

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, Sections 2.1 and 2.5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, Section 2.6 is repealed and a new Section 2.6 is added, Section 405.3 is amended and a new Section 58-1.14 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

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

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

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Section 2.5 is amended to read as follows:

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

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

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Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

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

- (1) Verify the existence of a disease or condition;
- (2) Ascertain the source of the disease-causing agent or condition;
- (3) Identify unreported cases;
- (4) Locate and evaluate contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;
- (5) Collect and submit, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the source of disease, or to assist with diagnosis; and furnish or cause to be furnished with

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

- (6) With the training or assistance of the State Department of Health, examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;
- (7) Instruct a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and
- (8) Take any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

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

(c) Investigation Updates and Reports.

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

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

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

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

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

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

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

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

investigative materials which were heretofore created by the local health authority.

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

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

* * *

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

(i) attendance;

(ii) date and duration of the meeting;

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

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

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

* * *

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.

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.

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

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

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.

Legislative Objectives:

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

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

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.

Needs and Benefits:

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

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

Part 2 Amendments:

- Amend sections 2.1 and 2.5 to reflect The World Health Organization's (WHO) decision to change the name of "monkeypox" to "Mpox" in an effort to reduce the stigma that monkeypox comes with and deal with possible misinformation falsely suggesting that monkeys are the main source of spreading the virus.
- Repeal and replace current section 2.6, related to investigations, to clarify existing local health department authority.

- Sets forth specific actions that local health departments must take to investigate a case, suspected case, outbreak, or unusual disease.
- Requires individuals and entities subject to a public health investigation to cooperate with the Department and local health departments.
- While the Department works collaboratively with local health departments on a variety of public health issues, including disease control, this regulation clarifies the authority for the Commissioner to lead disease investigation activities under certain circumstances (i.e., where there is potential for statewide impact, multiple jurisdictions impacted, or impact on one or more New York State jurisdictions and another state or states), while working collaboratively with impacted local health departments. In all other situations, local health departments retain the primary authority and responsibility to control communicable disease within their respective jurisdictions, with the Department providing assistance as needed.
- Codify in regulation the requirement that local health departments send reports to the Department during an outbreak.

Part 405 Amendments

- Mandates hospitals to report syndromic surveillance data during an outbreak of a 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).

Part 58 Amendments

- New section 58-1.14 added clarifying reporting requirements for certain communicable diseases
 - Requires the Commissioner to designate those communicable diseases that require prompt action, and to make available a list of such diseases 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 results, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

COSTS:

Costs to Regulated Parties:

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

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

patients during an outbreak of a 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 impose any substantial additional costs beyond those costs that laboratories 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.

Paperwork:

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

Local Government Mandates:

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

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

The alternative would be to leave in place the current regulations on disease investigation. However, many of these regulatory provisions have not been updated in fifty years and should be modernized to ensure appropriate response to 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.

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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 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, 405 and 58.

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.