected with or suspected of being affected with any of the diseases mentioned in this section shall submit to an approved laboratory, or to the laboratory

of the State Department of Health, for examination of such specimens as may be designated by the State Commissioner of Health, together with data concerning the history and clinical manifestations pertinent to the examination:

* * *

[Monkeypox] Mpox

* * *

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

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

(1) Verify the existence of a disease or condition;

(2) Ascertain the source of the disease-causing agent or condition;

(3) Identify unreported cases;

(4) Locate and evaluate contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;

(5) Collect and submit, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the

source of disease, or to assist with diagnosis; and furnish or cause to be furnished with such specimens pertinent data on forms prescribed by the State Commissioner of Health, including but not limited to the history of cases, physical findings and details of the epidemiological investigation;

(6) With the training or assistance of the State Department of Health, examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;

(7) Instruct a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and

(8) Take any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

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

(c) Investigation Updates and Reports.

(1) Upon request of the State Department of Health, the local health authority shall submit updates and reports on outbreak investigations to the State Department of Health. The

content, timeframe, and manner of submission of such updates shall be determined by the State Department of Health.

(2) The local health authority shall complete investigation reports of outbreaks within 30 days of the conclusion of the investigation in a manner prescribed by the State Commissioner of Health, unless the State Commissioner of Health prescribes a different time period.

(d) Commissioner authority to lead investigation and response activities.

(1) The State Commissioner of Health may elect to lead investigation and response 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 another state or states 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 and response activities pursuant to paragraph (1) of this subdivision, local health authorities shall take all reasonable steps to assist in such investigation and response, 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 or

response 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.

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:

(d) Records and reports. Any information, records or documents provided to the department shall be subject to the applicable provisions of the Public Health Law, Mental Hygiene Law, Education Law, and the Public Officers Law in relation to disclosure. The hospital shall maintain and furnish to the Department of Health, immediately upon written request, copies of all documents, including but not limited to:

* * *

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

(i) attendance;

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(iii) synopsis of issues discussed and actions or recommendations made; [and]

(12) whenever the commissioner determines that there exists an outbreak of a communicable disease of high public health consequence pursuant to Part 2 of this Title or other public health emergency, such syndromic and disease 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 405.3 is amended by adding a new subdivision (g) as follows:

(g) Whenever the commissioner determines that there exists an outbreak of a communicable disease of high public health consequence 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 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 PHHPC, with the approval of the Commissioner, to amend the SSC to address public health issues related to communicable disease.

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

Needs and Benefits:

These regulations update, clarify and strengthen the Department's authority as well as that of local health departments to take specific actions to monitor the spread of disease, including actions related to investigation and response to a disease outbreak.

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

Part 2 Amendments:

- Amend sections 2.1 and 2.5 to reflect The World Health Organization's (WHO) decision to change the name of "monkeypox" to "Mpox" in an effort to reduce the stigma that monkeypox comes with and deal with possible misinformation falsely suggesting that monkeys are the main source of spreading the virus.
- Repeal and replace current section 2.6, related to investigations, to clarify existing local health department authority.
    - Sets forth specific actions that local health departments must take to investigate a case, suspected case, outbreak, or unusual disease.
    - Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.
    - While the Department works collaboratively with local health departments on a variety of public health issues, including disease control, this regulation clarifies the authority for the Commissioner to lead disease investigation activities under certain circumstances (i.e., where there is potential for statewide impact, multiple jurisdictions impacted, or impact on one or more New York State jurisdictions and another state or states), while working collaboratively with impacted local health departments. In all other situations, local health

departments retain the primary authority and responsibility to control communicable disease within their respective jurisdictions, with the Department providing assistance as needed.

- Codify in regulation the requirement that local health departments send reports to the Department during an outbreak.

Part 405 Amendments

- Mandates hospitals to report syndromic surveillance data during an outbreak of a communicable disease of high public health consequence or other public health emergency.
- Permits the Commissioner to direct general hospitals to accept patients during an outbreak of a communicable disease of high public health consequence or other public health emergency, provided it's done consistent with the federal Emergency Medical Treatment and Labor Act (EMTALA).

COSTS:

Costs to Regulated Parties:

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.

The requirement that hospitals submit syndromic surveillance reports when requested 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 communicable disease of high public health consequence, 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.

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.

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. However, many of these regulatory provisions have not been updated in fifty years and should be modernized to ensure appropriate response to communicable disease outbreaks.

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 communicable disease of high public health consequence, hospitals are already reporting syndromic surveillance data regularly and voluntarily.

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:

These regulations have been proposed for permanent adoption, so all parties have had an opportunity to provide comments during the notice and comment period.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

The following 44 counties have a population of less than 200,000 based upon 2020 United States Census data:

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

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

As the proposed regulations largely clarify existing responsibilities and duties among regulated entities and individuals, no additional recordkeeping, compliance requirements, or professional services are expected. With respect to mandating syndromic surveillance reporting during an outbreak of a communicable disease of high public health consequence, hospitals are already reporting syndromic surveillance data regularly and voluntarily. Additionally, the requirement for local health departments to continually report to the Department during such an outbreak is historically a practice that already occurs.

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 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:

These regulations have been proposed for permanent adoption, so all parties have had an opportunity to provide 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 Public Health and Health Planning Council and the Commissioner of Health by Section 2803 of the Public Health Law, section 405.45 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon filing with the Secretary of State, to read as follows:

405.45 Trauma Centers

(a) *Definitions*. The following terms when used in this section shall have the following meanings:

* * *

(3) "Level I trauma center" means a facility verified by the American College of Surgeons Committee on Trauma (ACS-COT), or other entity determined by the Department, and designated by the Department as a facility that is capable of providing the full range of services required of trauma patients; conducts trauma research; and provides training to surgical residents that comports with the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022). The standards set forth in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) are hereby incorporated by reference with the same force and effect as if fully set forth herein. A copy of *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) is available for inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Copies are also available from the American College of Surgeons Committee on Trauma, 633 North Saint Clair Street, Chicago,

Illinois 60611. A Level I trauma center shall have a transfer agreement with at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

* * *

(c) *Trauma Center Designation*

(1) A hospital seeking designation as a trauma center must receive verification by the American College of Surgeons, Committee on Trauma (ACS-COT), or other entity determined by the Department. To receive verification, the hospital must undergo a consultation site visit and verification site visit by the ACS-COT, or other entity determined by the Department. During the verification site visit, the hospital must exhibit that it is capable of providing Level I, Level II, Level III, Level IV or pediatric trauma care in accordance with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

* * *

(ii) Verification site visit.

A hospital seeking designation as a trauma center shall request an official verification site visit by the ACS-COT, or other entity determined by the Department, no later than two years following a hospital's receipt of its consultation site visit report. The hospital must receive confirmation from the ACS-COT, or other entity determined by the Department, that the hospital meets the criteria for trauma center verification in accordance with the criteria outlined in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

* * *

(d) *Requirements for Operating a Trauma Center.*

(1) Upon designation, a hospital operating a trauma center shall:

* * *

(ii) comply with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022);

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) section 2803. Pursuant to PHL § 2803(2), the Public Health and Health Planning Council (PHHPC) is authorized 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 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.

Needs and Benefits:

The criteria and standards in the *Resources for the Optimal Care of the Injured Patient* are used to ensure that trauma center applications are compliant with the most current standards and the ACS uses these standards to issue the verification of trauma center status. The current edition of the *Resources for Optimal Care of the Sick and Injured Patient* (2014) is out-of-date and the proposed rule change would update the edition of *Resources for Optimal Care of the Sick and Injured Patient* to the most current version dated 2022. This change is necessary because the American College of Surgeons (ACS) will be using the updated edition to perform hospital trauma center verifications and re-verifications starting on September 1, 2023.

COSTS:

Costs to Regulated Parties:

The proposed rule change may impose additional costs on trauma center hospitals due to new education requirements, expansion of available surgical and medical experts, the addition of a performance improvement coordinator, and the number of trauma registrars required in the updated 2022 standards set forth in *Resources for Optimal Care of the Sick and Injured* compared to the 2014 standards. The Department cannot provide an accurate estimate of these costs because they will vary significantly depending on what actions each trauma center hospital will need to take, or may have already taken, to meet the updated 2022 standards.

Costs to State and Local Governments:

This regulation imposes no new costs or fees to state and local governments. General hospitals operated by local governments may be affected as regulated entities if they are also designated as trauma centers pursuant to 10 NYCRR section 405.45.

Costs to the Department of Health:

This regulation imposes no new costs or fees to the Department of Health.

Local Government Mandates:

This regulation imposes no new government mandates.

Paperwork:

This regulation imposes no additional paperwork.

Duplication:

This regulation does not duplicate any State or federal rules.

Alternatives:

No alternatives to the proposed rule change were considered viable. The regulation needs to be updated since the ACS will be using the updated edition of *Resources for Optimal Care of the Injured Patient* to perform hospital trauma center verifications and re-verifications starting on September 1, 2023.

Federal Standards:

There are no federal standards.

Compliance Schedule:

Beginning September 1, 2023, designated trauma center hospitals will need to use the new 2022 edition of *Resources for Optimal Care of the Sick and Injured*.

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STATEMENT IN LIEU OF

REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

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

The proposed regulatory changes to Title 10 NYCRR section 405.45 will update the publication date of *Resources for Optimal Care of the Injured Patient* from 2014 to 2022. This change is immediately needed because the American College of Surgeons (ACS) will be using the updated edition to perform hospital trauma center verifications and re-verifications starting on September 1, 2023. The Bureau of Emergency Medical Services and Trauma Systems (the Bureau) works in concert with the ACS to issue preliminary verification to hospitals seeking trauma center verification. The Bureau uses the criteria and standards in the *Resources for the Optimal Care of the Injured Patient* to ensure that trauma center applications are compliant with the most current standards. The ACS uses these standards to issue the verification of trauma center status and once received, the Bureau issues the trauma center designation.

Failure to adopt the emergency regulation will result in a delay of verification and designation of new and existing trauma centers in New York State (NYS). It may also negatively affect trauma centers that have received notices of deficiencies in their ability to timely correct those deficiencies. The Bureau uses the standards set forth by ACS to re-inspect and assist trauma centers in resolving any deficiencies found with re-verification by

the ACS. Any delays in trauma center designation may cause delays in appropriate patient care because of traumatic injury, especially in rural areas, because trauma center designation provides the guideline for emergency medical services for transport to the appropriate facility.

As such, an emergency rule is necessary to ensure that the most current standards for trauma centers are employed in preliminary and permanent trauma center designation. Updating this rule prior to September 1, 2023, was not feasible because the ACS was still conducting verifications and re-verifications of trauma centers using the 2014 version of the standards and was not prepared to incorporate the new version until now. Accordingly, current circumstances necessitate immediate action, and pursuant to SAPA § 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 2803 of the Public Health Law, section 405.45 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon publication of a Notice of Adoption in the New York State Register to read as follows:

405.45 Trauma Centers

(a) *Definitions*. The following terms when used in this section shall have the following meanings:

* * *

(3) "Level I trauma center" means a facility verified by the American College of Surgeons Committee on Trauma (ACS-COT), or other entity determined by the Department, and designated by the Department as a facility that is capable of providing the full range of services required of trauma patients; conducts trauma research; and provides training to surgical residents that comports with the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022). The standards set forth in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) are hereby incorporated by reference with the same force and effect as if fully set forth herein. A copy of *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) is available for inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Copies are also available from the American College of Surgeons Committee on Trauma, 633 North Saint Clair Street, Chicago,

Illinois 60611. A Level I trauma center shall have a transfer agreement with at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

* * *

(c) *Trauma Center Designation*

(1) A hospital seeking designation as a trauma center must receive verification by the American College of Surgeons, Committee on Trauma (ACS-COT), or other entity determined by the Department. To receive verification, the hospital must undergo a consultation site visit and verification site visit by the ACS-COT, or other entity determined by the Department. During the verification site visit, the hospital must exhibit that it is capable of providing Level I, Level II, Level III, Level IV or pediatric trauma care in accordance with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

* * *

(ii) Verification site visit.

A hospital seeking designation as a trauma center shall request an official verification site visit by the ACS-COT, or other entity determined by the Department, no later than two years following a hospital's receipt of its consultation site visit report. The hospital must receive confirmation from the ACS-COT, or other entity determined by the Department, that the hospital meets the criteria for trauma center verification in accordance with the criteria outlined in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

* * *

(d) *Requirements for Operating a Trauma Center.*

(1) Upon designation, a hospital operating a trauma center shall:

* * *

(ii) comply with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022);

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) section 2803. Pursuant to PHL § 2803(2), the Public Health and Health Planning Council (PHHPC) is authorized 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 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.

Needs and Benefits:

The criteria and standards in the *Resources for the Optimal Care of the Injured Patient* are used to ensure that trauma center applications are compliant with the most current standards and the ACS uses these standards to issue the verification of trauma center status. The current edition of the *Resources for Optimal Care of the Sick and Injured Patient* (2014) is out-of-date and the proposed rule change would update the edition of *Resources for Optimal Care of the Sick and Injured Patient* to the most current version dated 2022. This change is necessary because the American College of Surgeons (ACS) will be using the updated edition to perform hospital trauma center verifications and re-verifications starting on September 1, 2023.

COSTS:

Costs to Regulated Parties:

The proposed rule change may impose additional costs on trauma center hospitals due to new education requirements, expansion of available surgical and medical experts, the addition of a performance improvement coordinator, and the number of trauma registrars required in the updated 2022 standards set forth in *Resources for Optimal Care of the Sick and Injured* compared to the 2014 standards. The Department cannot provide an accurate estimate of these costs because they will vary significantly depending on what actions each trauma center hospital will need to take, or may have already taken, to meet the updated 2022 standards.

Costs to State and Local Governments:

This regulation imposes no new costs or fees to state and local governments. General hospitals operated by local governments may be affected as regulated entities if they are also designated as trauma centers pursuant to 10 NYCRR section 405.45.

Costs to the Department of Health:

This regulation imposes no new costs or fees to the Department of Health.

Local Government Mandates:

This regulation imposes no new government mandates.

Paperwork:

This regulation imposes no additional paperwork.

Duplication:

This regulation does not duplicate any State or federal rules.

Alternatives:

No alternatives to the proposed rule change were considered viable. The regulation needs to be updated since the ACS will be using the updated edition of *Resources for Optimal Care of the Injured Patient* to perform hospital trauma center verifications and re-verifications starting on September 1, 2023.

Federal Standards:

There are no federal standards.

Compliance Schedule:

Beginning September 1, 2023, designated trauma center hospitals will need to use the new 2022 edition of *Resources for Optimal Care of the Sick and Injured*.

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STATEMENT IN LIEU OF

REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

A Job Impact Statement for these amendments 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 Public Health and Health Planning Council and the Commissioner of Health by section 225 of the Public Health Law, Section 2.1 of 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:

Subdivision (a) of section 2.1 is amended to read as follows:

(a) When used in the Public Health Law and in this Chapter, the term infectious, contagious or communicable disease, shall be held to include the following diseases and any other disease which the commissioner, in the reasonable exercise of his or her medical judgment, determines to be communicable, rapidly emergent or a significant threat to public health, provided that the disease which is added to this list solely by the commissioner's authority shall remain on the list only if confirmed by the Public Health and Health Planning Council at its next scheduled meeting:

* * *

Rabies

<u>Respiratory syncytial virus (RSV) (laboratory confirmed cases of RSV or deaths caused by laboratory confirmed RSV in persons younger than 18 years)</u>

Rocky Mountain spotted fever

* * *

Typhoid

<u>Varicella (not zoster/shingles)</u>

Vaccinia disease: (as defined in Section 2.2 of this Part)

* * *

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 (the Department).

Section 2102 of the Public Health Law requires clinical laboratories to report suspected or confirmed positive findings or markers of communicable diseases, and other pertinent facts, to local or state health officials. Additionally, Section 576-c of the Public Health Law requires clinical laboratories to report such test results, and other data elements, electronically on a schedule determined by the commissioner.

Legislative Objectives:

These amendments are consistent with section 225 of the Public Health Law (PHL), which authorizes the PHHPC, subject to the approval of the Commissioner, to establish and amend the SSC 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.

Needs and Benefits:

The proposed amendments to Section 2.1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR), would add required reporting of laboratory-confirmed cases of respiratory syncytial virus (RSV), pediatric deaths from RSV, and cases of varicella (not zoster/shingles) to the list of reportable communicable disease conditions. The proposed amendment would provide critical surveillance data that could be used to help anticipate hospital bed capacity challenges and could also help quantify the impact of newly approved RSV vaccines. Additionally, pediatric deaths from RSV are expected to become nationally notifiable in September 2023. As of 2020, case-based varicella surveillance is conducted in 39 states and the District of Columbia. Varicella can be severe and is highly contagious, and it has become more important to investigate individual cases as the disease becomes rare. Additionally, making varicella reportable will allow the Department and local health departments to better understand the burden and epidemiology of disease and better anticipate vaccination needs, such as in geographies and in demographics that have lower rates of immunity.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

While it is estimated that there is a sizeable number of cases of RSV and varicella that occur in NYS each year, the Department expects that costs associated with these additional requirements will be minimal. The most serious cases of RSV are hospitalized and diagnosed in the acute care setting, and hospitals already have robust human and electronic resources in place

to comply with their public health reporting and specimen submission requirements. For varicella, the Department is proposing to limit costs for laboratory submissions by issuing guidance on laboratory reporting in outbreak and non-outbreak settings that consider the relative benefits versus the costs/burdens of testing.

The Department does not expect that there will be significant cost burdens associated with regulated entities complying with investigations conducted by a local health authority. The proposed regulations related to investigations would only apply where there are cases or suspect cases of reportable diseases or organisms, outbreaks, or unusual diseases. Further, while businesses, organizations, private homes, and those required to report pursuant to proposed section 2.1 would be required to cooperate with such investigations, historically, the types of cooperation sought during disease investigations has primarily consisted of providing information determined to be necessary for the local health authority to control the spread of disease and/or to provide preventive treatment.

Costs to State and Local Governments:

The cost of the proposed disease/organism reporting is expected to be minimal because current systems and procedures already exist for such entities to receive, process, and follow-up on reportable diseases/organisms. Further, by monitoring the spread of reportable diseases/organisms, appropriate precautions can be taken to prevent or contain exposures, thereby reducing costs associated with public health control measures, morbidity, and treatment. Lastly, the Department does not expect that there will be any significant additional cost burden to local or State governments associated with the proposed changes to laboratory submission

requirements; minimal resources may need to be shifted to clean and analyze the incoming data. The infrastructure to electronically receive positive reports from laboratories is already in place.

The Department does not anticipate there will be a significant cost burden for government entities resulting from the proposed investigation of varicella cases and pediatric RSV fatalities. Local health authorities already receive funding through Article 6 of the Public Health Law for core public health work, including investigations of reportable diseases. As local health authorities are the primary entities responsible for controlling diseases within their jurisdictions, the additions proposed here will become part of the requirements that local health authorities already have in place to control disease within their jurisdictions. In addition to the reporting requirement that already exists in regulation which requires local health authorities to submit reports of outbreak investigations within 30 days of the conclusion of such investigations, the proposed amendments also would require the local health authority to submit updates on outbreak investigations to the Department as requested. The Department currently works very closely with local health authorities during outbreak investigations, so this new requirement is not expected to result in any significant cost burden to either State or local governments. It is expected the volume of investigations of varicella or pediatric RSV fatalities will be minimal in most counties.

Costs to the Department of Health:

There are no costs to the Department associated with this regulatory amendment.

Local Government Mandates:

As is currently the case, local health officers receiving reports of diseases/organisms listed in section 2.1 will be required to forward such reports to the State Department of Health and investigate the sources of infection of reported or suspect cases. Additionally, local health authorities are also required to submit updates on outbreak investigations to the Department upon request.

Paperwork:

There will be no new paperwork associated with these proposed amendments; however, revisions will need to be made to the existing general communicable disease reporting form. Practically all laboratory reporting is currently done electronically.

Duplication:

No relevant laws of the State and/or federal government exist that duplicate, overlap, or conflict with this proposed rule.

Alternatives:

The alternative to the proposed amendments would be to maintain the current list of communicable diseases. However, adding required reporting of laboratory-confirmed cases of respiratory syncytial virus (RSV), pediatric deaths from RSV, and cases of varicella (not zoster/shingles) to the list of reportable communicable diseases is necessary to enable local health authorities and the Department to conduct critically important disease surveillance. In turn, this will reduce disease transmission, as well as streamline and provide needed clarification

on the control measures local health authorities can implement to control the spread of disease within their jurisdictions.

Federal Standards:

State and local health departments have primary authority for controlling disease within their respective jurisdictions. There are existing national case definitions for varicella and RSV-associated mortality.

Compliance Schedule:

It is anticipated that regulated entities would be able to comply with the rule upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulation will apply to all local health departments, as well as physicians, hospitals, nursing homes, diagnostic and treatment centers, and laboratories. There are approximately 76,500 licensed and registered physicians in New York State; it is not known how many of them practice in small businesses. It is estimated that approximately five hospitals, 130 nursing homes, 311 diagnostic and treatment centers, and 150 clinical laboratories employ less than 100 persons and qualify as small businesses.

Compliance Requirements:

Hospitals, clinics, physicians, nursing homes, and clinical laboratories that are small businesses and local governments will utilize revised Department of Health reporting forms and existing laboratory referral forms to report the three conditions being added to the list of communicable diseases set forth in 10 NYCRR § 2.1. Local health officers receiving reports of laboratory-confirmed cases of respiratory syncytial virus (RSV), pediatric deaths from RSV, and cases of varicella (not zoster/shingles) will be required to forward such reports to the State Health Commissioner and to investigate and monitor the cases reported.

Professional Services:

These amendments regard the reporting of laboratory test results to the Department and subsequent investigation of cases. Entities impacted include public and private laboratories that perform varicella or RSV tests on New York State residents and those that receive and

investigate disease reports and test results, including physicians, heads of a private household, or person in charge of any institution, school, hotel, boarding house, camp or vessel or any public health nurse or any other person having knowledge of an individual affected with any disease presumably communicable. Investigation is performed by local health departments.

Compliance Costs:

While it is estimated that there is a large number of cases of RSV and fewer but sizeable cases of varicella in NYS each year, the Department expects that costs associated with these additional requirements will be minimal. Local health authorities already receive funding through Article 6 of the Public Health Law for core public health work, including investigations of reportable diseases. The most serious cases of RSV are hospitalized and diagnosed in the acute care setting, and hospitals already have robust human and electronic resources in place to comply with their public health reporting and specimen submission requirements. For varicella, the Department is proposing to limit costs for laboratory submissions by issuing guidance on laboratory reporting in outbreak and non-outbreak settings that consider the relative benefits versus the costs/burdens of testing.

The Department does not expect that there will be significant cost burdens associated with regulated entities complying with investigations conducted by a local health authority. The proposed regulations related to investigations would only apply where there are cases or suspect cases of reportable diseases or organisms, outbreaks, or unusual diseases. Further, while businesses, organizations, private homes, and those required to report pursuant to proposed section 2.1 would be required to cooperate with such investigations, historically the type of cooperation sought during disease investigations has primarily consisted of providing

information determined to be necessary for the local health authority to control the spread of disease and/or to provide preventive treatment.

The cost of the proposed disease/organism reporting to local governments is expected to be minimal because current systems and procedures already exist for such entities to receive, process, and follow-up on reportable diseases/organisms. Further, by monitoring the spread of reportable diseases/organisms, appropriate precautions can be taken to prevent or contain exposures, thereby reducing costs associated with public health control measures, morbidity, and treatment. Lastly, the Department does not expect that there will be any additional cost burdens to local or State governments associated with the proposed changes to laboratory submission requirements. The infrastructure to electronically receive positive reports from laboratories is already in place.

The Department does not anticipate there will be a substantial cost burden for government entities as a result of the proposed investigation of varicella cases and pediatric RSV fatalities. Local health authorities are the primary entities responsible for controlling diseases within their jurisdictions, the additions proposed here will become part of the requirements that local health authorities already have in place to control disease within their jurisdictions, which already include investigations of other reportable diseases. In addition to the reporting requirement that already exists in regulation, requiring local health authorities to submit reports of outbreak investigations within 30 days of the conclusion of such investigations, the proposed amendments also would require the local health authority to submit updates on outbreak investigations to the Department as requested. The Department often works very closely with local health authorities during outbreak investigations already, so this new requirement is not expected to result in any significant new cost burden to either State or local governments.

Economic and Technological Feasibility:

The entities impacted will use existing reporting, receiving, and investigation infrastructure that are already in place for reporting of other communicable diseases designated by Public Health Law. As such, there are no economic or technological impediments to the rule change.

Minimizing Adverse Impact:

The entities impacted will use existing reporting, receiving, and investigation infrastructure that are already in place for reporting of other communicable diseases designated by public health law. This minimizes impact, and these amendments are not expected to result in significant additional costs to small business or local governments.

Small Business and Local Government Participation:

The Department has consulted with local governments through ongoing communication on this issue with local health departments and the New York State Association of County Health Officers in the process of making these conditions reportable. They should see very little impact from making RSV reportable but recognize the potential investigative burden from varicella. Local health departments are supportive and view investigating cases of this vaccine-preventable disease as an aid to reducing spread and to encouraging vaccination.

Businesses that are impacted, including private and commercial laboratories, already perform the tests that detect these pathogens, use existing reporting mechanisms, and many report already, even though not currently required to do so.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:

N/A.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

A Job Impact Statement for these amendments 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.