Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225 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of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, Section 2.6 is repealed and a new Section 2.6 is added, and Section 405.3 is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read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 (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:

* * *

[Monkeypox] <u>Mpox</u>

* * *

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:

* * *

[Monkeypox] Mpox

* * *

Section 2.6 is repealed and replaced as follows: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 communicable disease of high public health consequence 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 communicable disease of high public health consequence 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 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 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.

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 communicable disease of high public health consequence or other public health emergency.
- Permits the Commissioner to direct general hospitals to accept patients during an outbreak of a communicable disease of high public health consequence or other public health emergency, provided it's done consistent with the federal Emergency Medical Treatment and Labor Act (EMTALA).

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 communicable disease of high public health consequence, 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.

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.

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 communicable disease outbreaks.

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 communicable disease of high public health consequence, hospitals are already reporting syndromic surveillance data regularly and voluntarily.

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:

These regulations have been proposed for permanent adoption, so all parties have had 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 a population of less than 200,000 based upon 2020 United States Census data:

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

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

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

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

As the proposed regulations largely clarify existing responsibilities and duties among regulated entities and individuals, no additional recordkeeping, compliance requirements, or professional services are expected. With respect to mandating syndromic surveillance reporting during an outbreak of a communicable disease of high public health consequence, hospitals are already reporting syndromic surveillance data regularly and voluntarily. Additionally, the requirement for local health departments to continually report to the Department during such an outbreak is historically a practice that already occurs.

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 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:

These regulations have been proposed for permanent adoption, so all parties have had an opportunity to provide 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.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (NYSDOH or "the Department") published a Notice of Proposed Rulemaking in the State Register on April 19, 2023. The Department received public comments from the New York City Department of Health and Mental Hygiene and from the New York State Association of County Health Officials (NYSACHO). These comments and the Department's responses are summarized below.

COMMENT: Commenters requested modifications to 10 NYCRR § 2.6(a) to allow for more flexibility in case investigations. Commenters noted that regulation as drafted requires local health departments to "immediately" investigate every suspected and confirmed case of disease. The New York City Health Department indicated that it receives millions of reports annually for the over 70 reportable diseases listed in 10 NYCRR § 2.1 and was concerned that it is not possible to investigate all such cases—much less all suspected cases— nor necessary or desirable from a public health, economic, or privacy perspective.

RESPONSE: The Department finds this comment to be reasonable. However, there are diseases that warrant immediate investigation to protect public health. These diseases include ones that involve an agent where post-exposure prophylaxis may prevent future cases or future spread of cases, ones that involve select agents, and ones that involve pathogens of high consequence. These are delineated in form DOH-389 and will continue to be indicated as such. No changes to the proposed regulation are being made as a result of these comments; however, the Department anticipates making future amendments to 10 NYCRR § 2.6(a) to incorporate additional flexibilities are suggested by commenters.

COMMENT: Commenters shared concerns that the proposed regulations include a list of activities that must be undertaken as part of a communicable disease investigation—including investigating all public and private places in which the local health department has reason to believe are associated with such disease, ascertaining the source of the disease-causing agent, and causing laboratory specimens to be collected or submitted for testing—which commenters pointed out was neither feasible nor necessary or desirable for all reported suspected and confirmed cases of disease. Commenters pointed out that the regulations being repealed (and replaced by the proposed regulations) allowed local health departments discretion to investigate cases "as the circumstances may require" and suggested such discretion be added back into the proposed regulations.

RESPONSE: The Department agrees that the modifying the regulation to require investigations "as the circumstances may require" would be appropriate. Although no changes to the proposed regulation are being made at this time, the Department anticipates making this change in future rulemaking.

COMMENT: A commentor recommended striking the phrase "as well as those reasonably expected to have been exposed to the disease" from 10 NYCRR § 2.6(a)(4), as they thought it was not clear what this phrase is meant to cover beyond contacts.

RESPONSE: The Department agrees with this comment. As contact tracing is not indicated in all investigations, and as some pathogens are not transmitted person-to-person, it makes sense to strike this or to alter language to include a phrase such as "when indicated" after the phrase the commenter highlights. Although no changes to the proposed regulation are being made at this time, the Department anticipates making this change in future rulemaking.

COMMENT: A commenter suggested revising 10 NYCRR § 2.6(c) to allow for more flexibility in the report submission process, particularly regarding timing, as thirty (30) days will often not allow sufficient time to gather necessary information. The commenter also noted that decisions regarding the manner, timing, and form of report submission should be made in consultation with local health departments.

RESPONSE: The Department understands the concern raised by this commenter; however, thirty (30) days should be sufficient to report closed investigations. It is also important to note that the proposed regulation includes a provision that allows the Commissioner of Health to set a different time period, which could allow for additional time. No amendments to the proposed regulation are necessary as a result of these comments.

COMMENT: A commenter strongly opposed 10 NYCRR § 2.6(d) of the proposed regulations, which allows the Department to lead local disease investigation and response activities if they impact multiple NYS jurisdictions, impact out-of-state jurisdictions, or involve an outbreak with a high potential for statewide impact. In such cases, the regulations require local health departments to "take all reasonable steps to assist in such investigation and response, including supply of personnel, equipment or information." The commenter stated that this requirement not only usurps local health departments' authority over such investigations but requires them to use their own staff and resources as dictated by NYSDOH, impacting other unrelated local health department activities and budgets. In addition, the commenter stated that there could be union and other labor issues as this seemingly allows for a secondment of staff.

RESPONSE: The Department understands the concerns of the commenter; however, pursuant to Public Health Law (PHL) § 206, the Commissioner of Health and the Department have the power and duty to investigate the causes of disease, epidemics, the sources of mortality, and the effect of localities, employments, and other conditions, upon the public health. While local health departments are authorized and have the power to investigate outbreaks within their respective jurisdictions, it is important that the Commissioner of Health has the power to elect to lead investigation in the interest of public health at large. No changes to the proposed regulation were made as a result of these comments.

COMMENT: One commenter recommended to amend 10 NYCRR § 2.12, which is cross-referenced in the proposed regulations in Section 2.6(b). Section 2.12 creates a duty for the head of a private household or the person in charge of any institution or school (among others) to immediately report the name and address of persons with a disease to the local health department "when no physician is in attendance." The commentor strongly recommended that this provision be modified to require such reporting only if directed by NYSDOH or the local health department. This provision has been in place for many years and the commenter does not believe it is complied with, nor reasonable or practicable to do so. They recommended modifying this provision to afford discretion for local health departments to require employer or school reporting of a reportable disease, as appropriate and necessary under the circumstances, but not create a blanket obligation that is not reasonable or practicable under all circumstances.

RESPONSE: Section 2.12 of Title 10 of the NYCRR is outside the scope of the proposed rulemaking; however, the Department understands the commenter's concerns and will consider making the recommended amendments in future rulemaking.

COMMENT: One commenter suggested amending Section 2.6(d)(1) by adding a new subparagraph (v) to allow the State Commissioner of Health to elect to lead investigation and response activities where: "A local health authority requests that the State Health Commissioner lead the investigation due to jurisdictional concerns, lack of regulatory/oversight authority, or absent the resources necessary to conduct or continue an investigation." The commenter stated that the proposed regulation fails to provide a regulatory pathway for a local health department to request the Health Commissioner lead the investigation. In these events, local health departments respond to the best of their ability, but resource and staffing barriers may impede this process and State assistance or takeover as lead in those situations may be warranted.

RESPONSE: Where a local health department declares a state of emergency due to a communicable disease outbreak, there is an avenue to request aid from the Governor, and in alignment with the Governor, the Health Commissioner. Pursuant to Executive Law § 24(7), in cases where the chief executive of the county where the local state of emergency is declared determines that the disaster is beyond the capacity of the local government to meet adequately and State assistance is necessary to amplify local efforts to save lives and protect property, public health and safety, or to avert or less the threat of a disaster, the chief executive may request the Governor to provide assistance. No changes to the proposed regulation were made as a result of these comments.