

STATE OF NEW YORK
SPECIAL PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

AGENDA

November 18, 2021

*Immediately following the Special Committee on Codes, Regulations and Legislation Meeting
(Codes scheduled to begin at 10:15 a.m.)*

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

I. INTRODUCTION OF OBSERVERS

Jeffrey Kraut, Chair

II. REGULATION

Report of the Committee on Codes, Regulations and Legislation

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

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)

21-07 Amendment of Section 415.3 of Title 10 NYCRR and Addition of Section 485.18 to
Title 18 NYCRR (Personal Caregiving and Compassionate Caregiving Visitors in
Nursing
Homes and Adult Care Facilities)

21-14 Addition of Section 2.61 to Title 10 NYCRR, Amendment of Sections 405.3, 415.19,
751.6, 763.13, 766.11, 794.3 & 1001.11 of Title 10 NYCRR & Sections 487.9, 488.9 and
490.9 of
Title 18 NYCRR (Prevention of COVID-19 Transmission by Covered Entities)

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

For Information

- 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)
- 21-07 Amendment of Section 415.3 of Title 10 NYCRR and Addition of Section 485.18 to Title 18 NYCRR (Personal Caregiving and Compassionate Caregiving Visitors in Nursing Homes and Adult Care Facilities)
- 21-14 Addition of Section 2.61 to Title 10 NYCRR, Amendment of Sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 & 1001.11 of Title 10 NYCRR & Sections 487.9, 488.9 and 490.9 of Title 18 NYCRR (Prevention of COVID-19 Transmission by Covered Entities)
- 21-08 Amendment of Section 756.3 and Repeal of Section 756.4 of Title 10 NYCRR (Abortion Services)

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) whenever the commissioner determines that there exists an outbreak of a highly contagious communicable disease pursuant to Part 2 of this Title or other public health emergency, such

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

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

* * *

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 PPHPC, with the approval of the Commissioner, to adopt regulations concerning the operation of facilities licensed pursuant to Article 28 of the PHL, including general hospitals.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that 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, over a year and half 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 Delta variant. Since early July, cases have risen more than 10-fold, and over 99 percent of the sequenced recent positives in New York State were the Delta 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 impose any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

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

Paperwork:

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

Local Government Mandates:

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

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

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

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

The following 44 counties have a population of less than 200,000 based upon 2020

United States Census data:

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

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

Census estimated county populations for 2010:

Albany County
Dutchess County
Erie County

Monroe County
Niagara County
Oneida County
Onondaga County

Orange County
Saratoga County
Suffolk County

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

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

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.

Now, over a year and half 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 Delta variant. Since early July, cases have risen more than 10-fold, and over 99 percent of the sequenced recent positives in New York State were the Delta variant.

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) Penalties 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 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, over a year and half after the first cases were identified in the United States, Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Cases in New York are over 10-fold their levels in late June 2021, and greater than 99 percent of the sequenced recent positives in New York State were the Delta variant.

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

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

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory 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, over a year and half after the first cases were identified in the United States, Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Cases in New York are over 10-fold their levels in late June 2021, and greater than 99 percent of the sequenced recent positives in New York State were the Delta variant.

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.

SUMMARY OF EXPRESS TERMS

These regulations are intended to implement section 2801-h of the Public Health Law (PHL) and section 461-u of the Social Services Law (SSL), as enacted by Chapter 108 of the Laws of 2021. These statutory amendments required the Commissioner of Health to promulgate regulations governing personal caregiving visitors in all licensed nursing homes and adult care facilities. According to the statute, a “personal caregiving visitor” means a family member, close friend, or legal guardian of a resident designated by such resident, or such resident’s lawful representative, to assist with personal caregiving or compassionate caregiving for the resident. Personal caregiving is defined as care and support of a resident to benefit such resident’s mental, physical, or social well-being, and compassionate caregiving is defined as personal caregiving provided in anticipation of the end of the resident’s life or in the instance of significant mental, physical or social decline or crisis (*see* PHL § 2801-h[1][a-c], SSL § 461-u[1][a-c]).

In accordance with the statutory directive, the new regulatory sections amend 10 NYCRR 415.3(d) to add new paragraphs (3), (4), and (5) concerning, respectively, personal caregiving visitation, additional provisions relating to compassionate caregiving, and authority for the Department of Health to review a nursing home’s personal caregiving visitation policies and procedures. Likewise, for adult care facilities, the regulation adds a new section 485.18 of 18 NYCRR to address general visitation rights in an adult care facility (section 485.18[b]), personal caregiving visitation (section 485.18[c]), additional provisions relating to compassionate caregiving (section 485.18[d]), and authority for the Department of Health to review an adult care facility’s personal caregiving visitation policies and procedures (section 485.18[e]).

More specifically, the regulatory amendments relating to personal caregiving visitation, as contained in the new 10 NYCRR 415.3(d)(3) and 18 NYCRR 485.18(c), provide that such

visitation shall be permitted in a nursing home and adult care facility during a public health emergency declared under section twenty-four or section twenty-eight of the Executive Law, notwithstanding general visitation restrictions in the facility, and subject to certain limitations, including the need to limit or temporarily suspend personal caregiving visitation due to an increase in local infection rates, temporary inadequate staff capacity, an acute emergency situation such as loss of an essential service, or because the personal caregiving visitor poses a threat to the safety and well-being of the resident or any resident or personnel in the facility. The regulations governing personal caregiving visitation further: (i) set forth procedures for residents or their lawful representatives to designate and change their designation of personal caregiving visitors; (ii) provide that a resident shall be entitled to designate at least two personal caregiving visitors; (iii) require that all personal caregiving visitors follow infection prevention safety protocols required for nursing home and adult care facility staff, such as communicable disease testing, health screenings, and donning appropriate personal protective equipment; and (iv) set forth standards for a facility to determine the maximum frequency and duration of personal caregiving visits and the total number of personal caregiving visitors allowed to visit the facility at any one time.

The new 10 NYCRR 415.3(d)(4) and 18 NYCRR 485.18(d) establish additional provisions for compassionate caregiving provided by personal caregiving visitors. These sections set forth the situations in which a resident is eligible for a compassionate caregiving visitor and the requirements for screening compassionate caregiving visitors prior to their entry into the facility.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2801-h and 2803 of the Public Health Law and sections 461, 461-e, and 461-u of the Social Services Law, Section 415.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended and a new Section 485.18 of Title 18 of the NYCRR is hereby added, to be effective upon filing with the Secretary of State, to read as follows:

Subparagraph (iv) of paragraph (2) of subdivision (d) of Section 415.3 of 10 NYCRR is amended to read as follows:

(iv) provide immediate access to any resident by the following:

* * *

(f) immediate family or other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time; [and]

(g) personal caregiving visitors, as defined in subdivision (1) of section 2801-h of the Public Health Law and pursuant to criteria specified in paragraph (3) of this subdivision, including those providing compassionate caregiving, as defined in subdivision (1) of section 2801-h of the Public Health Law and pursuant to criteria specified in paragraph (4) of this subdivision; and
[(g)] (h) others who are visiting with the consent of the resident, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time;

Subdivision (d) of Section 415.3 of 10 NYCRR is amended to add new paragraphs (3), (4), and (5) to read as follows:

(3) Personal caregiving visitors.

(i) During a public health emergency declared under section twenty-four or section twenty-eight of the executive law, the facility must continue to allow residents to access their designated personal caregiving visitors, notwithstanding any restrictions or prohibitions relating to residential health care visitation resulting from the declared public health emergency, subject to the following restrictions:

(a) If a facility has reasonable cause to believe that a resident will not benefit from accessing their designated personal caregiving visitors, and such reasoning has been documented in the resident's individualized comprehensive plan of care, a facility may require a health or mental health professional duly licensed or certified in New York State under the Education Law, and who need not be associated with the nursing home, including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist, to provide a written statement that the personal caregiving will substantially benefit the resident's quality of life, including a statement from such medical provider that the personal caregiving visitation will enhance the resident's mental, physical, or psychosocial well-being, or any additional criteria evidencing a benefit to quality of life as determined by the Department. Such written statements from the medical provider shall be maintained in the resident's individualized comprehensive plan of care.

(b) Notwithstanding any provision of this subparagraph (i), a facility may temporarily suspend or limit personal caregiving visitors to protect the health, safety and welfare of residents if: the declared public health emergency is related to a communicable disease and the Department determines that local infection rates are at a level that presents a serious risk of transmission of such communicable disease within local facilities; the

facility is experiencing temporary inadequate staffing and has reported such staffing shortage to the Department of Health and any other State or federal agencies as required by law, regulation, or other directive; or an acute emergency situation exists at the facility, including loss of heat, loss of elevator service, or other temporary loss of an essential service. Provided, however, that in the event a facility suspends or limits personal caregiving visitation pursuant to this clause, the facility shall notify residents, all designated personal caregiving visitors, and the applicable Department regional office of such suspension or limitation and the duration thereof within twenty-four hours of implementing the visitation suspension or limitation. Additionally, for each day of the suspension or limitation, the facility shall document the specific reason for the suspension or limitation in their administrative records. The facility shall further provide a means for all residents to engage in remote visitation with their designated personal caregiving visitor(s), including but not limited to phone or video calls, until such time that the suspension or limitation on personal caregiving visitation has ended.

(c) Notwithstanding any provision of this subparagraph (i), a facility may prohibit a personal caregiving visitor from entering if the facility has reasonable cause to believe that permitting the personal caregiving visitor to meet with the resident is likely to pose a threat of serious physical, mental, or psychological harm to such resident. In the event the facility determines that denying such personal caregiving visitor access to the resident is in the resident's best interests pursuant to this subparagraph, the facility must document the date of and reason for visitation refusal in the resident's individualized comprehensive plan of care, and on the same date of the refusal the facility shall communicate its decision to the resident and their designated representative. Further, a

facility may refuse access to or remove from the premises any personal caregiving visitor who is causing or reasonably likely to cause physical injury to any facility resident or personnel.

(ii) The facility shall develop written policies and procedures to ask residents, or their designated representatives in the event the resident lacks capacity, at time of admission or readmission, or for existing residents within fourteen days of the effective date of this paragraph, which individuals the resident elects to serve as their personal caregiving visitor during declared public health emergencies. A resident shall be entitled to designate at least two personal caregiving visitors at one time.

(iii) The facility shall maintain a written record of the resident's designated personal caregiving visitors in the resident's individualized comprehensive plan of care, and shall document when personal caregiving and compassionate caregiving is provided in the resident's individualized comprehensive plan of care.

(iv) As part of its ongoing review of a resident's comprehensive plan of care, the facility shall regularly inquire of all current residents, or their designated representative if the resident lacks capacity, whether the facility's current record of designated personal caregiving visitors remains accurate, or whether the resident, or their designated representative if the resident lacks capacity, wishes to make any changes to their personal caregiving visitor designations. The facility shall update the resident's individualized comprehensive plan of care with the date the facility sought updates from the resident and indicate any changes to the resident's personal caregiving visitor designations therein. Such inquiries shall be made no less frequently than quarterly and upon a change in the resident's condition; upon review of a facility's visitation policies and procedures,

the Department may also require the facility inquire of any resident whether the facility's current record of designated personal caregiving visitors remains accurate.

(v) The facility shall require all personal caregiving visitors to adhere to infection control measures established by the facility and consistent with any guidelines from the Department, or in the absence of applicable Department guidance, consistent with long term care facility infection control guidelines from the U.S. Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services. Such infection control measures may include, but need not be limited to:

(a) testing all personal caregiving visitors for any communicable disease that is the subject of the declared public health emergency, which may include rapid on-site testing or requiring the visitor to present a negative test result dated no more than seven days prior to the visit;

(b) checking the personal caregiving visitor's body temperature upon entry to the facility, and denying access to any visitor with a temperature above 100 degrees Fahrenheit;

(c) conducting health screenings of all personal caregiving visitors upon entry to the facility, including screenings for signs and symptoms of any communicable disease that is the subject of the declared public health emergency or any other communicable disease which is prevalent in the facility's geographic area, and recording the results of such screenings;

(d) requiring all personal caregiving visitors to don all necessary personal protective equipment appropriately, and providing such personal protective equipment to all personal caregiving visitors; and

(e) enforcing social distancing between persons during visitation, including personal caregiving visitation, except as necessary to provide personal caregiving by the personal caregiving visitor for the resident.

(vi) The facility shall establish policies and procedures regarding the frequency and duration of personal caregiving visits and limitations on the total number of personal caregiving visitors allowed to visit the resident and the facility at any one time. Such policies shall not be construed to limit access by other visitors that would otherwise be permitted under state or federal law or regulation. The facility shall ensure its policies and procedures respect resident privacy and take into account visitation protocols in the event a resident occupies a shared room. In establishing frequency and duration limits, the facility policy shall ensure that residents are able to receive their designated personal caregiving visitors for the resident's desired frequency and length of time, and any restrictions on that desired frequency and duration must be:

(a) attributable to the resident's clinical or personal care needs;

(b) necessary to ensure the resident's roommate has adequate privacy and space to receive their own designated personal caregiving visitors; or

(c) because the desired visitation frequency or duration would impair the effective implementation of applicable infection control measures, including social distancing of at least six feet between the visitors and others in the facility, having sufficient staff to effectively screen all personal caregiving visitors and monitor visits to ensure infection control protocols are being followed throughout, and having a sufficient supply of necessary personal protective equipment for all personal caregiving visitors.

(4) Compassionate caregiving.

(i) In the event a resident experiences a long-term or acute physical, mental, or psychosocial health condition for which, in the opinion of the resident, their representative, or a health care professional (including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist), a compassionate caregiving visitor would improve the resident's quality of life, the resident or their representative shall designate at least two compassionate caregiving visitors at one time, and the facility shall record such designation in the resident's individualized comprehensive plan of care. A resident's designated personal caregiving visitors may also provide compassionate caregiving.

(ii) Situations in which a resident is eligible for a compassionate caregiving visitor include but are not limited to the following:

(a) end of life;

(b) the resident, who was living with their family before recently being admitted to an adult care facility, is struggling with the change in environment and lack of physical family support;

(c) the resident is grieving after a friend or family member recently passed away;

(d) the resident needs cueing and encouragement with eating or drinking, and such cueing was previously provided by family and/or caregiver(s), and the resident is now experiencing weight loss or dehydration; and

(e) the resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

(iii) Compassionate caregiving visitation shall be permitted at all times, regardless of any general visitation restrictions or personal caregiving visitation restrictions in effect in the facility.

Provided, however, that the facility shall require compassionate caregiving visitors to be screened for communicable diseases prior to entering the facility and visits must be conducted using appropriate social distancing between the resident and visitor if applicable based on guidance from the Department or the U.S. Centers for Disease Control and Prevention; if, however, personal contact would be beneficial for the resident's mental or psychosocial well-being, the facility shall establish policies and procedures to ensure that such necessary physical contact follows appropriate infection prevention guidelines, including the visitor's use of personal protective equipment and adhering to hand hygiene protocols before and after resident contact, and that the physical contact is limited in duration.

(5) The Department shall have discretion to review and require modifications to a facility's personal caregiving visitation and compassionate caregiving visitation policies and procedures to ensure conformity with paragraphs (3) and (4) of this subdivision and any applicable visitation guidelines issued by the Department or the Centers for Medicare and Medicaid Services.

A new Section 485.18 of 18 NYCRR, titled Personal and Compassionate Caregiving Visitation, is added to read as follows:

(a) This section shall apply to all adult care facilities, including every adult care facility regulated pursuant to Parts 487, 488 and 490 of this Title and Part 1001 of Title 10 of the NYCRR.

(b) Subject to the resident's right to deny or withdraw consent at any time, all adult care facilities must provide immediate access to any resident of visitors of their choice, including but not limited to immediate family or other relatives of the resident and any others who are visiting with the consent of the resident. Provided, however, that the facility may establish policies and

procedures to establish reasonable restrictions on such visitation, including but not limited to: setting forth visitation hours; denying access to any visitor suffering from a communicable disease; terminating visitation with any visitor causing a threat to the health or safety of any resident; and setting a cap on the number of visitors allowed in the facility at any one time. Any such restrictions or limitations on visitation shall be communicated in writing to residents.

(c) Personal caregiving visitors.

(1) During a public health emergency declared under section twenty-four or section twenty-eight of the executive law, the facility must continue to allow residents to access their designated personal caregiving visitors, as defined in subdivision (1) of section 2801-h of the Public Health Law, notwithstanding any restrictions or prohibitions relating to residential health care facility visitation resulting from the declared public health emergency, subject to the following restrictions:

(i) If a facility has reasonable cause to believe that a resident will not benefit from accessing their designated personal caregiving visitors, and such reasoning has been documented in the resident's case management record, a facility may require a health or mental health professional duly licensed or certified in New York State under the Education Law, and who is not associated with the facility, including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist, to provide a written statement that the personal caregiving will substantially benefit the resident's quality of life, including a statement from such medical provider that the personal caregiving visitation will enhance the resident's mental, physical, or psychosocial well-being, or any additional criteria evidencing a benefit to quality of life

as determined by the Department. Such written statements shall be maintained in the resident's case management record.

(ii) Notwithstanding any provision of this paragraph, a facility may temporarily suspend or limit personal caregiving visitors to protect the health, safety and welfare of residents, if: the declared public health emergency is related to a communicable disease and the Department determines that local infection rates are at a level that presents a serious risk of transmission of such communicable disease within local facilities; the facility is experiencing temporary inadequate staffing and has reported such staffing shortage to the Department of Health any other State or federal agencies as required by law, regulation, or other directive; or an acute emergency situation exists at the facility, including loss of heat, loss of elevator service, or other temporary loss of an essential service. Provided, however, that in the event a facility suspends or limits personal caregiving visitation pursuant to this subparagraph, the facility shall notify residents, all designated personal caregiving visitors, and the applicable Department regional office of such suspension or limitation and the duration thereof within twenty-four hours of implementing the visitation suspension or limitation. Additionally, for each day of the suspension or limitation, the facility shall document the specific reason for the suspension or limitation in their administrative records. The facility shall further provide a means for all residents to engage in remote visitation with their designated personal caregiving visitor(s), including but not limited to phone or video calls, until such time that the suspension or limitation on personal caregiving visitation has ended.

(iii) Notwithstanding any provision of this paragraph, a facility may also prohibit a personal caregiving visitor from entering if the facility has reasonable cause to believe

that permitting the personal caregiving visitor to meet with the resident is likely to pose a threat of serious physical, mental, or psychological harm to such resident. In the event the facility determines that denying such personal caregiving visitor access to the resident is in the resident's best interests pursuant to this subparagraph, the facility must document the date of and reason for visitation refusal in the resident's case management record, and on the same date of the refusal the facility shall communicate its decision to the resident and their designated representative. Further, a facility may refuse access to or remove from the premises any personal caregiving visitor who is causing or reasonably likely to cause physical injury to any facility resident or personnel.

(2) The facility shall develop written policies and procedures to ask residents, or their designated representatives in the event the resident lacks capacity, at time of admission or readmission, or for existing residents within fourteen days of the effective date of this paragraph, which individuals the resident elects to serve as their personal caregiving visitor during declared local or state health emergencies. A resident shall be entitled to designate at least two personal caregiving visitors at one time.

(3) The facility shall maintain a written record of the resident's designated personal caregiving visitors in the resident's case management record, and shall document when personal caregiving and compassionate caregiving is provided in the case management record.

(4) As part of its ongoing review of a resident's case management needs, the facility shall regularly inquire of all current residents, or their designated representative if the resident lacks capacity, whether the facility's current record of designated personal caregiving visitors remains accurate, or whether the resident, or their designated representative if the resident lacks capacity, wishes to make any changes to their personal caregiving visitor designations. The facility shall

update the resident's case management record with the date the facility sought updates from the resident and indicate any changes to the resident's personal caregiving visitor designations therein. Such inquiries shall be made no less frequently than every six months and upon a change in the resident's condition; upon review of a facility's visitation policies and procedures, the Department may also require the facility inquire of any resident whether the facility's current record of designated personal caregiving visitors remains accurate.

(5) The facility shall require all personal caregiving visitors to adhere to infection control measures established by the facility and consistent with any guidelines from the Department, or in the absence of applicable Department guidance, consistent with long term care facility infection control guidelines from the U.S. Centers for Disease Control and Prevention. Such infection control measures may include, but need not be limited to:

- (i) testing all personal caregiving visitors for any communicable disease that is the subject of the declared public health emergency, which may include rapid on-site testing or requiring the visitor to present a negative test result from no more than seven days prior to the visit;
- (ii) checking the personal caregiving visitor's body temperature upon entry to the facility, and denying access to any visitor with a temperature above 100 degrees Fahrenheit;
- (iii) conducting health screenings of all personal caregiving visitors upon entry to the facility, including screenings for signs and symptoms of any communicable disease that is the subject of the declared public health emergency or any other communicable disease which is prevalent in the facility's geographic area, and recording the results of such screenings;

(iv) requiring all personal caregiving visitors to don all necessary personal protective equipment appropriately, and providing such personal protective equipment to all personal caregiving visitors; and

(v) enforcing social distancing between persons during visitation, including personal caregiving visitation, except as necessary to provide personal caregiving by the personal caregiving visitor for the resident.

(6) The facility shall establish policies and procedures regarding the frequency and duration of personal caregiving visits and limitations on the total number of personal caregiving visitors allowed to visit the resident and the facility at any one time. Such policies shall not be construed to limit access by other visitors that would otherwise be permitted under state or federal law or regulation. The facility shall ensure its policies and procedures respect resident privacy and take into account visitation protocols in the event a resident occupies a shared room. In establishing frequency and duration limits, the facility policy shall ensure that residents are able to receive their designated personal caregiving visitors for the resident's desired frequency and length of time, and any restrictions on that desired frequency and duration must be:

(i) attributable to the resident's clinical or personal care needs;

(ii) necessary to ensure the resident's roommate has adequate privacy and space to receive their own designated personal caregiving visitors; or

(iii) because the desired visitation frequency or duration would impair the effective implementation of applicable infection control measures, including social distancing of at least six feet between the visitors and others in the facility, having sufficient staff to effectively screen all personal caregiving visitors and monitor visits to ensure infection

control protocols are being followed throughout, and having a sufficient supply of necessary personal protective equipment for all personal caregiving visitors.

(d) Compassionate caregiving.

(1) In the event a resident experiences a long-term or acute physical, mental, or psychosocial health condition for which, in the opinion of the resident, their representative, or a health care professional (including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist), a compassionate caregiving visitor would improve the resident's quality of life, the resident or their representative shall designate at least two compassionate caregiving visitors at one time, and the facility shall record such designation in the resident's case management record. A resident's designated personal caregiving visitors may also provide compassionate caregiving.

(2) Situations in which a resident is eligible for a compassionate caregiving visitor include but are not limited to the following:

(i) end of life;

(ii) the resident, who was living with their family before recently being admitted to an adult care facility, is struggling with the change in environment and lack of physical family support;

(iii) the resident is grieving after a friend or family member recently passed away;

(iv) the resident needs cueing and encouragement with eating or drinking, and such cueing was previously provided by family and/or caregiver(s), and the resident is now experiencing weight loss or dehydration; and

(v) the resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

(3) Compassionate caregiving visitation shall be permitted at all times, regardless of any general visitation restrictions or personal caregiving visitation restrictions in effect in the facility.

Provided, however, that the facility shall require compassionate caregiving visitors to be screened for communicable diseases prior to entering the facility and visits must be conducted using appropriate social distancing between the resident and visitor if applicable based on guidance from the Department or the U.S. Centers for Disease Control and Prevention; if, however, personal contact would be beneficial for the resident's well-being, the facility shall establish policies and procedures to ensure such physical contact follows appropriate infection prevention guidelines, including the visitor's use of personal protective equipment and adhering to hand hygiene protocols before and after resident contact, and that physical contact is limited in duration.

(e) The Department shall have discretion to review and require modifications to a facility's personal caregiving visitation and compassionate caregiving visitation policies and procedures to ensure conformity with subdivisions (c) and (d) of this section and any applicable visitation guidelines issued by the Department or the Centers for Medicare and Medicaid Services.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under sections 2801-h and 2803 of the Public Health Law (PHL) and sections 461, 461-e, and 461-u of the Social Services Law (SSL).

PHL § 2801-h and SSL § 461-u specifically authorize the New York State Department of Health (Department) to promulgate regulations relating to personal caregiving visitors and compassionate caregiving visitors in nursing homes and adult care facilities (ACFs).

SSL § 461 requires the Department to promulgate regulations establishing general standards applicable to ACFs. SSL § 461-e authorizes the Department to promulgate regulations to require ACFs to maintain certain records with respect to the facilities' residents and the operation of the facility.

Legislative Objectives:

The legislative objective of PHL § 2801-h and SSL § 461-u is to ensure residents' rights to visitation are respected by allowing residents of nursing homes and ACFs to have access to their designated personal caregiving visitors and compassionate caregiving visitors during a declared State or local public health emergency. Further, the legislative objective of SSL § 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

These regulations are necessary pursuant to the statutory directives in PHL § 2801-h and SSL § 461-u, which direct the Commissioner of Health to promulgate regulations governing personal caregiving visitation and compassionate caregiving visitation in nursing homes and ACFs during a declared State or local public health emergency.

These regulations are beneficial insofar as they will provide clarity to facility operators and administrators, residents, and their family members regarding whether certain visitors are permitted to access a nursing home or ACF during a declared local or State health emergency, notwithstanding any visitation restrictions currently in effect within the facility.

COSTS:

Costs to Regulated Parties:

There are no anticipated costs to regulated parties. The regulations require facilities to establish policies and procedures regarding personal caregiving visitation and compassionate caregiving visitation that comply with these regulations and the governing statutes, PHL § 2801-h and SSL § 461-u. Insofar as facilities are obligated to establish policies and procedures for other facility operations, this responsibility should be managed using existing resources.

Costs to Local and State Governments:

There are no anticipated costs to any regulated parties, including nursing homes and ACFs operated by a local or State government.

Costs to the Department of Health:

This regulation will not result in any additional operational costs to the Department of Health. Any increased surveillance and enforcement activities relating to this regulation will be handled with existing resources.

Paperwork:

This regulation requires facilities to develop and maintain visitation policies relating to personal caregiving visitation and compassionate caregiving visitation. However, this requirement is expected to be of minimal burden to facilities, which are currently obligated to

develop and maintain other policies and procedures relating to facility operations, and the requirements for such visitation policies and procedures are thoroughly detailed in these regulations and the governing statutes, PHL § 2801-h and SSL § 461-u.

Local Government Mandates:

Nursing homes and ACFs operated by local governments will be affected and will be subject to the same requirements as any other nursing home licensed under PHL Article 28 or ACF licensed under SSL Article 7, Title 2. Currently, there are 21 nursing homes operated by local governments (counties and municipalities) and 6 nursing homes operated by the State. Additionally, there are currently two adult care facilities operated by county governments.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

There are no viable alternatives. The alternative of not issuing these regulations was rejected given the statutory directive to promulgate these regulations, pursuant to PHL § 2801-h and SSL § 461-u.

Federal Standards:

The federal Centers for Medicare & Medicaid Services (CMS) has issued visitation guidance applicable to Medicaid- and Medicare-enrolled nursing homes, titled “Nursing Home Visitation - COVID-19 (REVISED)” (QSO-20-39-NH), revised April 27, 2021. This visitation guidance discusses general visitation in nursing homes including compassionate care visitation. The Department has reviewed this CMS guidance and finds that the proposed regulations are consistent with the CMS guidance insofar as they both relate to compassionate care visitation in nursing homes. No other federal standards apply.

Compliance Schedule:

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

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

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a nursing home or adult care facility (ACF). Currently, there are 21 nursing homes operated by local governments (counties and municipalities) and 6 nursing homes operated by the State. Additionally, there are currently two ACFs operated by county governments (Chenango and Warren Counties). Additionally, to date, 79 nursing homes in New York qualify as small businesses given that they have 100 or fewer employees. There are also 483 ACFs that have 100 or fewer employees and therefore qualify as small businesses.

Compliance Requirements:

This regulation requires nursing homes and ACFs to develop policies and procedures relating to compassionate caregiver visitation and personal caregiver visitation that are consistent with these regulations and the governing statutes, Public Health Law (PHL) § 2801-h and Social Services Law (SSL) § 461-u.

Professional Services:

No professional services are required by this regulation.

Compliance Costs:

There are no costs associated with this regulation.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is consistent with resident right standards and current CMS and Department visitation guidance. Therefore, the Department expects no adverse impact to facilities given that nursing homes and ACFs are currently required to comply with similar standards and are expected to have already developed policies and procedures in accordance with those existing standards. In any event, the Department is required by PHL § 2801-h and SSL § 461-u to promulgate these regulations; as such, any adverse impact on covered facilities cannot be avoided due to the statutory mandate.

Small Business and Local Government Participation:

Facilities were put on notice of the forthcoming promulgation of these regulations upon the enactment of PHL § 2801-h and SSL § 461-u, as enacted by Chapter 108 of the Laws of 2021. Additionally, the Department plans to advise all facilities, including those operated by small businesses and local governments, of the publication of these regulations and the opportunity to submit any questions relating to such regulations to the Department.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

This regulation imposes no additional paperwork.

Compliance Costs:

There are no costs associated with this regulation.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is consistent with resident right standards and current CMS and Department visitation guidance. Therefore, the Department expects no adverse impact to facilities given that nursing homes and ACFs are currently required to comply with similar standards and are expected to have already developed policies and procedures in accordance with those existing standards. In any event, the Department is required by PHL § 2801-h and SSL § 461-u to promulgate these regulations; as such, any adverse impact on covered facilities cannot be avoided due to the statutory mandate.

Rural Area Participation:

Facilities were put on notice of the forthcoming promulgation of these regulations upon the enactment of PHL § 2801-h and SSL § 461-u, as enacted by Chapter 108 of the Laws of 2021. Additionally, the Department plans to advise all facilities, including those located in rural areas, of the publication of these regulations and the opportunity to submit any questions relating to such regulations to the Department.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

Chapter 108 of the Laws of 2021, which amended Public Health Law (PHL) § 2801-h and Social Services Law (SSL) § 461-u, requires nursing homes and adult care facilities (ACFs) to permit personal and compassionate caregiving visitations. The new law became effective immediately and required that regulations be promulgated within forty-five days after enactment. Thus, the law authorized the promulgation of emergency regulations.

The purpose of the new law is to benefit the health and general well-being of nursing home and ACF residents. This emergency rulemaking is necessary to satisfy the statutory requirement, provide clarity to facility operators and administrators as well as residents and their families regarding the process for implementing personal caregiving requirements under the newly enacted law.

Furthermore, throughout the COVID-19 pandemic, visitation guidance for long-term care facilities has been issued by several authorities, including the Department and federal Centers for Medicare & Medicaid Services (CMS). Facility outreach to the Department and surveillance activities show that many nursing homes and adult care facilities have not appropriately adhered to these guidance documents or have implemented their own form of personal caregiving visitation policies. This emergency rulemaking will assist facilities in understanding their legal obligations with respect to visitation, for the purposes of preparing the facility's visitation policies and procedures in the event of a declared State or local public health emergency, by providing additional information as to who may access a facility during periods of visitation closure, and what, if any, restrictions can be implemented on personal caregiving and compassionate caregiving visitation.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon filing with the Department of State, to read as follows:

Part 2 is amended to add a new section 2.61, as follows:

2.61. Prevention of COVID-19 transmission by covered entities.

(a) Definitions.

- (1) “Covered entities” for the purposes of this section, shall include:
 - (i) any facility or institution included in the definition of “hospital” in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;
 - (ii) any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies;
 - (iii) hospices as defined in section 4002 of the Public Health Law; and
 - (iv) adult care facility under the Department’s regulatory authority, as set forth in Article 7 of the Social Services Law.

(2) “Personnel,” for the purposes of this section, shall mean all persons employed or affiliated with a covered entity, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.

(3) “Fully vaccinated,” 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 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; or

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

(c) Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, absent receipt of an exemption as allowed below. Covered entities shall require all personnel to receive at least their first dose before engaging in activities covered under paragraph (2) of subdivision (a) of this section. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in subdivision (d) of this section.

(d) Exemptions. Personnel shall be exempt from the COVID-19 vaccination requirements set forth in subdivision (c) of this section as follows:

(1) Medical exemption. If any licensed physician, physician assistant, or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of member of a covered entity's personnel, based upon a pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be inapplicable only until such immunization is found no longer to be detrimental to such personnel member's health. The nature and duration of the medical exemption must be stated in the personnel employment medical record, or other appropriate record, and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services), and any reasonable accommodation may be granted and must likewise be documented in such record. Covered entities shall document medical exemptions in personnel records or other appropriate records in accordance with applicable privacy laws by: (i) September 27, 2021 for general hospitals and nursing homes; and (ii) October 7, 2021 for all other covered entities. For all covered

entities, documentation must occur continuously, as needed, following the initial dates for compliance specified herein, including documentation of any reasonable accommodation therefor.

(e) Upon the request of the Department, covered entities must report and submit documentation, in a manner and format determined by the Department, for the following:

- (1) the number and percentage of personnel that have been vaccinated against COVID-19;
- (2) the number and percentage of personnel for which medical exemptions have been granted;
- (3) the total number of covered personnel.

(f) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of this section and submit such documents to the Department upon request.

(g) The Department may require all personnel, whether vaccinated or unvaccinated, to wear an appropriate face covering for the setting in which such personnel are working in a covered entity. Covered entities shall supply face coverings required by this section at no cost to personnel.

Subparagraph (vi) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:

(vi) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 is added to read as follows:

(5) collects documentation of COVID-19 or documentation of a valid medical exemption to such vaccination, for all personnel pursuant to section 2.61 of this title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 751.6 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (6) of subdivision (c) of Section 763.13 is added to read as follows:

(6) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making

such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 766.11 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (8) of subdivision (d) of Section 794.3 is added to read as follows:

(8) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (q) of Section 1001.11 is added to read as follows:

(5) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is added to read as follows:

(18) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is added to read as follows:

(14) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is added to read as follows:

(15) Operator shall collect documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 225(5), 2800, 2803(2), 3612 and 4010 (4). PHL 225(5) authorizes the Public Health and Health Planning Council (PHHPC) to issue regulations in the State Sanitary Code pertaining to any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises.

PHL Article 28 (Hospitals), Section 2800 specifies that “hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.”

PHL Section 2803(2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

PHL Section 3612 authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Section 4010 (4) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

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

Legislative Objectives:

The legislative objective of PHL Section 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional

curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

The vaccine mandate for health care workers, which required general hospital and nursing home personnel to receive their first dose of COVID-19 vaccine by September 27, 2021, and required all other covered entities to receive their first dose of COVID-19 vaccine by October 7, 2021, has greatly increased the percentage of health care workers who are vaccinated against COVID-19. COVID cases, hospitalizations, and deaths are decreasing in New York State, and the continuation of these regulations will help ensure that the epidemiology curve continues downward in furtherance of the New York State Department of Health's mission to reduce morbidity and mortality. These regulations are helping New York State reduce sickness and death from COVID-19.

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen more than 10-fold, and over 99 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 10 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and

congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

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

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, as well as any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

Cost to State and Local Government:

The State operates several healthcare facilities subject to this regulation. Most county health departments are licensed under Article 28 or Article 36 of the PHL and are therefore also subject to regulation. Similarly, certain counties and the City of New York operate facilities licensed under Article 28. These State and local public facilities would be required to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. They must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations.

Although the costs to the State or local governments cannot be determined with precision, the Department does not expect these costs to be significant. State facilities should already be ensuring COVID-19 vaccination among their personnel, subject to State directives. Further, these entities are expected to realize savings as a result of the reduction in COVID-19 in personnel and the attendant loss of productivity and available staff.

Cost to the Department of Health:

There are no additional costs to the State or local government, except as noted above. Existing staff will be utilized to conduct surveillance of regulated parties and to monitor compliance with these provisions.

Local Government Mandates:

Covered entities operated by local governments will be subject to the same requirements as any other covered entity subject to this regulation.

Paperwork:

This measure will require covered entities to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Duplication:

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

Alternative Approaches:

One alternative would be to require covered entities to test all personnel in their facility before each shift worked. This approach is limited in its effect because testing only provides a

person's status at the time of the test and testing every person in a healthcare facility every day is impractical and would place an unreasonable resource and financial burden on covered entities if PCR tests couldn't be rapidly turned around before the commencement of the shift. Antigen tests have not proven as reliable for asymptomatic diagnosis to date.

Another alternative to requiring covered entities to mandate vaccination would be to require covered entities to mandate all personnel to wear a fit-tested N95 face covering at all times when in the facility, in order to prevent transmission of the virus. However, acceptable face coverings, which are not fit-tested N95 face coverings have been a long-standing requirement in these covered entities, and, while helpful to reduce transmission it does not prevent transmission and; therefore, masking in addition to vaccination will help reduce the numbers of infections in these settings even further.

Federal Requirements:

There are no minimum standards established by the federal government for the same or similar subject areas.

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 rule making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

Contact Person:

Ms. Katherine E. Ceroalo
NYS Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 –FAX
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a covered entity as defined in the emergency regulation. Currently, 5 general hospitals, 79 nursing homes, 75 certified home health agencies (CHHAs), 20 hospices and 1,055 licensed home care service agencies (LHCSAs), and 483 adult care facilities (ACFs) are small businesses (defined as 100 employees or less), independently owned and operated affected by this rule. Local governments operate 19 hospitals, 137 diagnostic and treatment facilities, 21 nursing homes, 12 CHHAs, at least 48 LHCSAs, 1 hospice, and 2 ACFs.

Compliance Requirements:

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

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 Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy

and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

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 Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department’s understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

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 to provide comments during the notice and comment period.

JOB IMPACT STATEMENT

Nature of Impact:

Covered entities may terminate personnel who are not fully vaccinated and do not have a valid medical exemption and are unable to otherwise ensure individuals are not engaged in patient/resident care or expose other covered personnel.

Categories and numbers affected:

This rule may impact any individual who falls within the definition of “personnel” who is not fully vaccinated against COVID-19 and does not have a valid medical exemption on file with the covered entity for which they work or are affiliated.

Regions of adverse impact:

The rule would apply uniformly throughout the State and the Department does not anticipate that there will be any regions of the state where the rule would have a disproportionate adverse impact on jobs or employment.

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 Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department’s understanding that many facilities across the State

have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

EMERGENCY JUSTIFICATION

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen 10-fold, and over 99 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 11 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as

well as exemption requests granted are required to be provided to the Department immediately upon request.

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

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 and/or those who have serious underlying medical conditions.

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 Delta variant. Cases in New York are over 10-fold their levels in late June 2021, and greater than 99 percent of the sequenced recent positives in New York State were the Delta variant.

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

These regulations also permit the Department to require reporting of testing and positive reports among school students, teaching staff, and any other employees or volunteers. It is important for the Department to monitor COVID-19 testing and positive reports in schools, given

the number of students that are currently unvaccinated. Children ages 5 through 11 years old were only recently authorized by the U.S. Food and Drug Administration (FDA) to receive COVID-19 vaccinations. For those in the 12-17 age group, the CDC data estimates that 70.2% of this population has been vaccinated in New York State, with 61.6% in this age group completing a COVID-19 vaccine series. By carrying forward the reporting requirements that were in place for the 2020-2021 school year, the Department will be able to track COVID-19 incidence and prevalence in school settings for the upcoming school year. This will allow the Department to work with school districts and local health departments to implement targeted prevention strategies, where needed to limit the spread of the virus.

COSTS:

Costs to Regulated Parties:

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

Expanded Testing which is free testing in K-12 schools and other congregate settings which is funded by the Department of Health and Human Services (HHS) and Department of Defense (DoD).

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

Costs to Local and State Governments:

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

Paperwork:

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

Local Government Mandates:

These regulations impose an obligation on schools and school districts to report COVID-19 testing and positive report data for students, teaching staff, and any other employees or

volunteers. Local government may also be impacted if subject to a Commissioner's testing determination.

Duplication:

There is no duplication of federal law.

Alternatives:

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

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

Federal Standards:

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

Compliance Schedule:

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

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

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

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

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

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

Compliance Costs:

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

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.

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 Delta variant. Cases in New York are over 10-fold their levels in late June 2021, and greater than 99 percent of the sequenced recent positives in New York State were the Delta variant.

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

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

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

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

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

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

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

* * *

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

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

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

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

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

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

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

- (1) Verify the existence of a disease or condition;
- (2) Ascertain the source of the disease-causing agent or condition;
- (3) Identify unreported cases;
- (4) Locate and evaluate contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;
- (5) Collect and submit, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the source of disease, or to assist with diagnosis; and furnish or cause to be furnished with such specimens pertinent data on forms prescribed by the State Commissioner of Health, including but not limited to the history of cases, physical findings and details of the epidemiological investigation;
- (6) Examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;

- (7) Instruct a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and
- (8) Take any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

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

(c) Investigation Updates and Reports.

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

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

(1) The State Commissioner of Health may elect to lead investigation and response activities

where:

(i) Residents of multiple jurisdictions within the State are affected by an outbreak of a reportable disease, condition, or unusual disease; or

(ii) Residents in a jurisdiction or jurisdictions within the State and in another state or states are affected by an outbreak of a reportable disease, condition, or unusual disease; or

(iii) An outbreak of an unusual disease or a reportable disease or condition involves a single jurisdiction with the high potential for statewide impact.

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

New section 2.13 is added to read as follows:

2.13 Isolation and Quarantine Procedures

(a) Duty to issue isolation and quarantine orders

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

(b) Any isolation or quarantine order shall specify:

- (1) The basis for the order;
- (2) The location where the person shall remain in isolation or quarantine, unless travel is authorized by the State or local health authority, such as for medical care;
- (3) The duration of the order;
- (4) Instructions for traveling to the isolation or quarantine location, if appropriate;
- (5) Instructions for maintaining appropriate distance and taking such other actions as to prevent transmission to other persons living or working at the isolation or quarantine location, consistent with any direction that the State Commissioner of Health may issue;
- (6) If the location of isolation or quarantine is not in a general hospital, instructions for contacting the State and/or local health authority to report the subject person's health condition, consistent with any direction that the State Commissioner of Health may issue;
- (7) If the location of isolation or quarantine is a multiple dwelling structure, that the person shall remain in their specific dwelling and in no instance come within 6 feet of any other person, and consistent with any direction that the State Commissioner of Health may issue;
- (8) If the location of isolation or quarantine is a detached structure, that the person may go outside while remaining on the premise, but shall not leave the premise or come within 6 feet of any person who does not reside at the premise, or such other distance as may be appropriate for the specific disease, and consistent with any direction that the State Commissioner of Health may issue;
- (9) Such other limitations on interactions with other persons as are appropriate, consistent with any direction that the State Commissioner of Health may issue;

- (10) Notification of the right to request that the public health authority issuing the order inform a reasonable number of persons of the conditions of the isolation or quarantine order;
- (11) A statement that the person has the right to seek judicial review of the order;
- (12) A statement that the person has the right to legal counsel, and that if the person is unable to afford legal counsel, counsel will be appointed upon request.

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

- (1) monitor such person to ensure compliance with the order and determine whether such person requires a higher level of medical care;
- (2) whenever appropriate, coordinate with local law enforcement to ensure that such person comply with the order; and
- (3) the extent such items and services are not available to such person, provide or arrange for the provision of appropriate supports, supplies and services, including, but not limited to: food, laundry, medical care, and medications.

(d) If the location of an isolation or quarantine order is owned by a landlord, hotel, motel or other person or entity, no such landlord or person associated with such hotel, motel or other person or entity shall enter the isolation or quarantine location without permission of the

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

(e) No article that is likely to be contaminated with infective material may be removed from a premise where a person is isolated or quarantined unless the local health authority determines that such article has been properly disinfected or protected from spreading infection, or unless the quarantine period expires and there is no risk of contamination. Such determinations shall be made pursuant to any direction that the State Commissioner of Health may issue.

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

(g) Duty of attending physician

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

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

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

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

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

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

* * *

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

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

(12) whenever the commissioner determines that there exists an outbreak of a highly contagious communicable disease pursuant to Part 2 of this Title or other public health emergency, such

syndromic 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 PPHPC, with the approval of the Commissioner, to adopt regulations concerning the operation of facilities licensed pursuant to Article 28 of the PHL, including general hospitals.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that 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, over a year and half 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 Delta variant. Since early July, cases have risen more than 10-fold, and over 99 percent of the sequenced recent positives in New York State were the Delta 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 impose any substantial additional costs beyond those costs that laboratories would incur in the absence of these regulations.

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

Paperwork:

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

Local Government Mandates:

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

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

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

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

The following 44 counties have a population of less than 200,000 based upon 2020

United States Census data:

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

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

Census estimated county populations for 2010:

Albany County
Dutchess County
Erie County

Monroe County
Niagara County
Oneida County
Onondaga County

Orange County
Saratoga County
Suffolk County

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

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

Pursuant to the authority vested in the 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 publication of a Notice of Adoption in the New York State Register, 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) Penalties 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 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, over a year and half after the first cases were identified in the United States, Centers for Disease Control and Prevention (CDC) and the Department have identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Cases in New York are over 10-fold their levels in late June 2021, and greater than 99 percent of the sequenced recent positives in New York State were the Delta variant.

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

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

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

SUMMARY OF EXPRESS TERMS

These regulations are intended to implement section 2801-h of the Public Health Law (PHL) and section 461-u of the Social Services Law (SSL), as enacted by Chapter 108 of the Laws of 2021. These statutory amendments required the Commissioner of Health to promulgate regulations governing personal caregiving visitors in all licensed nursing homes and adult care facilities. According to the statute, a “personal caregiving visitor” means a family member, close friend, or legal guardian of a resident designated by such resident, or such resident’s lawful representative, to assist with personal caregiving or compassionate caregiving for the resident. Personal caregiving is defined as care and support of a resident to benefit such resident’s mental, physical, or social well-being, and compassionate caregiving is defined as personal caregiving provided in anticipation of the end of the resident’s life or in the instance of significant mental, physical or social decline or crisis (*see* PHL § 2801-h[1][a-c], SSL § 461-u[1][a-c]).

In accordance with the statutory directive, the new regulatory sections amend 10 NYCRR 415.3(d) to add new paragraphs (3), (4), and (5) concerning, respectively, personal caregiving visitation, additional provisions relating to compassionate caregiving, and authority for the Department of Health to review a nursing home’s personal caregiving visitation policies and procedures. Likewise, for adult care facilities, the regulation adds a new section 485.18 of 18 NYCRR to address general visitation rights in an adult care facility (section 485.18[b]), personal caregiving visitation (section 485.18[c]), additional provisions relating to compassionate caregiving (section 485.18[d]), and authority for the Department of Health to review an adult care facility’s personal caregiving visitation policies and procedures (section 485.18[e]).

More specifically, the regulatory amendments relating to personal caregiving visitation, as contained in the new 10 NYCRR 415.3(d)(3) and 18 NYCRR 485.18(c), provide that such

visitation shall be permitted in a nursing home and adult care facility during a public health emergency declared under section twenty-four or section twenty-eight of the Executive Law, notwithstanding general visitation restrictions in the facility, and subject to certain limitations, including the need to limit or temporarily suspend personal caregiving visitation due to an increase in local infection rates, temporary inadequate staff capacity, an acute emergency situation such as loss of an essential service, or because the personal caregiving visitor poses a threat to the safety and well-being of the resident or any resident or personnel in the facility. The regulations governing personal caregiving visitation further: (i) set forth procedures for residents or their lawful representatives to designate and change their designation of personal caregiving visitors; (ii) provide that a resident shall be entitled to designate at least two personal caregiving visitors; (iii) require that all personal caregiving visitors follow infection prevention safety protocols required for nursing home and adult care facility staff, such as communicable disease testing, health screenings, and donning appropriate personal protective equipment; and (iv) set forth standards for a facility to determine the maximum frequency and duration of personal caregiving visits and the total number of personal caregiving visitors allowed to visit the facility at any one time.

The new 10 NYCRR 415.3(d)(4) and 18 NYCRR 485.18(d) establish additional provisions for compassionate caregiving provided by personal caregiving visitors. These sections set forth the situations in which a resident is eligible for a compassionate caregiving visitor and the requirements for screening compassionate caregiving visitors prior to their entry into the facility.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2801-h and 2803 of the Public Health Law and sections 461, 461-e, and 461-u of the Social Services Law, Section 415.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended and a new Section 485.18 of Title 18 of the NYCRR is hereby added, to be effective publication of a Notice of Adoption in the New York State Register, to read as follows:

Subparagraph (iv) of paragraph (2) of subdivision (d) of Section 415.3 of 10 NYCRR is amended to read as follows:

(iv) provide immediate access to any resident by the following:

* * *

(f) immediate family or other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time; [and]

(g) personal caregiving visitors, as defined in subdivision (1) of section 2801-h of the Public Health Law and pursuant to criteria specified in paragraph (3) of this subdivision, including those providing compassionate caregiving, as defined in subdivision (1) of section 2801-h of the Public Health Law and pursuant to criteria specified in paragraph (4) of this subdivision; and

[(g)] (h) others who are visiting with the consent of the resident, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time;

Subdivision (d) of Section 415.3 of 10 NYCRR is amended to add new paragraphs (3), (4), and (5) to read as follows:

(3) Personal caregiving visitors.

(i) During a public health emergency declared under section twenty-four or section twenty-eight of the executive law, the facility must continue to allow residents to access their designated personal caregiving visitors, notwithstanding any restrictions or prohibitions relating to residential health care visitation resulting from the declared public health emergency, subject to the following restrictions:

(a) If a facility has reasonable cause to believe that a resident will not benefit from accessing their designated personal caregiving visitors, and such reasoning has been documented in the resident's individualized comprehensive plan of care, a facility may require a health or mental health professional duly licensed or certified in New York State under the Education Law, and who need not be associated with the nursing home, including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist, to provide a written statement that the personal caregiving will substantially benefit the resident's quality of life, including a statement from such medical provider that the personal caregiving visitation will enhance the resident's mental, physical, or psychosocial well-being, or any additional criteria evidencing a benefit to quality of life as determined by the Department. Such written statements from the medical provider shall be maintained in the resident's individualized comprehensive plan of care.

(b) Notwithstanding any provision of this subparagraph (i), a facility may temporarily suspend or limit personal caregiving visitors to protect the health, safety and welfare of residents if: the declared public health emergency is related to a communicable disease and the Department determines that local infection rates are at a level that presents a serious risk of transmission of such communicable disease within local facilities; the

facility is experiencing temporary inadequate staffing and has reported such staffing shortage to the Department of Health and any other State or federal agencies as required by law, regulation, or other directive; or an acute emergency situation exists at the facility, including loss of heat, loss of elevator service, or other temporary loss of an essential service. Provided, however, that in the event a facility suspends or limits personal caregiving visitation pursuant to this clause, the facility shall notify residents, all designated personal caregiving visitors, and the applicable Department regional office of such suspension or limitation and the duration thereof within twenty-four hours of implementing the visitation suspension or limitation. Additionally, for each day of the suspension or limitation, the facility shall document the specific reason for the suspension or limitation in their administrative records. The facility shall further provide a means for all residents to engage in remote visitation with their designated personal caregiving visitor(s), including but not limited to phone or video calls, until such time that the suspension or limitation on personal caregiving visitation has ended.

(c) Notwithstanding any provision of this subparagraph (i), a facility may prohibit a personal caregiving visitor from entering if the facility has reasonable cause to believe that permitting the personal caregiving visitor to meet with the resident is likely to pose a threat of serious physical, mental, or psychological harm to such resident. In the event the facility determines that denying such personal caregiving visitor access to the resident is in the resident's best interests pursuant to this subparagraph, the facility must document the date of and reason for visitation refusal in the resident's individualized comprehensive plan of care, and on the same date of the refusal the facility shall communicate its decision to the resident and their designated representative. Further, a

facility may refuse access to or remove from the premises any personal caregiving visitor who is causing or reasonably likely to cause physical injury to any facility resident or personnel.

(ii) The facility shall develop written policies and procedures to ask residents, or their designated representatives in the event the resident lacks capacity, at time of admission or readmission, or for existing residents within fourteen days of the effective date of this paragraph, which individuals the resident elects to serve as their personal caregiving visitor during declared public health emergencies. A resident shall be entitled to designate at least two personal caregiving visitors at one time.

(iii) The facility shall maintain a written record of the resident's designated personal caregiving visitors in the resident's individualized comprehensive plan of care, and shall document when personal caregiving and compassionate caregiving is provided in the resident's individualized comprehensive plan of care.

(iv) As part of its ongoing review of a resident's comprehensive plan of care, the facility shall regularly inquire of all current residents, or their designated representative if the resident lacks capacity, whether the facility's current record of designated personal caregiving visitors remains accurate, or whether the resident, or their designated representative if the resident lacks capacity, wishes to make any changes to their personal caregiving visitor designations. The facility shall update the resident's individualized comprehensive plan of care with the date the facility sought updates from the resident and indicate any changes to the resident's personal caregiving visitor designations therein. Such inquiries shall be made no less frequently than quarterly and upon a change in the resident's condition; upon review of a facility's visitation policies and procedures,

the Department may also require the facility inquire of any resident whether the facility's current record of designated personal caregiving visitors remains accurate.

(v) The facility shall require all personal caregiving visitors to adhere to infection control measures established by the facility and consistent with any guidelines from the Department, or in the absence of applicable Department guidance, consistent with long term care facility infection control guidelines from the U.S. Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services. Such infection control measures may include, but need not be limited to:

(a) testing all personal caregiving visitors for any communicable disease that is the subject of the declared public health emergency, which may include rapid on-site testing or requiring the visitor to present a negative test result dated no more than seven days prior to the visit;

(b) checking the personal caregiving visitor's body temperature upon entry to the facility, and denying access to any visitor with a temperature above 100 degrees Fahrenheit;

(c) conducting health screenings of all personal caregiving visitors upon entry to the facility, including screenings for signs and symptoms of any communicable disease that is the subject of the declared public health emergency or any other communicable disease which is prevalent in the facility's geographic area, and recording the results of such screenings;

(d) requiring all personal caregiving visitors to don all necessary personal protective equipment appropriately, and providing such personal protective equipment to all personal caregiving visitors; and

(e) enforcing social distancing between persons during visitation, including personal caregiving visitation, except as necessary to provide personal caregiving by the personal caregiving visitor for the resident.

(vi) The facility shall establish policies and procedures regarding the frequency and duration of personal caregiving visits and limitations on the total number of personal caregiving visitors allowed to visit the resident and the facility at any one time. Such policies shall not be construed to limit access by other visitors that would otherwise be permitted under state or federal law or regulation. The facility shall ensure its policies and procedures respect resident privacy and take into account visitation protocols in the event a resident occupies a shared room. In establishing frequency and duration limits, the facility policy shall ensure that residents are able to receive their designated personal caregiving visitors for the resident's desired frequency and length of time, and any restrictions on that desired frequency and duration must be:

(a) attributable to the resident's clinical or personal care needs;

(b) necessary to ensure the resident's roommate has adequate privacy and space to receive their own designated personal caregiving visitors; or

(c) because the desired visitation frequency or duration would impair the effective implementation of applicable infection control measures, including social distancing of at least six feet between the visitors and others in the facility, having sufficient staff to effectively screen all personal caregiving visitors and monitor visits to ensure infection control protocols are being followed throughout, and having a sufficient supply of necessary personal protective equipment for all personal caregiving visitors.

(4) Compassionate caregiving.

(i) In the event a resident experiences a long-term or acute physical, mental, or psychosocial health condition for which, in the opinion of the resident, their representative, or a health care professional (including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist), a compassionate caregiving visitor would improve the resident's quality of life, the resident or their representative shall designate at least two compassionate caregiving visitors at one time, and the facility shall record such designation in the resident's individualized comprehensive plan of care. A resident's designated personal caregiving visitors may also provide compassionate caregiving.

(ii) Situations in which a resident is eligible for a compassionate caregiving visitor include but are not limited to the following:

(a) end of life;

(b) the resident, who was living with their family before recently being admitted to an adult care facility, is struggling with the change in environment and lack of physical family support;

(c) the resident is grieving after a friend or family member recently passed away;

(d) the resident needs cueing and encouragement with eating or drinking, and such cueing was previously provided by family and/or caregiver(s), and the resident is now experiencing weight loss or dehydration; and

(e) the resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

(iii) Compassionate caregiving visitation shall be permitted at all times, regardless of any general visitation restrictions or personal caregiving visitation restrictions in effect in the facility.

Provided, however, that the facility shall require compassionate caregiving visitors to be screened for communicable diseases prior to entering the facility and visits must be conducted using appropriate social distancing between the resident and visitor if applicable based on guidance from the Department or the U.S. Centers for Disease Control and Prevention; if, however, personal contact would be beneficial for the resident's mental or psychosocial well-being, the facility shall establish policies and procedures to ensure that such necessary physical contact follows appropriate infection prevention guidelines, including the visitor's use of personal protective equipment and adhering to hand hygiene protocols before and after resident contact, and that the physical contact is limited in duration.

(5) The Department shall have discretion to review and require modifications to a facility's personal caregiving visitation and compassionate caregiving visitation policies and procedures to ensure conformity with paragraphs (3) and (4) of this subdivision and any applicable visitation guidelines issued by the Department or the Centers for Medicare and Medicaid Services.

A new Section 485.18 of 18 NYCRR, titled Personal and Compassionate Caregiving Visitation, is added to read as follows:

(a) This section shall apply to all adult care facilities, including every adult care facility regulated pursuant to Parts 487, 488 and 490 of this Title and Part 1001 of Title 10 of the NYCRR.

(b) Subject to the resident's right to deny or withdraw consent at any time, all adult care facilities must provide immediate access to any resident of visitors of their choice, including but not limited to immediate family or other relatives of the resident and any others who are visiting with the consent of the resident. Provided, however, that the facility may establish policies and

procedures to establish reasonable restrictions on such visitation, including but not limited to: setting forth visitation hours; denying access to any visitor suffering from a communicable disease; terminating visitation with any visitor causing a threat to the health or safety of any resident; and setting a cap on the number of visitors allowed in the facility at any one time. Any such restrictions or limitations on visitation shall be communicated in writing to residents.

(c) Personal caregiving visitors.

(1) During a public health emergency declared under section twenty-four or section twenty-eight of the executive law, the facility must continue to allow residents to access their designated personal caregiving visitors, as defined in subdivision (1) of section 2801-h of the Public Health Law, notwithstanding any restrictions or prohibitions relating to residential health care facility visitation resulting from the declared public health emergency, subject to the following restrictions:

(i) If a facility has reasonable cause to believe that a resident will not benefit from accessing their designated personal caregiving visitors, and such reasoning has been documented in the resident's case management record, a facility may require a health or mental health professional duly licensed or certified in New York State under the Education Law, and who is not associated with the facility, including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist, to provide a written statement that the personal caregiving will substantially benefit the resident's quality of life, including a statement from such medical provider that the personal caregiving visitation will enhance the resident's mental, physical, or psychosocial well-being, or any additional criteria evidencing a benefit to quality of life

as determined by the Department. Such written statements shall be maintained in the resident's case management record.

(ii) Notwithstanding any provision of this paragraph, a facility may temporarily suspend or limit personal caregiving visitors to protect the health, safety and welfare of residents, if: the declared public health emergency is related to a communicable disease and the Department determines that local infection rates are at a level that presents a serious risk of transmission of such communicable disease within local facilities; the facility is experiencing temporary inadequate staffing and has reported such staffing shortage to the Department of Health any other State or federal agencies as required by law, regulation, or other directive; or an acute emergency situation exists at the facility, including loss of heat, loss of elevator service, or other temporary loss of an essential service. Provided, however, that in the event a facility suspends or limits personal caregiving visitation pursuant to this subparagraph, the facility shall notify residents, all designated personal caregiving visitors, and the applicable Department regional office of such suspension or limitation and the duration thereof within twenty-four hours of implementing the visitation suspension or limitation. Additionally, for each day of the suspension or limitation, the facility shall document the specific reason for the suspension or limitation in their administrative records. The facility shall further provide a means for all residents to engage in remote visitation with their designated personal caregiving visitor(s), including but not limited to phone or video calls, until such time that the suspension or limitation on personal caregiving visitation has ended.

(iii) Notwithstanding any provision of this paragraph, a facility may also prohibit a personal caregiving visitor from entering if the facility has reasonable cause to believe

that permitting the personal caregiving visitor to meet with the resident is likely to pose a threat of serious physical, mental, or psychological harm to such resident. In the event the facility determines that denying such personal caregiving visitor access to the resident is in the resident's best interests pursuant to this subparagraph, the facility must document the date of and reason for visitation refusal in the resident's case management record, and on the same date of the refusal the facility shall communicate its decision to the resident and their designated representative. Further, a facility may refuse access to or remove from the premises any personal caregiving visitor who is causing or reasonably likely to cause physical injury to any facility resident or personnel.

(2) The facility shall develop written policies and procedures to ask residents, or their designated representatives in the event the resident lacks capacity, at time of admission or readmission, or for existing residents within fourteen days of the effective date of this paragraph, which individuals the resident elects to serve as their personal caregiving visitor during declared local or state health emergencies. A resident shall be entitled to designate at least two personal caregiving visitors at one time.

(3) The facility shall maintain a written record of the resident's designated personal caregiving visitors in the resident's case management record, and shall document when personal caregiving and compassionate caregiving is provided in the case management record.

(4) As part of its ongoing review of a resident's case management needs, the facility shall regularly inquire of all current residents, or their designated representative if the resident lacks capacity, whether the facility's current record of designated personal caregiving visitors remains accurate, or whether the resident, or their designated representative if the resident lacks capacity, wishes to make any changes to their personal caregiving visitor designations. The facility shall

update the resident's case management record with the date the facility sought updates from the resident and indicate any changes to the resident's personal caregiving visitor designations therein. Such inquiries shall be made no less frequently than every six months and upon a change in the resident's condition; upon review of a facility's visitation policies and procedures, the Department may also require the facility inquire of any resident whether the facility's current record of designated personal caregiving visitors remains accurate.

(5) The facility shall require all personal caregiving visitors to adhere to infection control measures established by the facility and consistent with any guidelines from the Department, or in the absence of applicable Department guidance, consistent with long term care facility infection control guidelines from the U.S. Centers for Disease Control and Prevention. Such infection control measures may include, but need not be limited to:

- (i) testing all personal caregiving visitors for any communicable disease that is the subject of the declared public health emergency, which may include rapid on-site testing or requiring the visitor to present a negative test result from no more than seven days prior to the visit;
- (ii) checking the personal caregiving visitor's body temperature upon entry to the facility, and denying access to any visitor with a temperature above 100 degrees Fahrenheit;
- (iii) conducting health screenings of all personal caregiving visitors upon entry to the facility, including screenings for signs and symptoms of any communicable disease that is the subject of the declared public health emergency or any other communicable disease which is prevalent in the facility's geographic area, and recording the results of such screenings;

(iv) requiring all personal caregiving visitors to don all necessary personal protective equipment appropriately, and providing such personal protective equipment to all personal caregiving visitors; and

(v) enforcing social distancing between persons during visitation, including personal caregiving visitation, except as necessary to provide personal caregiving by the personal caregiving visitor for the resident.

(6) The facility shall establish policies and procedures regarding the frequency and duration of personal caregiving visits and limitations on the total number of personal caregiving visitors allowed to visit the resident and the facility at any one time. Such policies shall not be construed to limit access by other visitors that would otherwise be permitted under state or federal law or regulation. The facility shall ensure its policies and procedures respect resident privacy and take into account visitation protocols in the event a resident occupies a shared room. In establishing frequency and duration limits, the facility policy shall ensure that residents are able to receive their designated personal caregiving visitors for the resident's desired frequency and length of time, and any restrictions on that desired frequency and duration must be:

(i) attributable to the resident's clinical or personal care needs;

(ii) necessary to ensure the resident's roommate has adequate privacy and space to receive their own designated personal caregiving visitors; or

(iii) because the desired visitation frequency or duration would impair the effective implementation of applicable infection control measures, including social distancing of at least six feet between the visitors and others in the facility, having sufficient staff to effectively screen all personal caregiving visitors and monitor visits to ensure infection

control protocols are being followed throughout, and having a sufficient supply of necessary personal protective equipment for all personal caregiving visitors.

(d) Compassionate caregiving.

(1) In the event a resident experiences a long-term or acute physical, mental, or psychosocial health condition for which, in the opinion of the resident, their representative, or a health care professional (including but not limited to a physician, registered nurse, licensed clinical social worker, psychologist, or psychiatrist), a compassionate caregiving visitor would improve the resident's quality of life, the resident or their representative shall designate at least two compassionate caregiving visitors at one time, and the facility shall record such designation in the resident's case management record. A resident's designated personal caregiving visitors may also provide compassionate caregiving.

(2) Situations in which a resident is eligible for a compassionate caregiving visitor include but are not limited to the following:

(i) end of life;

(ii) the resident, who was living with their family before recently being admitted to an adult care facility, is struggling with the change in environment and lack of physical family support;

(iii) the resident is grieving after a friend or family member recently passed away;

(iv) the resident needs cueing and encouragement with eating or drinking, and such cueing was previously provided by family and/or caregiver(s), and the resident is now experiencing weight loss or dehydration; and

(v) the resident, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently (when the resident had rarely cried in the past).

(3) Compassionate caregiving visitation shall be permitted at all times, regardless of any general visitation restrictions or personal caregiving visitation restrictions in effect in the facility.

Provided, however, that the facility shall require compassionate caregiving visitors to be screened for communicable diseases prior to entering the facility and visits must be conducted using appropriate social distancing between the resident and visitor if applicable based on guidance from the Department or the U.S. Centers for Disease Control and Prevention; if, however, personal contact would be beneficial for the resident's well-being, the facility shall establish policies and procedures to ensure such physical contact follows appropriate infection prevention guidelines, including the visitor's use of personal protective equipment and adhering to hand hygiene protocols before and after resident contact, and that physical contact is limited in duration.

(e) The Department shall have discretion to review and require modifications to a facility's personal caregiving visitation and compassionate caregiving visitation policies and procedures to ensure conformity with subdivisions (c) and (d) of this section and any applicable visitation guidelines issued by the Department or the Centers for Medicare and Medicaid Services.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under sections 2801-h and 2803 of the Public Health Law (PHL) and sections 461, 461-e, and 461-u of the Social Services Law (SSL).

PHL § 2801-h and SSL § 461-u specifically authorize the New York State Department of Health (Department) to promulgate regulations relating to personal caregiving visitors and compassionate caregiving visitors in nursing homes and adult care facilities (ACFs).

SSL § 461 requires the Department to promulgate regulations establishing general standards applicable to ACFs. SSL § 461-e authorizes the Department to promulgate regulations to require ACFs to maintain certain records with respect to the facilities' residents and the operation of the facility.

Legislative Objectives:

The legislative objective of PHL § 2801-h and SSL § 461-u is to ensure residents' rights to visitation are respected by allowing residents of nursing homes and ACFs to have access to their designated personal caregiving visitors and compassionate caregiving visitors during a declared State or local public health emergency. Further, the legislative objective of SSL § 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

These regulations are necessary pursuant to the statutory directives in PHL § 2801-h and SSL § 461-u, which direct the Commissioner of Health to promulgate regulations governing personal caregiving visitation and compassionate caregiving visitation in nursing homes and ACFs during a declared State or local public health emergency.

These regulations are beneficial insofar as they will provide clarity to facility operators and administrators, residents, and their family members regarding whether certain visitors are permitted to access a nursing home or ACF during a declared local or State health emergency, notwithstanding any visitation restrictions currently in effect within the facility.

COSTS:

Costs to Regulated Parties:

There are no anticipated costs to regulated parties. The regulations require facilities to establish policies and procedures regarding personal caregiving visitation and compassionate caregiving visitation that comply with these regulations and the governing statutes, PHL § 2801-h and SSL § 461-u. Insofar as facilities are obligated to establish policies and procedures for other facility operations, this responsibility should be managed using existing resources.

Costs to Local and State Governments:

There are no anticipated costs to any regulated parties, including nursing homes and ACFs operated by a local or State government.

Costs to the Department of Health:

This regulation will not result in any additional operational costs to the Department of Health. Any increased surveillance and enforcement activities relating to this regulation will be handled with existing resources.

Paperwork:

This regulation requires facilities to develop and maintain visitation policies relating to personal caregiving visitation and compassionate caregiving visitation. However, this requirement is expected to be of minimal burden to facilities, which are currently obligated to

develop and maintain other policies and procedures relating to facility operations, and the requirements for such visitation policies and procedures are thoroughly detailed in these regulations and the governing statutes, PHL § 2801-h and SSL § 461-u.

Local Government Mandates:

Nursing homes and ACFs operated by local governments will be affected and will be subject to the same requirements as any other nursing home licensed under PHL Article 28 or ACF licensed under SSL Article 7, Title 2. Currently, there are 21 nursing homes operated by local governments (counties and municipalities) and 6 nursing homes operated by the State. Additionally, there are currently two adult care facilities operated by county governments.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

There are no viable alternatives. The alternative of not issuing these regulations was rejected given the statutory directive to promulgate these regulations, pursuant to PHL § 2801-h and SSL § 461-u.

Federal Standards:

The federal Centers for Medicare & Medicaid Services (CMS) has issued visitation guidance applicable to Medicaid- and Medicare-enrolled nursing homes, titled “Nursing Home Visitation - COVID-19 (REVISED)” (QSO-20-39-NH), revised April 27, 2021. This visitation guidance discusses general visitation in nursing homes including compassionate care visitation. The Department has reviewed this CMS guidance and finds that the proposed regulations are consistent with the CMS guidance insofar as they both relate to compassionate care visitation in nursing homes. No other federal standards apply.

Compliance Schedule:

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

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

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a nursing home or adult care facility (ACF). Currently, there are 21 nursing homes operated by local governments (counties and municipalities) and 6 nursing homes operated by the State. Additionally, there are currently two ACFs operated by county governments (Chenango and Warren Counties). Additionally, to date, 79 nursing homes in New York qualify as small businesses given that they have 100 or fewer employees. There are also 483 ACFs that have 100 or fewer employees and therefore qualify as small businesses.

Compliance Requirements:

This regulation requires nursing homes and ACFs to develop policies and procedures relating to compassionate caregiver visitation and personal caregiver visitation that are consistent with these regulations and the governing statutes, Public Health Law (PHL) § 2801-h and Social Services Law (SSL) § 461-u.

Professional Services:

No professional services are required by this regulation.

Compliance Costs:

There are no costs associated with this regulation.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is consistent with resident right standards and current CMS and Department visitation guidance. Therefore, the Department expects no adverse impact to facilities given that nursing homes and ACFs are currently required to comply with similar standards and are expected to have already developed policies and procedures in accordance with those existing standards. In any event, the Department is required by PHL § 2801-h and SSL § 461-u to promulgate these regulations; as such, any adverse impact on covered facilities cannot be avoided due to the statutory mandate.

Small Business and Local Government Participation:

Facilities were put on notice of the forthcoming promulgation of these regulations upon the enactment of PHL § 2801-h and SSL § 461-u, as enacted by Chapter 108 of the Laws of 2021. Additionally, the Department plans to advise all facilities, including those operated by small businesses and local governments, of the publication of these regulations and the opportunity to submit any questions relating to such regulations to the Department.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

This regulation imposes no additional paperwork.

Compliance Costs:

There are no costs associated with this regulation.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is consistent with resident right standards and current CMS and Department visitation guidance. Therefore, the Department expects no adverse impact to facilities given that nursing homes and ACFs are currently required to comply with similar standards and are expected to have already developed policies and procedures in accordance with those existing standards. In any event, the Department is required by PHL § 2801-h and SSL § 461-u to promulgate these regulations; as such, any adverse impact on covered facilities cannot be avoided due to the statutory mandate.

Rural Area Participation:

Facilities were put on notice of the forthcoming promulgation of these regulations upon the enactment of PHL § 2801-h and SSL § 461-u, as enacted by Chapter 108 of the Laws of 2021. Additionally, the Department plans to advise all facilities, including those located in rural areas, of the publication of these regulations and the opportunity to submit any questions relating to such regulations to the Department.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

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

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

Part 2 is amended to add a new section 2.61, as follows:

2.61. Prevention of COVID-19 transmission by covered entities.

(a) Definitions.

- (1) “Covered entities” for the purposes of this section, shall include:
 - (i) any facility or institution included in the definition of “hospital” in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;
 - (ii) any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies;
 - (iii) hospices as defined in section 4002 of the Public Health Law; and
 - (iv) adult care facility under the Department’s regulatory authority, as set forth in Article 7 of the Social Services Law.

(2) “Personnel,” for the purposes of this section, shall mean all persons employed or affiliated with a covered entity, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.

(3) “Fully vaccinated,” 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 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; or

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

(c) Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, absent receipt of an exemption as allowed below. Covered entities shall require all personnel to receive at least their first dose before engaging in activities covered under paragraph (2) of subdivision (a) of this section. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in subdivision (d) of this section.

(d) Exemptions. Personnel shall be exempt from the COVID-19 vaccination requirements set forth in subdivision (c) of this section as follows:

(1) Medical exemption. If any licensed physician, physician assistant, or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of member of a covered entity's personnel, based upon a pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be inapplicable only until such immunization is found no longer to be detrimental to such personnel member's health. The nature and duration of the medical exemption must be stated in the personnel employment medical record, or other appropriate record, and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services), and any reasonable accommodation may be granted and must likewise be documented in such record. Covered entities shall document medical exemptions in personnel records or other appropriate records in accordance with applicable privacy laws by: (i) September 27, 2021 for general hospitals and nursing homes; and (ii) October 7, 2021 for all other covered entities. For all covered

entities, documentation must occur continuously, as needed, following the initial dates for compliance specified herein, including documentation of any reasonable accommodation therefor.

(e) Upon the request of the Department, covered entities must report and submit documentation, in a manner and format determined by the Department, for the following:

- (1) the number and percentage of personnel that have been vaccinated against COVID-19;
- (2) the number and percentage of personnel for which medical exemptions have been granted;
- (3) the total number of covered personnel.

(f) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of this section and submit such documents to the Department upon request.

(g) The Department may require all personnel, whether vaccinated or unvaccinated, to wear an appropriate face covering for the setting in which such personnel are working in a covered entity. Covered entities shall supply face coverings required by this section at no cost to personnel.

Subparagraph (vi) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:

(vi) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 is added to read as follows:

(5) collects documentation of COVID-19 or documentation of a valid medical exemption to such vaccination, for all personnel pursuant to section 2.61 of this title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 751.6 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (6) of subdivision (c) of Section 763.13 is added to read as follows:

(6) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making

such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 766.11 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (8) of subdivision (d) of Section 794.3 is added to read as follows:

(8) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (q) of Section 1001.11 is added to read as follows:

(5) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is added to read as follows:

(18) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is added to read as follows:

(14) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is added to read as follows:

(15) Operator shall collect documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 225(5), 2800, 2803(2), 3612 and 4010 (4). PHL 225(5) authorizes the Public Health and Health Planning Council (PHHPC) to issue regulations in the State Sanitary Code pertaining to any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises.

PHL Article 28 (Hospitals), Section 2800 specifies that “hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.”

PHL Section 2803(2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

PHL Section 3612 authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Section 4010 (4) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

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

Legislative Objectives:

The legislative objective of PHL Section 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional

curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

The vaccine mandate for health care workers, which required general hospital and nursing home personnel to receive their first dose of COVID-19 vaccine by September 27, 2021, and required all other covered entities to receive their first dose of COVID-19 vaccine by October 7, 2021, has greatly increased the percentage of health care workers who are vaccinated against COVID-19. COVID cases, hospitalizations, and deaths are decreasing in New York State, and the continuation of these regulations will help ensure that the epidemiology curve continues downward in furtherance of the New York State Department of Health’s mission to reduce morbidity and mortality. These regulations are helping New York State reduce sickness and death from COVID-19.

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen more than 10-fold, and over 99 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 10 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and

congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

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

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, as well as any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

Cost to State and Local Government:

The State operates several healthcare facilities subject to this regulation. Most county health departments are licensed under Article 28 or Article 36 of the PHL and are therefore also subject to regulation. Similarly, certain counties and the City of New York operate facilities licensed under Article 28. These State and local public facilities would be required to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. They must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations.

Although the costs to the State or local governments cannot be determined with precision, the Department does not expect these costs to be significant. State facilities should already be ensuring COVID-19 vaccination among their personnel, subject to State directives. Further, these entities are expected to realize savings as a result of the reduction in COVID-19 in personnel and the attendant loss of productivity and available staff.

Cost to the Department of Health:

There are no additional costs to the State or local government, except as noted above. Existing staff will be utilized to conduct surveillance of regulated parties and to monitor compliance with these provisions.

Local Government Mandates:

Covered entities operated by local governments will be subject to the same requirements as any other covered entity subject to this regulation.

Paperwork:

This measure will require covered entities to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Duplication:

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

Alternative Approaches:

One alternative would be to require covered entities to test all personnel in their facility before each shift worked. This approach is limited in its effect because testing only provides a person's status at the time of the test and testing every person in a healthcare facility every day is impractical and would place an unreasonable resource and financial burden on covered entities if PCR tests couldn't be rapidly turned around before the commencement of the shift. Antigen tests have not proven as reliable for asymptomatic diagnosis to date.

Another alternative to requiring covered entities to mandate vaccination would be to require covered entities to mandate all personnel to wear a fit-tested N95 face covering at all times when in the facility, in order to prevent transmission of the virus. However, acceptable face coverings, which are not fit-tested N95 face coverings have been a long-standing requirement in these covered entities, and, while helpful to reduce transmission it does not prevent transmission and; therefore, masking in addition to vaccination will help reduce the numbers of infections in these settings even further.

Federal Requirements:

There are no minimum standards established by the federal government for the same or similar subject areas.

Compliance Schedule:

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

Contact Person:

Ms. Katherine E. Ceroalo
NYS Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 –FAX
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a covered entity as defined in the emergency regulation. Currently, 5 general hospitals, 79 nursing homes, 75 certified home health agencies (CHHAs), 20 hospices and 1,055 licensed home care service agencies (LHCSAs), and 483 adult care facilities (ACFs) are small businesses (defined as 100 employees or less), independently owned and operated affected by this rule. Local governments operate 19 hospitals, 137 diagnostic and treatment facilities, 21 nursing homes, 12 CHHAs, at least 48 LHCSAs, 1 hospice, and 2 ACFs.

Compliance Requirements:

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

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 Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy

and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

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 Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department’s understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

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 to provide comments during the notice and comment period.

JOB IMPACT STATEMENT

Nature of Impact:

Covered entities may terminate personnel who are not fully vaccinated and do not have a valid medical exemption and are unable to otherwise ensure individuals are not engaged in patient/resident care or expose other covered personnel.

Categories and numbers affected:

This rule may impact any individual who falls within the definition of “personnel” who is not fully vaccinated against COVID-19 and does not have a valid medical exemption on file with the covered entity for which they work or are affiliated.

Regions of adverse impact:

The rule would apply uniformly throughout the State and the Department does not anticipate that there will be any regions of the state where the rule would have a disproportionate adverse impact on jobs or employment.

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 Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department’s understanding that many facilities across the State

have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Pursuant to the authority vested in the Commissioner of Health by Public Health Law section 2803, Section 756.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended and Section 756.4 is repealed and replaced, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 756.3 is amended to read as follows:

The operator shall ensure that:

- (a) prior to performing the procedure, the patient receives a [complete physical examination] clinically relevant examination, which may be satisfied, when clinically appropriate, through a review of the patient's medical history and discussion of patient symptoms conducted through telemedicine. [with appropriate tests for a positive pregnancy diagnosis and sonography if there is a question of gestational age, and] T[t]he results [are] of such examination shall be documented in the patient's medical record;
- (b) after the procedure, an evaluation of the [physical and emotional] status of the patient is made and documented in the patient's medical record;
- (c) information and counseling about [alternative] methods of [birth control] contraception are made available [by a health care professional] to all patients who want such information;
- (d) referral is made to another facility for family planning services, if not available at the center, and if desired by the patient; and
- (e) [the determination of blood group and Rh type is made prior to the termination of pregnancy. The patient is evaluated for the risk of sensitization to Rho(D) antigen and,] a determination of blood group and Rh type, if clinically indicated, is made in accordance

with evidence based clinical guidelines. [i]If the use of Rh immune globulin is indicated and the patient consents, an appropriate dosage is administered within 72 hours after the termination of pregnancy.

Section 756.4 is REPEALED and a new section 756.4 is added to read as follows:

756.4 Health care practitioner services

The operator shall ensure that:

- (a) a health care practitioner licensed, certified, or authorized under title eight of the education law, acting within such practitioner's lawful scope of practice, performs the abortion; and
- (b) an abortion is performed only when, according to the practitioner's reasonable and good faith professional judgment based on the facts of the patient's case: the patient is within twenty-four weeks from the commencement of pregnancy, or there is an absence of fetal viability, or the abortion is necessary to protect the patient's life or health.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under Public Health Law (PHL) § 2803(2), which permits the Public Health and Health Planning Council (PHHPC), upon approval of the Commissioner of Health, to adopt rules necessary to effectuate the provisions and purposes of PHL Article 28.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost. Specifically, PHL § 2800 provides that “Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.”

Needs and Benefits:

The proposed regulatory changes are necessary to protect and promote the health of New Yorkers seeking to access abortion services, consistent with PHL § 2800. The proposed amendments will better enable abortion service clinics, as PHL Article 28 diagnostic and treatment centers, to provide safe, high-quality services by aligning the regulations with current clinical standards for providing abortion care. In particular, repeal of section 756.4, which limited provision of abortion care to physicians, and replacement with language that mirrors PHL § 2599-bb, is necessary in light of the passage of the Reproductive Health Act of 2019. Specifically, the Act affirmed that any health care provider—not merely physicians—licensed and certified under Title 8 of the Education Law and acting within their scope of practice may provide abortion care. The proposed regulatory changes will thus advance the purposes of the Reproductive Health Act, which aimed to codify into state law the fundamental protections relating to abortion access articulated in *Roe v. Wade* and ensure access to safe, legal abortion in New York State.

The proposed regulatory amendments are also necessary to conform New York's abortion regulations to recent federal case law relating to abortion access, including *Whole Women's Health v. Hellerstedt* (579 U.S. ___, 136 S.Ct. 2292 [2016]), *June Medical Services LLC v. Russo* (591 U.S. ___, Nos. 18-1323, 18-1460, [2020]), and *Am. Coll. of Obstetricians & Gynecologists v. United States FDA* (2020 US Dist LEXIS 122017 [D Md July 13, 2020]). Specifically, section 756.4(b), which requires a physician with admitting privileges at a hospital to conduct an abortion, is unconstitutional according to a recent United States Supreme Court case in *June Medical Services*, which held that a similar Louisiana law requiring physician hospital admitting privileges in order to conduct an abortion poses an undue burden on a woman's right to abortion and is therefore unconstitutional.

With respect to the proposed amendments to section 756.3(a), which would permit clinically-relevant examinations to be conducted via telemedicine, this change is required for consistency with a recent ruling from the United States District Court for the District of Maryland. In that case, the court granted a nationwide preliminary injunction requiring that the U.S. Food and Drug Administration (FDA) temporarily suspend enforcement of the in-person dispensing requirements for the medication mifepristone, when used for medication abortion (*Am. Coll. of Obstetricians & Gynecologists v United States FDA*, 2020 US Dist LEXIS 122017, at *1 [D Md July 13, 2020]). The Court held that the FDA's requirement that mifepristone be dispensed in person during the COVID-19 emergency improperly infringed on access to constitutionally protected medication abortions.

Similarly, subdivisions (a) and (e) of section 756.3 unnecessarily subject all patients, regardless of clinical necessity, to COVID-19 risks by requiring in-person physical examinations and Rh factor testing in order to access abortion during the pandemic. Although the COVID-19 state of emergency will eventually resolve, subdivisions (a) and (e) of section 756.3 must be amended as proposed to ensure that current regulatory requirements do not create barriers to accessing abortion services when in-person visits are not clinically necessary.

COSTS:

Costs to Private Regulated Parties:

The private parties subject to the proposed regulations are licensed diagnostic and treatment centers (D&TCs). This proposal is expected to have minimal costs on D&TCs, because the amendments will bring the regulations in line with current clinical practices.

Costs to Local Government:

This proposal will not impact local governments.

Costs to the Department of Health:

The Department will utilize existing resources to review compliance with the amended regulatory requirements.

Costs to Other State Agencies:

The proposed regulatory changes will not result in any additional costs to other state agencies.

Local Government Mandate:

No new local government program, project or activity is required by the proposed regulations.

Paperwork:

No new paperwork requirements would be imposed under the proposed regulatory changes.

Duplication:

These regulatory amendments do not duplicate existing State or federal requirements.

Alternatives:

The Department found no viable alternatives to the proposed regulations. Not amending the regulations was rejected as an option, because the existing regulations, adopted over 30 years ago, are not aligned with current clinical best practices. Failing to make the proposed regulatory changes would also place New York State at odds with federal law, to the extent that current regulations require that at least one physician in the clinic has admitting privileges at a hospital; similar admitting privileges requirements were found unconstitutional by the U.S. Supreme Court in 2016 and 2020 (see *Whole Women's Health v Hellerstedt*, 136 S.Ct. at 2292; *June Medical Services*, Nos. 18-1323, 18-1460).

Federal Standards:

The proposed regulations do not duplicate or conflict with any federal regulations. Indeed, this proposal will bring the Department's regulations in line with federal case law, including two recent U.S. Supreme Court decisions: *Whole Women's Health v Hellerstedt* (136 S.Ct. at 2292) and *June Medical Services* (Nos. 18-1323, 18-1460).

Compliance Schedule:

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

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

**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

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

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

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

**STATEMENT IN LEIU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for the proposed regulatory 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.