Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting
Agenda and Informational Announcements

February 10, 2022
10:15 AM

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

I. WELCOME AND INTRODUCTION

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

II. REGULATIONS

For Emergency Adoption

20-06 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)

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

For Adoption

21-19 Amendment of Sections 600.1 and 600.2 of Title 10 NYCRR (Article 28 Nursing Homes; Establishment; Notice and Character and Competence Requirements)

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 surveillance data to the Department upon direction from the Commissioner and clarify reporting requirements for clinical laboratories with respect to communicable diseases.

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of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, Section 2.6 is repealed and a new Section 2.6 is added, a new Section 2.13 is added, Sections 2.25 through 2.30 are repealed, a new Section 58-1.14 is added, and Section 405.3 is amended, to be effective upon filing with the Secretary of State, to read as follows:

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

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

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

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

* * *

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

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

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

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

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

(l) *Congregate quarantine* shall mean quarantine at a location operated or contracted by the State or local health authority, consistent with this Part and any direction that the State Commissioner of Health may issue, where multiple persons are quarantined;

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

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

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

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

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

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

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

syndromic surveillance data as the commissioner deems appropriate, which the hospital shall submit in the manner and form determined by the commissioner; and

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

* * *

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 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, Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. Since late November 2021, cases have risen more than 40-fold, and over 98 percent of the sequenced recent positives in New York State were the Omicron variant.

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.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Nearly two years after the first cases were identified in the United States, the Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. The substantial majority of sequenced positive cases in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

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

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

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

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

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

(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 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 Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. Cases in New York are currently over 10-fold their levels in late June 2021, and the substantial majority of the sequenced positives in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

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.

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 sec. 2100 and Part 2 of the State Sanitary Code.

Duplication:

There is no duplication of federal law.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

The regulations will become effective upon filing with the Department of State and will expire, unless renewed, 60 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 60-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.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

The following 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 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 Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. Cases in New York are currently over 10-fold their levels in late June 2021, and the substantial majority of the sequenced positives in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

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 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 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 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 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.

Nearly two years after the first cases were identified in the United States, the Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. Cases in New York are over 10-fold their levels in late June 2021, and the substantial majority of the sequenced positives in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

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.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

As part of ongoing efforts to address the COVID-19 pandemic, 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).

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.

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.

Nearly two years after the first cases were identified in the United States, the Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Omicron variant. The substantial majority of the sequenced positives in New York State over the past 30 days were of the Omicron variant. Additionally, the rate of breakthrough infections among the vaccinated population has increased significantly since the Omicron variant became dominant.

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. Children ages 5 through 11 years old only recently were authorized by the 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.

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.

SUMMARY OF EXPRESS TERMS

This regulation amends Title 10 NYCRR Sections 600.1 and 600.2.

Subdivision (d) is added to section 600.1 to articulate notice requirements for nursing home establishment applications, as required by new *Subdivision 2-b* of Article 2801-a of the Public Health Law. The State Long-Term Care Ombudsman and residents, staff, and other parties affiliated with an existing nursing home, will be notified once a nursing home establishment application has been acknowledged by the Department and also, when a nursing home establishment application is placed on the Establishment and Project Review Committee agenda of the Public Health and Health Planning Council, for consideration.

Paragraph (2) of subdivision (b) of section 600.2 is amended to make the "character, competence, and standing in the community" review standard comparable for all applicants; and to include a limited liability company as an acceptable legal entity applicant, whose members are subject to the "character, competence, and standing in the community" review.

Paragraph (4) of subdivision (b) of section 600.2 is amended to include additional titles of applicant individuals, it removes a reference to outdated reporting requirements that no longer appear in statute, it clarifies establishment application review criteria, and defines the terms 'recurrent' and 'prompt correction' related to violations at article 28 facilities.

Paragraph (5) is added to subdivision (b) of section 600.2 to incorporate additional information the Public Health and Health Planning Council is required to consider when making a determination about a "consistently high level of care" rendered at a nursing home. This required information is found in the new *Subdivision 3-b* of Article 2801-a of the Public Health Law. In addition, the proposed regulation clearly sets forth five (5) occurrences that automatically render a determination that a consistently high level of care is not found, including determining the percentage of nursing homes in an applicant individual's portfolio with a CMS star rating of two stars or less. And finally, it also includes the amendments made to paragraph (4) of subdivision (b) of section 600.2, which applies to all article 28 facilities, generally.

Altogether, the proposed regulation in paragraph (5) of subdivision (b) of section 600.2 responds to legislative actions and recommendations and sets forth uniform, transparent, and outcome-based standards to determine when a "consistently high level of care" has been delivered by applicant operators in the nursing homes that they own or have owned over the last seven years.

Together the proposed regulations in Sections 600.1 and 600.2 of Title 10 NYCRR, strengthen the establishment application review process for all article 28 facilities, generally and nursing homes, specifically. They also provide the transparency and clarity necessary to determine when a nursing home establishment application (includes changes of ownership and transfers of ownership applications) will be considered by the Establishment and Project Review Committee of the Public Health and Health Planning Council.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2803 of the Public Health Law, Sections 600.1 and 600.2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

New subdivision (d) is added to section 600.1 to read as follows:

(d) Notice about an application for establishment shall be administered in the following manner:

(1) Long-term care ombudsman (LTCO)

(i) Once an application for establishment of a nursing home has been acknowledged by the Department, the Department shall notify the office of the LTCO of such application for establishment, by regular mail or email, within thirty days of acknowledgement of an application for establishment.

(ii) Once an application for establishment of a nursing home has been scheduled for consideration by a committee designated by the public health and health planning council, the Department shall notify the office of the LTCO by regular mail or email.

(2) Residents, staff, and others

(i) Once an application for establishment of an existing nursing home has been acknowledged by the Department, the current operator of the facility and the applicant, shall notify the residents and their designated

representatives and the staff, including their union representatives, if applicable, of such application for establishment. Notification shall be completed by regular mail, email, or the delivery method designated by the resident, their designated representative, the staff, and union representatives, within thirty days of the Department's acknowledgement of an application for establishment.

(a) The notification shall include the pending change of ownership, as well as the legal entity and individual name(s) of the proposed buyer; the application number; instruction on how to submit comments about the application; and a link for the general public to view the application using the New York State Electronic Certificate-of-Need (NYSE-CON) system where applications are submitted.

(ii) Once an application for establishment of an existing nursing home has been scheduled for consideration by a committee designated by the public health and health planning council, within twenty-four (24) hours, the current operator of the facility and the applicant shall notify the residents and their designated representatives and the staff, including their union representatives, if applicable by regular mail, email, or the delivery method designated by the resident, their designated representative, the staff, and union representatives.

(a) The notification shall include the date, location(s), and time of the meeting of the committee designated by the public health and health planning council.

Paragraph (2) of subdivision (b) of section 600.2 is amended to read as follows:

(2) (i) If a nonprofit corporation, that the members of the board of directors and the officers of the corporation are of such character, experience, competence and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation in its best interests and in the public interest and so as to provide proper care for the patients or residents to be served by the facility or the proposed facility;

(ii) if a proprietary business, that the owner, or all the partners, if a partnership, are persons of good moral character [who are competent] with the experience, competence and standing as to give reasonable assurance of their ability to operate the business so as to provide proper care for the patients or residents to be served by the facility or the proposed facility;

(iii) if a business corporation, that the members of the board of directors, the officers and the stockholders of the corporation are of such character, experience, competence and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation so as to provide proper care for the patients or residents to be served by the facility or the proposed facility;

(iv) if a limited liability company, that the members, managers, and officers of the company, are of such character, experience, competence and standing as to give reasonable assurance of their ability to conduct the affairs of the company so as to provide proper care for the patients or residents to be served by the facility or the proposed facility;

Paragraph (4) of subdivision (b) of section 600.2 is amended to read as follows:

(4) that, with respect to an applicant who is already or within the past 10 years, [has] been an incorporator, director, sponsor, stockholder, member, controlling person, principal stockholder, principal member, or operator of any facility as specified in paragraph (b) of subdivision (3) of *section 2801-a of the Public Health Law*, a substantially consistent high level of care has been rendered in each such facility [with which] the applicant is or has been affiliated [during the past 10 years or during the period of affiliation, as appropriate]. [In reaching this determination, the Public Health Council shall consider findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter, periodic medical review/independent professional review (PMR/IPR) findings, routine and patient abuse complaint investigation results, and other available information. The Public Health Council's determination that a substantially consistent high level of care has been rendered shall be made after reviewing the following criteria: the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility

operation, and the remedial action, if any, taken after the violation was discovered.]

(i) <u>In reaching this determination, the Public Health and Health Planning Council shall consider findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter and routine and patient abuse complaint investigation results; and other available information.</u>

<u>(ii)</u> <u>The Public Health and Health Planning Council's determination that a substantially consistent high level of care has been rendered shall be made after evaluating the aforementioned information, with the following criteria: the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered.</u>

(a) In [reviewing] <u>evaluating</u> the gravity of the violation, the Public Health and Health Planning Council shall consider whether the violation threatened, or resulted in direct, significant harm to the health, safety or welfare of patients/residents.

(b) In [reviewing] <u>evaluating</u> the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, the Public Health <u>and Health Planning</u> Council shall consider whether a reasonably prudent <u>individual of the</u>

applicant/operator should have been aware of the conditions which resulted in the violation and was notified about the conditions which resulted in the violation and whether the individual of the applicant/operator was notified about the condition(s) which resulted in the violation.

(c) In [reviewing] evaluating any remedial action taken, the Public Health and Health Planning Council shall consider whether the applicant/operator investigated the circumstances surrounding the violation, and took steps which a reasonably prudent applicant/operator would take to prevent the reoccurrence of the violation.

(iii) When violations were found which either threatened to directly affect patient/resident health, safety or welfare, or resulted in direct, significant harm to the health, safety or welfare of patients/residents, there shall not be a determination of a substantially consistent high level of care if the violations [reoccurred] were recurrent or were not promptly corrected.

(a) A violation is recurrent if it has the same root cause as a violation previously cited within the last ten (10) years.

(b) A violation is not promptly corrected if a plan of correction has not been submitted to the Department within ten (10) calendar days of the issuance of the statement of deficiencies, Form CMS-2567 and the facility has failed to provide an acceptable date of compliance based on the violation(s) requiring correction.

New Paragraph (5) of subdivision (b) of section 600.2 is added to read as follows:

(5) that, with respect to an application to incorporate or establish a nursing home, an applicant who is already or within the past 7 years, been an incorporator, director, sponsor, stockholder, or member, has held a controlling interest or has been a controlling person, principal stockholder or principal member, or operator of a nursing home as specified in paragraph (b) of subdivision (3-b) of *section 2801-a of the Public Health Law*, has demonstrated satisfactory character, competence and standing in the community and a consistently high level of care has been rendered in each such nursing home that the applicant is or has been affiliated.

(i) In reaching this determination, the Public Health and Health Planning Council shall consider, at a minimum, the following:

(a) findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter and routine and patient abuse complaint investigation results;

(b) any instance of a facility affiliated with the applicant/operator earning a two-star rating or less by the federal centers for Medicare and Medicaid Services (CMS) (or a comparable rating under a successor CMS rating system); provided that a further consideration and mitigating factor in determining whether such star rating reflects a consistently high level of care is where an

applicant's ownership interest in the star rated facility commenced within the prior five years;

(c) any instance where there have been violations of the state or federal nursing home code, or other applicable rules and regulations, that threatened to directly affect the health, safety or welfare of any patient or resident, including but not limited to a finding of immediate jeopardy, or actual harm, and were recurrent or were not promptly corrected, including but not limited to repeat deficiencies for the same or similar violations over a three year period or during the entire duration of ownership if less than three years, or any facility which has been in receivership;

(d) any instance where a facility has closed or has closed as a result of a settlement agreement from a decertification action or licensure revocation.

(e) any instance where a health care related facility, agency, or program was the subject of a decertification action or licensure revocation;

(f) any involuntary termination from the Medicare or Medicaid program; and

(g) any instance of a nursing home being designated a Special Focus Facility or Special Focus Facility Candidate.

The applicant shall be provided with the opportunity to submit an explanation and other supporting documentation regarding any of the

aforementioned occurrences which shall be considered by the Public Health and Health Planning Council prior to reaching a determination.

(ii) The Public Health and Health Planning Council's determination that a consistently high level of care has been rendered shall be made after evaluating the aforementioned information, with the following criteria: (i) the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered and (ii) the percentage of nursing homes in a portfolio with a two-star or less rating.

(a) In evaluating the gravity of the violation, the Public Health and Health Planning Council shall consider whether the violation threatened, or resulted in direct, significant harm to the health, safety or welfare of patients/residents.

(b) In evaluating the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, the Public Health and Health Planning Council shall consider whether a reasonably prudent individual of the applicant/operator should have been aware of the conditions which resulted in the violation and whether the individual of the applicant/operator was notified about the condition(s) which resulted in the violation.

(c) In evaluating any remedial action taken, the Public Health and Health Planning Council shall consider whether the

applicant/operator investigated the circumstances surrounding the violation, and took steps which a reasonably prudent applicant/operator would take to prevent the reoccurrence of the violation.

(d) In evaluating instances of a facility affiliated with the applicant/operator earning a two-star or less rating, the Public Health and Health Planning Council shall determine the percentage of nursing homes in the portfolio, that each individual of the applicant/operator has held an ownership interest for forty-eight (48) months or more and has earned a CMS star rating of two-stars or less.

(iii) When any of the following has occurred in the prior five years, there shall not be a determination of a consistently high level of care:

(a) Closure of a facility or a facility has closed as a result of a settlement agreement from a decertification action or licensure revocation.

(b) A health care related facility, agency, or program was the subject of a decertification action or licensure revocation.

(c) Involuntary termination of a health care related facility, agency, or program from the Medicare or Medicaid program.

(d) Violations found, which either threatened to directly affect patient/resident health, safety or welfare, or resulted in direct, significant harm to the health, safety or welfare of

patients/residents, and were recurrent or were not promptly corrected.

(1) A violation is recurrent if it has the same root cause as a violation previously cited within the last seven (7) years.

(2) A violation is not promptly corrected if a plan of correction has not been to submitted to the Department within ten (10) calendar days of the issuance of the statement of deficiencies, Form CMS-2567 and the facility has failed to provide an acceptable date of compliance based on the violation(s) requiring correction.

(iv) When any individual of the applicant/operator has greater than 40% of the nursing homes in their portfolio with a CMS star rating of two stars or less and has held an ownership interest in such nursing home for forty-eight (48) months or more, there shall not be a determination of a consistently high level of care; unless the portfolio contains fewer than five (5) facilities, then the Public Health and Health Planning Council shall make a determination on a case-by-case basis, using the criteria set forth in subparagraph (ii) of this paragraph.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 2803(2) authorizes the Public Health and Health Planning Council (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, including the establishment or incorporation of health care facilities.

Legislative Objectives:

The legislative objective of PHL Article 2801-a is to provide a deliberate and reasonable application process for the establishment or incorporation of health care facilities in New York. The purpose of the establishment application process is to codify an application review process that includes an assessment of character and competence, quality of care metrics, financial feasibility, and other relevant factors, for the benefit of those who seek health care services at State-regulated facilities.

Needs and Benefits:

Rulemaking was necessitated by revisions to Public Health Law section 2801-a via Chapter 102 and 141 of the Laws of 2021. Regulations are being amended to codify the procedure for the notification to the Long-term care ombudsman (LTCO), Residents, staff, and others of an application for the establishment of a nursing home operator. Notification will occur when an application has been received and acknowledged by the State Department of Health (Department) and again when the application has been

scheduled for consideration by a committee designated by the Public Health and Health Planning Council. Notification to those who may be impacted by a nursing home establishment application will allow a chance for public comment to be submitted for consideration by the Public Health and Health Planning Council (PHHPC) before PHHPC acts upon the application. Regulations are being amended to add language for limited liability corporations for character and competence, consistent with other business types. Regulations are being amended for character and competence to require PHHPC to consider, in some cases, specified information and evaluate the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered before determining that a substantially consistent or a consistently high level of care has been rendered. New language has been added to codify standards of review for nursing home character and competence, using certain quality of care metrics when evaluating and making a determination that a consistently high level of care has or has not been rendered. The changes reflect the intent of the law to provide increased transparency to those with an interest in the establishment of a nursing home operator and to codify the metrics used for evaluating character and competency of proposed operators.

Costs:

Costs to Regulated Parties:

Nominal costs may be incurred by nursing home providers to adhere to the notification requirements when the establishment of a new operator is proposed. This

cost will be incurred by the current operator of the facility and the applicant for establishment. The nominal costs will be related to postage, supplies, and staff time to prepare the notice and establish distribution lists for those to be notified. Labor, legal and consulting costs may be incurred by applicants who have previously filed an establishment application which is pending PHHPC consideration, should they feel the need to revise their application based on the rule changes.

Costs to State Government and the Department of Health:

The Office of the State Long-Term Care Ombudsman will incur costs related to the labor involved in reviewing notices filed on nursing home establishment applications and, thereafter, submitting a recommendation about the application to the Department. The Department will incur additional staff time required to re-review pending establishment applications and revise materials previously prepared during the review of such applications. Costs to the Department for notification requirements will be absorbed into current costs.

Costs to Local Governments:

There should be no local government costs unless a County operated facility is the subject of a new operator nursing home establishment application. Should this occur the County would incur the costs associated with the current operator outlined in the Cost to the Regulated Parties Section.

Local Government Mandates:

There are no local mandates in the amended regulations. However, County operated nursing homes will be required to meet the notification requirements under the amended regulations.

Paperwork:

Under the amended regulations, the current facility and the applicant for establishment will be required to prepare written notification to residents, staff and other impacted parties after a nursing home establishment application has been acknowledged by the Department. Distribution lists for notifications will be required. All other requirements are consistent with the paperwork currently required during the establishment application process.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The Department considered current standards used in character and competence review and alternative metrics, ratings, and data available. The Department also considered the impact of the use of absolute thresholds to be achieved for determining that a consistently high level of care has been rendered. The Department found that currently published ratings, such as the CMS Star rating system, take into account many of the alternative factors and data being considered. To avoid duplication and promote

transparency, the Department incorporated the CMS Star Ratings, surveillance findings and enforcements that are available to the public via the NYS Nursing Home Page of the Department's website, and CMS special focus facility designations available to the public – all information and data familiar to the health care industry, in general, and the nursing home industry, specifically, to make a determination about a consistently high level of care at facilities. This combination of information incorporates a cross section of factors relevant to assessing quality of care at nursing homes. The Department also included additional factors to supplement information that may not be apparent in the main evaluation criteria such as length of time a facility was owned, the overall number of facilities owned, revocation of a license, involuntary closure of a facility, and if severe deficiencies were recurrent or were not promptly corrected.

The amended regulations reflect a regulatory framework to evaluate the general quality of care rendered by a proposed operator historically and incentivizes improvement in quality as a condition to acquiring additional facilities in New York State.

Federal Standards:

The amended regulations do not exceed any minimum standards of the federal government.

Compliance Schedule:

The amended regulations will take effect upon a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Local governments and small businesses will not be affected by this rule, unless they operate a nursing home and, in such cases, will be impacted by the new, statutory notification requirements defined in Section 600.1. The current number of local governments and identified-small businesses (employ less than 100 staff) that operate a nursing home are seventy-nine (79). The Department does not anticipate an increase in nursing home establishment applications by such applicants as a result of the proposed regulations.

Compliance Requirements:

Regulated parties are expected to be in compliance with the amended regulations upon adoption. The amended regulations will define new, statutory notice requirements when an application for the establishment of a nursing home has been acknowledged by the Department and when the application has been scheduled for consideration by a committee designated by the Public Health and Health Planning Council.

Professional Services:

These regulations are not expected to require any additional use of professional services.

Compliance Costs:

Nominal costs may be incurred by a nursing home operator and applicant to adhere to the notification requirements after a nursing home establishment application has been acknowledged by the Department. This cost will be incurred by the current operator of the facility and the applicant for establishment. The nominal costs will be related to postage, supplies, and staff time to prepare the notice and establish distribution lists for individuals to be notified.

Economic and Technological Feasibility:

The Department has considered feasibility and the amended regulations are economically and technically feasible.

Minimizing Adverse Impact:

Minimal flexibility exists to minimize impact since the new requirements are statutory and apply to all nursing home establishment applicants, however, an effort was made to broaden the method used for notice distribution.

Small Business and Local Government Participations:

Organizations who represent the affected parties will have several opportunities for participation. There are several opportunities to provide public comment, both written and orally, at the Public Health and Health Planning Council (PHHPC). Initially, the regulations will be presented twice in a public PHHPC meeting; first, for discussion and second, for final adoption. In both instances, the public, including any affected party,

is invited to provide comments during the PHHPC Committee on Codes, Regulations and Legislation meeting.

Second, the affected parties have the opportunity via the 60-day State Register process to provide comments and suggestions to the regulation. If substantial and material changes are made as a result of the public comments, the amended regulation will be subject to an additional 45-day comment period.

Finally, before going to PHHPC, a call was held with industry representatives highlighting the proposed regulation and to answer any questions industry representatives had regarding the regulation and the process of regulation adoption.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov).

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

The following eleven counties have certain townships with population densities of 150 persons or less per square mile:

Albany
Broome
Dutchess
Erie
Monroe
Niagara
Oneida
Onondaga
Orange
Saratoga
Suffolk

Reporting, Record Keeping and Other Compliance Requirements and Professional Services:

Nursing home operators and applicants for establishment of new operators are expected to be in compliance with the amended regulations upon adoption. There are several licensed nursing homes in rural areas. The amended regulations will define new, statutory notice requirements when an application for the establishment of a nursing home has been acknowledged by the Department and when the application has been scheduled for consideration by a committee designated by the Public Health and Health Planning Council. There are no new reporting requirements, but record keeping will be required by nursing home operators and applicants for establishment of a new operator to ensure notification to required parties. No additional professional staff are expected to be needed as a result of the amended regulations.

Costs:

Nominal costs may be incurred by a nursing home operator and applicant to adhere to the notification requirements after a nursing home establishment application has been acknowledged by the Department. This cost will be incurred by the current operator of the facility and the applicant for establishment.

Minimizing Adverse Impact:

The amended regulations do not create any adverse effect on regulated parties.

Rural Area Impact:

Organizations who represent the affected parties and the public can obtain the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council and a copy of the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

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

Further, the new notification requirements in Section 600.1 will only impact an employer over a limited period and can be performed by existing staff resources. The amended regulations for Section 600.2 should not cause a change to the workload of applicants for establishment of new nursing home operators and will not increase nor decrease jobs and employment opportunities.