Investigation of Communicable Disease; Isolation and Quarantine

Effective date: 6/5/20

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of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, Section 2.6 is repealed and a new Section 2.6 is added, a new Section 2.13 is added, Sections 2.25 through 2.30 are repealed, a new Section 58-1.14 is added, and Section 405.3 is amended, to be effective upon filing with the Secretary of State, to read as follows: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] <u>*Case* shall mean</u> a person who has been diagnosed [as likely to have] <u>as having</u> a particular disease or condition. The diagnosis may be based [solely] on clinical judgment<u>, signs and symptoms combined with known exposure based on the best available evidence of transmissibility to a case or suspected case,</u> [solely] <u>and/or</u> on laboratory evidence, [or on both criteria] <u>as applicable</u>.

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

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

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(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 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 section 2.10 of this Part, shall cooperate with the State Department of Health and local health authorities in the investigation of such disease, condition, outbreak, or unusual disease.

(c) Investigation Updates and Reports.

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

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

(d) Commissioner authority to lead investigation activities.

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

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

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

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

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

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:

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

(i) attendance;

(ii) date and duration of the meeting;

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

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

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

* * *

Section 58-1.14 Reporting of certain communicable diseases

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

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

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

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

* * *

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

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

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

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

Legislative Objectives:

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

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

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

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that has caused mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a hospital and can be fatal.

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

The situation continues to rapidly evolve throughout the world and the United States. In particular, the United States has quickly progressed from identifying travel-associated cases and person-to-person transmission of COVID-19 among close contacts of travel-associated cases, to the identification of community spread of the disease in certain parts of California, Oregon, and Washington states.

As of March 1, 2020, New York State has reported cases of COVID-19. Given the rate spread to date, the Centers for Disease Control and Prevention (CDC) expects that it is likely widespread transmission of COVID-19 will occur in the United States.

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.
    - Clarifies authority for the Commissioner to lead investigation activities.

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

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

Part 58 Amendments

- New section 58-1.14 added clarifying reporting requirements for certain communicable diseases
  - Requires the Commissioner to designate those communicable disease that require prompt action, and to make available a list of such disease on the State Department of Health website.
  - Requires clinical laboratories to immediately report positive test results for communicable diseases identified as requiring prompt attention, in a manner and format identified by the Commissioner.

- Requires clinical laboratories to report all test result, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

Part 405 Amendments

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

COSTS:

Costs to Regulated Parties:

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

Clinical laboratories must already report communicable disease testing results using the ECLRS and must also immediately report communicable diseases pursuant to PHL § 2102. The regulation simply clarifies existing requirements and is not anticipated to imposes any substantial

additional costs beyond those costs that laboratories would incur in the absence of these regulations.

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

Costs to Local and State Governments:

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

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

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

Paperwork:

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

Local Government Mandates:

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

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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 has caused mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a hospital and can be fatal.

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

The situation continues to rapidly evolve throughout the world and the United States. In particular, the United States has quickly progressed from identifying travel-associated cases and person-to-person transmission of COVID-19 among close contacts of travel-associated cases, to the identification of community spread of the disease in certain parts of California, Oregon, and Washington states.

Additionally, as of March 1, 2020 New York State has reported cases of COVID-19. Given the spread so far, the Centers for Disease Control and Prevention (CDC) expects that it is likely widespread transmission of COVID-19 will occur in the United States.

Given the emergent nature of the COVID-19 outbreak, these emergency regulations are necessary to clarify and strengthen the Department's authority and that of the 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.