Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting
Agenda and Informational Announcements

April 5, 2022
10:15 AM

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 Emergency Adoption

20-06 Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to Title 10 NYCRR
(Investigation of Communicable Disease; Isolation and Quarantine)

20-07 Amendment of Section 2.60 of Title 10 NYCRR & Repeal of Subpart 66-3 of Title 10 NYCRR
(Face Coverings for COVID-19 Prevention)

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

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

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

21-15 Addition of Sections 2.9 and 2.62 to Title 10 NYCRR
(COVID-19 Reporting and Testing)

III. ADJOURNMENT

SUMMARY OF EXPRESS TERMS

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

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of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, Section 2.6 is repealed and a new Section 2.6 is added, a new Section 2.13 is added, Sections 2.25 through 2.30 are repealed, a new Section 58-1.14 is added, and Section 405.3 is amended, to be effective upon filing with the Secretary of State, to read as follows:

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

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

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

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

* * *

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

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

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

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

(k) *Home quarantine* or *home isolation* shall mean quarantine or isolation in a person's home, consistent with this Part and any direction that the State Commissioner of Health may issue;

(l) *Highly contagious communicable disease* shall mean a communicable disease or unusual disease that the State Commissioner of Health determines may present a serious risk of harm to the public health, for which isolation or quarantine may be required to prevent its spread.

(m) *Monitor* shall mean contacting a person who is the subject of an isolation or quarantine order by the State Department of Health or local health authority, to ensure compliance with the order and to determine whether such person requires a higher level of medical care, consistent with any direction that the State Commissioner of Health may issue.

(n) *Mandatory quarantine* shall mean quarantine pursuant to a legal order consistent with this Part.

(o) *Voluntary quarantine* shall mean quarantine pursuant to a voluntary agreement with a public health authority.

(p) *Confinement* shall mean enforcement of an isolation or quarantine order through the use or possible use of law enforcement personnel.

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

(a) Except where other procedures are specifically provided in law, every local health authority, either personally or through a qualified representative, shall immediately upon receiving a report of a case, suspected case, outbreak, or unusual disease, investigate the circumstances

of such report at any and all public and private places in which the local health authority has reason to believe, based on epidemiological or other relevant information available, that such places are associated with such disease. Such investigations 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) 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.

New section 2.13 is added to read as follows:

2.13 Isolation and Quarantine Procedures

(a) Duty to issue isolation and quarantine orders

(1) Whenever appropriate to control the spread of a highly contagious communicable disease, the State Commissioner of Health may issue and/or may direct the local health authority to issue isolation and/or quarantine orders, consistent with due

process of law, to all such persons as the State Commissioner of Health shall determine appropriate.

(2) Paragraph (1) of this subdivision shall not be construed as relieving the authority and duty of local health authorities to issue isolation and quarantine orders to control the spread of a highly contagious communicable disease, consistent with due process of law, in the absence of such direction from the State Commissioner of Health.

(3) For the purposes of isolation orders, isolation locations may include home isolation or such other residential or temporary housing location that the public health authority issuing the order determines appropriate, where symptoms or conditions indicate that medical care in a general hospital is not expected to be required, and consistent with any direction that the State Commissioner of Health may issue. Where symptoms or conditions indicate that medical care in a general hospital is expected to be required, the isolation location shall be a general hospital.

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

(b) Any isolation or quarantine order shall specify:

(1) The basis for the order;

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

(3) The duration of the order;

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

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

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

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

(8) If the location of isolation or quarantine is a detached structure, that the person may go outside while remaining on the premise, but shall not leave the premise or come within 6 feet of any person who does not reside at the premise, or such other distance as may be appropriate for the specific disease, and consistent with any direction that the State Commissioner of Health may issue;

(9) Such other limitations on interactions with other persons as are appropriate, consistent with any direction that the State Commissioner of Health may issue;

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

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

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

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

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

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

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

(d) If the location of an isolation or quarantine order is owned by a landlord, hotel, motel or other person or entity, no such landlord or person associated with such hotel, motel or other person or entity shall enter the isolation or quarantine location without permission of the local health authority, and consistent with any direction that the State Commissioner of Health may issue.

(e) No article that is likely to be contaminated with infective material may be removed from a premise where a person is isolated or quarantined unless the local health authority determines

that such article has been properly disinfected or protected from spreading infection, or unless the quarantine period expires and there is no risk of contamination. Such determinations shall be made pursuant to any direction that the State Commissioner of Health may issue.

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

(g) Duty of attending physician

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

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

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

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

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

(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 highly contagious communicable disease 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.

* * *

New section 58-1.14 is added to read as follows:

Section 58-1.14 Reporting of certain communicable diseases.

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

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

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

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

* * *

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

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

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

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

Legislative Objectives:

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

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

The legislative objective of PHL § 2803 includes among other objectives authorizing 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:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory and other 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.

Now, two years after the first cases were identified in the United States, the COVID-19 pandemic continues to impact New York State. In light of this situation, these regulations update, clarify and strengthen the Department's authority as well as that of local health departments to take specific actions to control the spread of disease, including actions related to investigation and response to a disease outbreak, as well as the issuance of isolation and quarantine orders.

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

Part 2 Amendments:

- Relocate and update definitions, and add new definitions

- Repeal and replace current section 2.6, related to investigations, to make existing clarify local health department authority.
    - Sets forth specific actions that local health departments must take to investigate a case, suspect case, outbreak, or unusual disease.
    - Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.
    - 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.

(i) Codifies in regulation the requirement that local health departments send reports the Department during an outbreak.

- New section 2.13 added to clarify isolation and quarantine procedures.
  - Clarify that the State Department of Health has the authority to issue isolation and quarantine orders, as do local departments of health.
  - Clarifies locations where isolation or quarantine may be appropriate.
  - Sets forth requirements for the content of isolation and quarantine orders.
  - Specifies other procedures that apply when a person is isolated or quarantined.
  - Explicitly states that violation of an order constitutes grounds for civil and/or criminal penalties
  - Relocates and updates existing regulatory requirements that require the attending physician to report cases and suspected cases to the local health authority, and to requires physicians to provide instructions concerning how to protect others.

Part 58 Amendments

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

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

Part 405 Amendments

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

COSTS:

Costs to Regulated Parties:

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

during an outbreak of a highly contagious communicable disease, hospitals are already required to adhere to the federal Emergency Medical Treatment and Labor Act (EMTALA). Accordingly, both of these proposed amendments will not impose any substantial additional cost to hospitals.

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

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

Costs to Local and State Governments:

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

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

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

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

Paperwork:

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

Local Government Mandates:

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

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

The alternative would be to leave in place the current regulations on disease investigation and isolation and quarantine. However, many of these regulatory provisions have not been

updated in fifty years and should be modernized to ensure appropriate response to a disease outbreak, such as COVID-19.

Federal Standards:

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

Compliance Schedule:

These emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed rulemaking for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

The following 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 highly infectious communicable disease, hospitals are already reporting syndromic surveillance data regularly and voluntarily. Additionally, the requirement for local health departments to continually report to the Department during an outbreak is historically a practice that already occurs. With respect to clinical laboratories, they must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102.

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

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

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

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19. New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak.

Now, two years after the first cases were identified in the United States, the COVID-19 pandemic continues to impact New York State. Based on the ongoing burden COVID-19, the Department has determined that these regulations, while applicable to several diseases, are necessary to promulgate on an emergency basis to control the spread of COVID-19 in New York State. Accordingly, current circumstances necessitate immediate action, and pursuant to the State Administrative Procedure Act Section 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 201, 206, and 225 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by repealing Subpart 66-3 and repealing and replacing Section 2.60, to be effective upon filing with the Secretary of State, to read as follows:

Subpart 66-3 is hereby repealed.

Section 2.60 is repealed and replaced to read as follows:

2.60. Face Coverings for COVID-19 Prevention

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

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

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

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

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

(f) Penalities and enforcement.

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

(ii) All local health officers shall take such steps as may be necessary to enforce the provisions of this Section accordance with the Public Health Law and this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for adding a new Section 2.60 is sections 201, 206, and 225 of the Public Health Law.

Legislative Objectives:

The legislative objective of PHL § 201 includes authorizing the New York State Department of Health ("Department") to control and promote the control of communicable diseases to reduce their spread. Likewise, the legislative objective of PHL § 206 includes authorizing the Commissioner of Health to take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law, including control of communicable diseases. The legislative objective of Public Health Law § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to amend the State Sanitary Code to address public health issues related to communicable disease.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory and other 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, those who have serious underlying medical health conditions and those who are unvaccinated.

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.

Now, two years after the first cases were identified in the United States, the COVID-19 pandemic continues to impact New York State. Beyond the ongoing COVID-19 burden in communities, certain settings such as crowded indoor spaces, public transit, nursing homes, and health care settings, have been at increased risk for transmission. These regulations provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. The regulations are necessary to permit flexibility to allow the Department to quickly adapt to changing circumstances related to the spread of COVID-19 and increasing transmission rates.

COSTS:

Costs to Regulated Parties:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19

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

Costs to Local and State Governments:

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

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

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

Duplication:

There is no duplication of federal law.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

The regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed ruling-making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Accordingly, any adverse impacts are expected to be minimal.

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

The following 44 counties have an estimated population of less than 200,000 based upon the 2019 United States Census county populations projections:

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

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

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

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

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

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

Compliance Costs:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of

COVID-19 within the state since March of 2020. Accordingly, this regulation does not impose additional costs to regulated parties.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Accordingly, adverse impacts are expected to be minimal.

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory and other 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.

Now, two years after the first cases were identified in the United States, the COVID-19 pandemic continues to impact New York State. Beyond the ongoing COVID-19 burden in communities, certain settings such as crowded indoor spaces, public transit, nursing homes, and health care settings, have been at increased risk for transmission.

To that end, these regulations provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. Based on the foregoing, the Department has determined that these emergency

regulations are necessary to permit flexibility to quickly adapt to changing circumstances and increasing transmission rates and control the spread of COVID-19, necessitating immediate action. Accordingly, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

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

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

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

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

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

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

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

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

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

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

(4) In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers and inventory should be rotated through regular usage and replace what has been used in order to ensure a consistent readiness level, and 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.

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

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

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

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

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

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

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

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

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

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

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

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

(3) In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers and inventory should be rotated through regular usage and replace what has been used in order to ensure a consistent readiness

level, and 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.

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

Legislative Objectives:

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

Needs and Benefits:

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

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

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

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

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

COSTS:

Costs to Regulated Parties:

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

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

Costs to Local and State Governments:

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

Costs to the Department of Health:

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

Paperwork:

This regulation imposes no addition paperwork.

Local Government Mandates:

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

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

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

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

These regulations are needed on an emergency basis to ensure hospital and nursing home staff, as well as the patients and residents for whom they provide care, are adequately protected during the current wave and in the event of another resurgence of the 2019 Coronavirus (COVID-19) or another communicable disease outbreak. These regulations are specifically meant to address the lessons learned in New York State from 2020 to 2021 during the COVID-19 pandemic with respect to PPE.

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 in January 2020 that a public health emergency existed. The federally-declared public health emergency remains in effect.

New York State first identified cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. However, as a result of global PPE shortages, many hospitals and nursing homes in New York State had difficulty obtaining adequate PPE necessary to care for their patients and residents. New York State provided general hospitals, nursing homes, and other medical facilities with PPE from the State's emergency stockpile from the beginning of the COVID-19 outbreak.

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

provide care for patients and residents with communicable diseases, while ensuring that they themselves do not become infected with a communicable disease.

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

SUMMARY OF EXPRESS TERMS

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

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

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225, 2800, and 2803 of the Public Health Law; and in the Commissioner of Health by Sections 576 and 4662 of the Public Health Law and Section 461 of the Social Services Law, Title 10 (Health) and Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon filing with the Secretary of State, to read as follows:

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

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

Part 360. Surge and Flex System

Section 360.1. Administrative Purpose, Application and Scope

(a) Administrative purpose.

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

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

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

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

(b) Application and Scope. In the event of a State disaster emergency declared pursuant to section 28 of the Executive Law, the Commissioner may exercise the authorities granted in this Part, thereby maximizing the efficiency and effectiveness of the State's hospital systems and mitigating the threat to the health of the people of New York. Further, this Part establishes certain ongoing emergency planning requirements, called the Surge and Flex Health Care Coordination System, for facilities and agencies regulated by the Department.

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

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

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

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

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

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

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

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

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

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

(4) Statewide Coordination.

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

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

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

Section 360.3. Hospital emergency Surge and Flex Response Plans.

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

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

(2) PPE surge plan. The plan shall explain how the hospital will increase its supply of personal protective equipment (PPE) appropriate for use in a pandemic to achieve continuous maintenance of its required 60-day supply of PPE, pursuant to section 405.11(g) of this Title. The plan shall list the contracted entities or other supply chain agreements executed by the hospital. Such plan shall further include, as appropriate,

how the hospital will repurpose existing equipment, replenish the inventory from other areas of the health system, and establish cooperative agreements to obtain PPE to accommodate supply chain interruptions. A PPE surge plan may provide for hospital utilization of some, but not all, of the stockpile reserves during a State disaster emergency, provided that within 30 days of the end of the State disaster emergency, the stockpile reserve is fully restored.

(3) Mass casualty plan. The plan shall explain how the hospital will receive and treat mass casualty victims, in the event of a secondary disaster arising from the interruption of normal services resulting from an epidemic, earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences, while addressing the continued need for surge capacity for the underlying state disaster emergency declaration.

(4) Staffing plan. The plan shall explain how the hospital will: identify and train backups for employees who may be unable to report to work during a pandemic; institute employee overtime protocols; and increase staffing by inter- and intra-system loan, cross-training, and volunteer programs, which would be operational on seven days' notice.

(5) Capital plan. The plan shall explain how the hospital shall ensure continuous operation of facilities and access to utilities, materials, electronic devices, machinery and equipment, vehicles, and communication systems. The plan shall ensure that the hospital routinely performs all required maintenance and peak load testing of its infrastructure systems, including: electrical, heating, ventilation and air conditioning (HVAC), and oxygen supply.

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

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

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

(e) Additional preparedness requirements.

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

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

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

(1) In the event of a declared state disaster emergency, upon the Commissioner's direction, hospitals or health systems shall report to the Department all data requested by the Commissioner, in a manner determined by the Commissioner under Section 306.2. Such data may include, but shall not be limited to:

(i) Bed availability, both in total and by designated service.

(ii) Bed capacity, meaning acute care operational beds as defined in paragraph (a)(1) of this Section.

(iii) Patient demographics.

(iv) Other health statistics, including deaths.

(v) PPE and other supplies, in stock and ordered.

(vi) PPE and other supply usage rates.

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

Section 360.4 Clinical laboratory testing

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

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

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

(1) Waive permit requirements for clinical laboratories and establish minimum qualifications to allow non-permitted clinical laboratories to accept and test

specimens from New York State, provided that such laboratories must meet any federal requirements.

(2) Establish minimum qualifications of individuals that may perform clinical laboratory tests, provided that such persons meet federal requirements.

(3) Allow clinical laboratories to accept specimens without an order, subject to a plan approved by Commissioner to ensure the result of any tests are reported to the patient or the patient's personal representative and there will be appropriate follow up with the patient based on the results.

(4) Authorize licensed pharmacists to order clinical laboratory tests, consistent with federal law, including certificate of waiver requirements.

(5) Permit licensed pharmacists to be designated as qualified healthcare professionals for the purpose of directing a limited service laboratory, pursuant to Section 579 of the Public Health Law.

(6) Permit licensed pharmacists to order and administer clinical tests.

(c) Prioritization of clinical laboratory tests. In the event the declared state disaster emergency requires utilization of clinical laboratory testing at a rate that exceeds available capacity, no laboratory shall perform such test unless the test has been ordered consistent with the testing prioritization published by the Commissioner.

(d) Reporting of results of any communicable disease during a Surge and Flex period shall be made immediately via the Electronic Clinical Laboratory Reporting system, if positive, and on a schedule as determined by the Commissioner if negative.

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

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

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

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

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

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

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

700.5 Commissioner authority to suspend and modify regulations

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

modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

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

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

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

1.2 Commissioner authority to suspend and modify regulations

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

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

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

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

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

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

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

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations with respect to facilities subject to Article 28 of the Public Health Law (PHL) is contained in PHL sections 2800 and 2803(2). PHL Article 28 (Hospitals), section 2800, specifies: "Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article." PHL section 2801 defines the term "hospital" as also including residential health care facilities (nursing homes) and diagnostic and treatment centers (D&TCs). PHL section 2803 (2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of such health care facilities.

PHL section 4662 authorizes the Commissioner to issue regulations governing assisted living residences. Social Services Law (SSL) section 461(1) authorizes the Commissioner to promulgate regulations establishing standards applicable to adult care facilities. PHL section 576 authorizes the Commissioner to regulate clinical laboratories.

PHL section 225 authorizes the Public Health and Health Planning Council (PHHPC) and the Commissioner to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

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

Legislative Objectives:

The objectives of PHL Article 28 include protecting the health of New York State residents by ensuring that they have access to safe, high-quality health services in medical facilities, while also protecting the health and safety of healthcare workers. Similarly, PHL Articles 36 and 40 ensure that the Department has the tools needed to achieve these goals in the home care and hospice spaces, and PHL section 4662 and SSL section 461 likewise ensure that the Department has appropriate regulatory authority with respect to assisted living residences and adult care facilities. PHL section 576 ensures that the Commissioner has appropriate regulatory authority over clinical laboratories. Finally, PHL section 225 ensures that the State Sanitary Code includes appropriate regulations in the areas of communicable disease control and environmental health, among others.

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

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

Needs and Benefits:

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

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

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

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

Costs:

Costs to Regulated Parties:

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

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

Costs to Local Governments:

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

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

Cost to State Government:

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

Paperwork:

It is not anticipated that the proposed regulatory amendments will impose any significant paperwork requirements. Although these proposed amendments require additional reporting,

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

Local Government Mandates:

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

Duplication:

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

Alternatives:

The alternative would be to not promulgate the regulation. However, this alternative was rejected, as the Department believes that these regulatory amendments are necessary to facilitate response to a state disaster emergency.

Federal Standards:

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

Compliance Schedule:

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

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Number of Rural Areas:

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

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

Genesee County	Rensselaer County	Yates County
	Schenectady County	

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

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

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

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

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

Compliance Costs:

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

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

Lastly, per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas.

Economic and Technological Feasibility

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

Minimizing Adverse Impact

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

Rural Area Participation

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

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

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

Executive Order 11, issued November 26, 2021, and continued by Executive Order 11.4 on March 16, 2022, declared a State disaster emergency that activated the Surge and Flex Health Care Coordination System under these regulations.

Of note, a Notice of Proposed Rule Making was published in the *State Register* on February 16, 2022, with a public comment period that ends on April 18, 2022. The Department intends these emergency regulations to be in effect only until such time as the Department can publish an Assessment of Public Comment and adopt a Final Rule, which would make the Proposed Rule permanent.

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

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

66-4.1. Requirements for Nursing Homes

(a) Every nursing home regulated pursuant to Part 415 of this Title shall offer all consenting, unvaccinated existing personnel and residents an opportunity to receive the first or any recommended next or booster dose of the COVID-19 vaccine.

(b) The operator and administrator of every nursing home regulated pursuant to Part 415 of this Title must ensure that all new personnel, including employees and contract staff, and every new resident and resident readmitted to the facility has an opportunity to receive the first or any recommended next or booster dose of the COVID-19 vaccine within fourteen days of having been hired by or admitted or readmitted to such facility, as applicable.

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

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

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

(d) Nursing homes must comply with the requirements for vaccination of personnel in 10 NYCRR § 415.19(a)(5).

66-4.2. Requirements for Adult Care Facilities

(a) The operator and administrator of every adult care facility regulated pursuant to Parts 487, 488 and 490 of Title 18 of the NYCRR and Part 1001 of this Title shall make diligent efforts to arrange for all consenting, unvaccinated existing personnel and residents to register for a vaccine appointment and an appointment to receive any recommended booster, and shall document attempts to schedule and methods used to schedule the vaccine in the individual's personnel file or case management notes, as applicable.

(b) The operator and administrator of every adult care facility regulated pursuant to Parts 487, 488 and 490 of Title 18 of the NYCRR and Part 1001 of this Title must arrange for the COVID-19 vaccination, including the first or any recommended next or booster dose, of all new personnel, including employees and contract staff, and every new resident and resident

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

(1) For residents:

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

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

(2) For personnel:

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

the prospective personnel's COVID-19 vaccination status, history, or interest in COVID-19 vaccination; and

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

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

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

66-4.3. Penalties.

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

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

486.5(a)(4)(v).

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

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

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

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

Legislative Objectives:

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

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

Needs and Benefits:

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

COVID-19 is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal. Given the disproportionate adverse health impacts of COVID-19 for older adults and those with comorbidities, many of whom reside in New York's nursing homes and ACFs, it is imperative that nursing homes and ACFs facilitate the prompt vaccination of its residents. Moreover, in order to ensure that nursing home and ACF personnel can safely provide resident care, it is critically important that nursing homes offer continued COVID-19 vaccinations on-site for their current and new personnel and that ACFs arrange for

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

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

COSTS:

Costs to Regulated Parties:

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

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

Costs to Local and State Governments:

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

Costs to the Department of Health:

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

Paperwork:

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

Local Government Mandates:

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

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

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

Federal Standards:

No federal standards apply.

Compliance Schedule:

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

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

Cure Period:

This regulation does not include a cure period given the serious threat the COVID-19 virus causes to all New Yorkers, particularly those residing in nursing homes and adult care facilities, considering such residents' age and comorbidities. As detailed more fully within the regulations, nursing homes and adult care facilities will have 14 and 7 days, respectively, to offer

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

Allegany County
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
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

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

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

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

Compliance Costs:

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

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

Recent New York State data show that unvaccinated individuals continue to be more likely to be diagnosed with COVID-19 compared to vaccinated individuals. In fact, those who are unvaccinated have over 10 times the risk of being hospitalized with COVID-19 compared with vaccinated individuals. To date, there are an approximate 8,200 (9%) nursing home and 1,100 (4%) adult care facility residents that remain unvaccinated. As such, the potential for COVID-19 introduction or re-introduction to this vulnerable population remains a risk and the need for protecting their health and safety a top high priority.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta and Omicron variants, which is a critical component to protecting public health. Booster doses of the COVID-19 vaccine are important to maximize protection against infection. Certain settings, such as healthcare facilities and congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Personnel in such settings who have not received all recommended doses of the COVID-19 vaccine have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing an unacceptably high risk of complications.

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

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 201, 206, and 225 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is adding new sections 2.9 and 2.62, to be effective upon filing with the Secretary of State, to read as follows:

Section 2.9 is added to read as follows:

2.9. COVID-19 Reporting in Schools. In addition to all other reporting requirements in this Part, every kindergarten, elementary, intermediate, or secondary school as well as any pre-kindergarten programs and school districts, as identified by the Department, shall report to the Department of Health, on a daily basis, in a form and manner to be determined by the Commissioner, all COVID-19 testing, positive test results reported in any manner to the school, and related information among students, teaching staff, and any other employees or volunteers. Such daily report shall include any other data elements as the Commissioner determines to be appropriate to track outbreaks of COVID-19 within such schools and school districts.

Section 2.62 is added to read as follows:

2.62. COVID-19 Testing Requirements.

(a) As determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread, the Commissioner may require routine COVID-19 testing in certain settings, which may include schools, homeless shelters, correctional facilities, nursing homes, and health care settings, and

which may distinguish between individuals who have received full vaccination against COVID-19 or have had laboratory confirmed COVID-19 infection within the previous 90-days, and those who have not. Such testing determination may also include alternatives to testing as well as prevention protocols pending test results based on symptoms and/or exposure in certain settings.

(1) Entities subject to routine COVID-19 testing pursuant to a Commissioner's determination may accept documentation demonstrating full vaccination, or laboratory confirmed COVID-19 infection within the previous 90-days, in lieu of imposing such testing requirements, if permitted in a Commissioner's determination. "Full vaccination", for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations. Unless otherwise specified by the Department, documentation of full vaccination must include the manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site, in one of the following formats:

(i) record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner's signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system;

(iii) Excelsior Pass; or

(iv) any other documentation determined acceptable by the Department.

(2) Entities subject to a Commissioner's determination pursuant to this section shall document testing or vaccination in appropriate records in accordance with applicable privacy laws and submit data and information related thereto to the Department in a manner and format set forth in such determination.

(3 The Commissioner shall issue findings regarding the necessity of testing requirements at the time such requirements are announced.

(b) Enforcement and Penalties

(1) All local health officers shall take such steps as may be necessary to assist with the enforcement of the provisions of this section in accordance with the Public Health Law and this Title.

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for adding a new section 2.9 and 2.60 is sections 201, 206, and 225 of the Public Health Law (PHL). Subdivision (c) of section 201 of the PHL requires the Department to supervise the reporting and control of disease. Subdivision (d) of section 206 of the PHL requires the Commissioner to investigate the causes of diseases and epidemics. Section 225 of the Public Health Law (PHL) 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.

Legislative Objectives:

The legislative objective of PHL § 201 includes authorizing the New York State Department of Health ("Department") to control and promote the control of communicable diseases to reduce their spread. Likewise, the legislative objective of PHL § 206 includes authorizing the Commissioner of Health to take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law, including control of communicable diseases. The legislative objective of Public Health Law § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to amend the State Sanitary Code to address public health issues related to communicable disease.

Needs and Benefits:

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

In response to this significant public health threat, the Department of Health seeks to empower the Commissioner through this emergency regulation to issue determinations requiring the immediate implementation of heightened COVID-19 testing protocols for population segments that may be at increased risk of transmission due, in part, to their employment or residential circumstances. Regular COVID-19 testing enables the immediate identification of COVID-19-positive individuals, even if they are not symptomatic, so that they can isolate and prevent further transmission. Additionally, the reporting of positive COVID-19 test results to public health authorities facilitates the rapid initiation of contact tracing to ensure close contacts are quarantined, tested, and isolated as needed.

These regulations also permit the Department to require reporting of testing and positive reports among school students, teaching staff, and any other employees or volunteers. It is important for the Department to monitor COVID-19 testing and positive reports in schools, given the number of students that are currently unvaccinated. Children ages 5 through 11 years old were only recently authorized by the U.S. Food and Drug Administration (FDA) to receive COVID-19 vaccinations. For those in the 12-17 age group, the CDC data estimates that 70.2% of this population has been vaccinated in New York State, with 61.6% in this age group

completing a COVID-19 vaccine series. By carrying forward the reporting requirements that were in place for the 2020-2021 school year, the Department will be able to track COVID-19 incidence and prevalence in school settings for the upcoming school year. This will allow the Department to work with school districts and local health departments to implement targeted prevention strategies, where needed to limit the spread of the virus.

COSTS:

Costs to Regulated Parties:

In imposing testing requirements pursuant to a Commissioner's determination, the Commissioner, in consultation with the Department, will consider costs and how they may be offset. For example, testing for certain populations is supported by federal grant funding. The State has received approximately 335 million dollars in federal Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative (ELC) Agreement School Reopening Funding through at least July 31, 2022 with the possibility for future funding periods. The New York City Department of Health and Mental Hygiene has received an award for this purpose of approximately 251 million dollars. These amounts are believed to be sufficient to offset any costs associated with any school-related testing in New York State that may be required pursuant to this regulation, such that the fiscal impact on Local Health Departments and schools is minimized. Costs for testing can also be offset by testing that is offered under Operation Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

With regard to the COVID-19 school reporting requirement, schools had to submit daily reports related to COVID-19 testing and positive reports for the 2020-2021 school year. These regulations carry forward this reporting requirement and is not expected to generate any additional cost.

Costs to Local and State Governments:

Costs to local health departments and the Department are expected to be minimal and related to monitoring compliance with these regulations, which can be incorporated into existing reporting and oversight activities and resources.

Paperwork:

This measure will require documentation related to the testing requirement, as well as documentation to opt-out of testing by providing documentation of full vaccination against COVID-19 in appropriate records. No additional paperwork requirements are anticipated for the school reporting requirement, which is expected to take the form of electronic submission to the Department.

Local Government Mandates:

These regulations impose an obligation on schools and school districts to report COVID-19 testing and positive report data for students, teaching staff, and any other employees or volunteers. Local government may also be impacted if subject to a Commissioner's testing determination.

Duplication:

There is no duplication of federal law.

Alternatives:

The alternative to the school reporting requirement would be to not require COVID-19 related reporting for schools and school districts. A lack of the regulation would translate to a lack of accuracy in case statistics and delays or inadequate contact tracing. In addition, the Department would lose the ability to communicate with the community about COVID transmission patterns at the individual school level.

The alternative to permitting the Commissioner to issue determinations to require testing in certain settings would limit the ability for the Department to monitor trends related to COVID-19 transmission in more vulnerable populations, making it more difficult to work with partners to implement prevention strategies. Regular testing also helps to isolate infected individuals more quickly, as well as identify any contacts that need to be quarantined to prevent additional spread of COVID-19.

Federal Standards:

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

Compliance Schedule:

The regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these

emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed ruling making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

As part of ongoing efforts to address the COVID-19 pandemic, small businesses and local governments have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the state since March of 2020. Given the testing and reporting mechanisms that have already been established in many settings, it is not anticipated that this regulation will have a significant impact on or cost to these entities. With regard to the school COVID-19 reporting requirement, this regulation will apply to private schools, including parochial schools, some of which may be small businesses, as well as public schools operated by local governments.

Compliance Requirements:

These regulations provide that testing may be required under certain circumstances, and in certain settings, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. As part of a Commissioner's testing-related determination, this regulation permits the Commissioner to request information/data related to the elements set forth in the determination. These regulations also set forth specific COVID-19 testing and positive report reporting requirements for schools, carrying forward the reporting requirements in place during the 2020-2021 school year.

Professional Services:

As testing is a requirement of this regulation, the types of professional services that will be needed to comply with this rule include diagnostic and screening testing services offered by clinical laboratories that hold the appropriate New York State approval to carry out testing. Because there will be flexibility in the types of tests that can be used to operationalize testing, the types of clinical laboratories that can be used for testing will depend on the type of testing being performed. If a laboratory-based nucleic acid amplification tests (e.g., PCR) will be used to meet the testing requirement, testing will need to be performed off-site by a fully permitted clinical laboratory. In this scenario, individuals are sent to a partner for testing, or an arrangement can be made to conduct sample collection on-site for testing off-site at the clinical laboratory. If rapid waived tests will be used to meet the testing requirement, testing can be performed by a Limited Service Laboratory (LSL). Due to the lower requirements that need to be met for waived testing, an LSL can be established for on-site testing of individuals (e.g., performing testing on-site at a school).

Compliance Costs:

In imposing testing requirements pursuant to a Commissioner's determination, the Commissioner, in consultation with the Department, will consider costs and how they may be offset. For example, testing for certain populations is supported by federal grant funding. The State has received approximately 335 million dollars in federal Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative (ELC) Agreement School Reopening Funding through at least July 31, 2022 with the possibility for future funding periods. The New York City Department of Health and Mental Hygiene has received an award for this purpose of

approximately 251 million dollars. These amounts are believed to be sufficient to offset any costs associated with any school-related testing in New York State that may be required pursuant to this regulation, such that the fiscal impact on Local Health Departments and schools is minimized. Costs for testing can also be offset by testing that is offered under Operation Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

With regard to the COVID-19 school reporting requirement, schools had to submit daily reports related to COVID-19 testing and diagnoses for the 2020-2021 school year. These regulations carry forward this reporting requirement and is not expected to generate any additional cost.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

Any adverse impacts related to school reporting requirements are expected to be minimal, as it carries forward reporting requirements that schools were required to implement last year. The Department, however, will work with schools to ensure they are aware of the new regulations and have the information necessary to comply.

With regard to minimizing adverse impacts related to the Commissioner's authority to issue test-related determinations, many settings have been increasingly implementing COVID-19 prevention strategies, with testing being one such example. Specifically, schools became

familiar with COVID-19 testing last year when the Department provided no cost antigen test cards as part of the microcluster testing initiative. Some schools have already implemented regular pooled surveillance testing to give communities confidence in the safety of their schools. Where the Commissioner issues a testing-related determination, the Department will work with the entities subject to such determination to provide the guidance necessary to comply.

Small Business and Local Government Participation:

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

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 an estimated population of less than 200,000 based upon the 2019 United States Census county populations projections:

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

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

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

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

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

These regulations provide that testing may be required under certain circumstances and in certain settings, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. As part of a Commissioner's testing-related determination, this regulation permits the Commissioner to request information/data related to the elements set forth in the determination. Lastly, these regulations also set forth specific COVID-19 testing and positive test reporting requirements for schools, carrying forward the reporting requirements in place during the 2020-2021 school year.

Compliance Costs:

In imposing testing requirements pursuant to a Commissioner's determination, the Commissioner, in consultation with the Department, will consider costs and how they may be offset. For example, testing for certain populations is supported by federal grant funding. The State has received approximately 335 million dollars in federal Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative (ELC) Agreement School Reopening Funding through at least July 31, 2022 with the possibility for future funding periods. The New York City Department of Health and Mental Hygiene has received an award for this purpose of approximately 251 million dollars. These amounts are believed to be sufficient to offset any costs associated with any school-related testing in New York State that may be required pursuant to this regulation, such that the fiscal impact on Local Health Departments and schools is minimized. Costs for testing can also be offset by testing that is offered under Operation Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

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Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

Any adverse impacts related to school reporting requirements are expected to be minimal, as it carries forward reporting requirements that schools were required to implement last year. The Department, however, will work with schools to ensure they are aware of the new regulations and have the information necessary to comply.

With regard to minimizing adverse impacts related to the Commissioner's authority to issue test-related determinations, many settings have been increasingly implementing COVID-19 prevention strategies, with testing being one such example. Specifically, schools became familiar with COVID-19 testing last year when the Department provided no cost antigen test cards as part of the microcluster testing initiative. Some schools have already implemented regular pooled surveillance testing to give communities confidence in the safety of their schools. Where the Commissioner issues a testing-related determination, the Department will work with the entities subject to such determination to provide the guidance necessary to comply.

Rural Area Participation:

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

JOB IMPACT STATEMENT

A Job Impact Statement is not being submitted with this rule because it is evident from the subject matter of the rule that it will have no impact on jobs and employment opportunities. The primary purposes of this rule is to carry forward COVID-19 related reporting and to permit the Commissioner to impose COVID-19 testing requirements in certain settings based on specified criteria.

EMERGENCY JUSTIFICATION

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are substantially similar to a common cold to severe pneumonia requiring 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.

In response to this significant public health threat, the Department of Health seeks to empower the Commissioner through this emergency regulation to issue determinations requiring the immediate implementation of heightened COVID-19 testing protocols for population segments that may be at increased risk of transmission due, in part, to their employment or residential circumstances. Regular COVID-19 testing enables the immediate identification of COVID-19-positive individuals, even if they are not symptomatic, so that they can isolate and prevent further transmission. Additionally, the reporting of positive COVID-19 test results to public health authorities facilitates the rapid initiation of contact tracing to ensure close contacts are quarantined, tested, and isolated as needed.

These regulations also permit the Department to require reporting of testing and diagnoses among school students, teaching staff, and any other employees or volunteers. It is important for the Department to monitor COVID-19 testing and diagnoses in schools, given the number of students that are currently unvaccinated. Only 40.5% of children ages 5 through 11 years old have received at least one COVID-19 vaccination, with 34.9% of this age group completing a COVID-19 vaccine series. For those in the 12-17 age group, the CDC data estimates that 77.2% of this population has been vaccinated in New York State, with 70.1% in

this age group completing a COVID-19 vaccine series. By carrying forward the reporting requirements that were in place for the 2020-2021 school year, the Department will be able to track COVID-19 incidence and prevalence in school settings for the remainder of the school year. This will allow the Department to continue working with school districts and local health departments to implement targeted prevention strategies, where needed, to limit the spread of the virus.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19, necessitating immediate action. Accordingly, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.