Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda
October 6, 2022
10:15 AM

90 Church Street, Conference Rooms 4 A/B, NYC

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

I. WELCOME AND INTRODUCTION

Thomas Holt, Chair of the Committee on Codes, Regulations and Legislation

II. REGULATIONS

For Emergency Adoption

20-06 Amendment of Part 2, Section 405.3 and Addition of Section 58-1.14 to Title 10 NYCRR (Investigation of Communicable Disease)

20-07 Addition of Section 2.60 to Title 10 NYCRR (Face Coverings for COVID-19 Prevention)

22-21 Amendment of Section 23.1 of Title 10 NYCRR (Monkeypox Virus to the List of Sexually Transmitted Diseases (STDs))

For Information

22-21 Amendment of Section 23.1 of Title 10 NYCRR (Monkeypox Virus to the List of Sexually Transmitted Diseases (STDs))

III. ADJOURNMENT

******Agenda items may be called in an order that differs from above******

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 2.6 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is repealed and a new Section 2.6 is added, Section 405.3 is amended and a new Section 58-1.14 is added, to be effective upon filing with the Secretary of State, to read as follows:

Section 2.6 is repealed and replaced as follows:

2.6 Investigations and Response Activities.

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

(1) Verify the existence of a disease or condition;

(2) Ascertain the source of the disease-causing agent or condition;

(3) Identify unreported cases;

(4) Locate and evaluate contacts of cases and suspected cases, as well as those reasonably expected to have been exposed to the disease;

(5) Collect and submit, or cause to be collected or submitted, for laboratory examination such specimens as may furnish necessary or appropriate information for determining the source of disease, or to assist with diagnosis; and furnish or cause to be furnished with

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

(6) Examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;

(7) Instruct a responsible member of a household or entity, as applicable, to implement appropriate actions to prevent further spread of a disease; and

(8) Take any other steps to reduce morbidity and mortality that the local health authority determines to be appropriate.

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

(c) Investigation Updates and Reports.

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

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

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

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

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

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

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

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

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

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:

- 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 imposes 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 imposes 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:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

Compliance Costs:

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

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.

As stated in the declaration of the State disaster emergency in Executive Orders No. 20 through 20.1 (July 29, 2022, through September 27, 2022), New York continues to experience one of the highest rates of monkeypox transmission in the country. New York State outside New York City has had 307 diagnosed cases as of September 21, 2022, and New York City has 3480 diagnosed cases as of September 18, 2022. Furthermore, as stated in the declaration of the State disaster emergency Executive Order 21, a polio outbreak has affected multiple counties in the State of New York, with one paralytic case and detections of genetically related virus in four counties, indicating circulation and transmission of the virus likely in hundreds of people. Additionally, New York continues to experience high rates of COVID-19 transmission as well. The constant threat of a possible resurgence of COVID-19 or another communicable disease outbreak alongside the recent outbreaks of monkeypox and polio necessitate the adoption of these regulatory amendments on an emergency basis. The emergency regulations are needed to continue requiring clinical laboratories to report all test results, including negative and indeterminate results, for communicable diseases such as monkeypox, polio and COVID-19; mandate hospitals to report syndromic surveillance data; and permit the Commissioner to direct hospitals to take patients during a disease outbreak such as monkeypox, polio and COVID-19.

Based on the ongoing burden of multiple outbreaks seen across the state, the Department has determined that these regulations, while applicable to several diseases, are necessary to promulgate on an emergency basis to control the spread of monkeypox, polio and COVID-19 in New York State. Accordingly, current circumstances necessitate immediate action, and pursuant to the State Administrative Procedure Act Section 206(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 201, 206, and 225 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new Section 2.60, to be effective upon filing with the Secretary of State, to read as follows:

Section 2.60 is added to read as follows:

2.60. Face Coverings for COVID-19 Prevention.

(a) As determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread, any person who is two years of age or older and able to medically tolerate a face-covering may be required to cover their nose and mouth with a mask or face-covering when: (1) in a public place and unable to maintain, or when not maintaining, physical distance; or (2) in certain settings as determined by the Commissioner, which may include schools, public transit, homeless shelters, correctional facilities, nursing homes, and health care settings, and which may distinguish between individuals who are vaccinated against COVID-19 and those that are not vaccinated. The Commissioner shall issue findings regarding the necessity of face-covering requirements at the time such requirements are announced.

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

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

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

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

(f) Penalities and enforcement.

(i) A violation of any provision of this Section is subject to all civil and criminal penalties as provided for by law. Individuals or entities that violate this Section are subject to a maximum fine of $1,000 for each violation. For purposes of civil penalties, each day that an entity operates in a manner inconsistent with the Section shall constitute a separate violation under this Section.

(ii) All local health officers shall take such steps as may be necessary to enforce the provisions of this Section accordance with the Public Health Law and this Title.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for adding a new Section 2.60 is sections 201, 206, and 225 of the Public Health Law.

Legislative Objectives:

The legislative objective of PHL § 201 includes authorizing the New York State Department of Health ("Department") to control and promote the control of communicable diseases to reduce their spread. Likewise, the legislative objective of PHL § 206 includes authorizing the Commissioner of Health to take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law, including control of communicable diseases. The legislative objective of Public Health Law § 225 is, in part, to protect the public health by authorizing PHHPC, with the approval of the Commissioner, to amend the State Sanitary Code to address public health issues related to communicable disease.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory and other symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults, those who have serious underlying medical health conditions and those who are unvaccinated.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

Now, more than two years after the first cases were identified in the United States COVID-19 continues to impact New York State. Beyond the ongoing COVID-19 burden in communities, certain settings such nursing homes and health care settings, have been at increased risk for transmission. These regulations provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. The regulations are necessary to permit flexibility to allow the Department to quickly adapt to changing circumstances related to the spread of COVID-19 and increasing transmission rates.

COSTS:

Costs to Regulated Parties:

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

state since March of 2020. Accordingly, this regulation does not impose additional costs to regulated parties.

Costs to Local and State Governments:

State and local government are authorized to enforce civil and criminal penalties related to the violation of these regulations, and there may be some cost of enforcement, however such costs are anticipated to be minimal as these provisions continue existing enforcement requirements.

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

As part of ongoing efforts to address COVID-19, local governments have been partners in implementing and enforcing measures to limit the spread and/or mitigate the impact of COVID-19 within their jurisdictions since March of 2020. Further, local governments have separate authority and responsibilities to control disease within their jurisdictions pursuant to PHL § 2100 and Part 2 of the State Sanitary Code.

Duplication:

There is no duplication of federal law.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

The regulations will become effective upon filing with the Department of State and will expire, unless renewed, 60 days from the date of filing. As COVID-19 is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 60-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed ruling-making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

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

Compliance Costs:

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

state since March of 2020. Accordingly, this regulation does not impose additional costs to regulated parties.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

JOB IMPACT STATEMENT

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

EMERGENCY JUSTIFICATION

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory and other symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

Now, more than two years after the first cases were identified in the United States COVID-19 continues to impact New York State. Beyond the ongoing COVID-19 burden in communities, certain settings such as nursing homes and health care settings, have been at increased risk for transmission.

To that end, these regulations provide that masking may be required under certain circumstances, as determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread. Based on the foregoing, the Department has determined that these emergency

regulations are necessary to permit flexibility to quickly adapt to changing circumstances and increasing transmission rates and control the spread of COVID-19, necessitating immediate action. Accordingly, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 225(4), 2304, 2305 and 2311 of the Public Health Law, Section 23.1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon filing with the Secretary of State, to read as follows:

Group B of Section 23.1 is amended to read as follows:

Group B

Facilities referred to in section 23.2 of this Part must provide diagnosis and treatment, including prevention services, as provided in section 23.2(d) of this Part for the following STDs:

Human Papilloma Virus (HPV)

Genital Herpes Simplex

Human Immunodeficiency Virus (HIV)

<u>Monkeypox Virus (MPV)</u>

Regulatory Impact Statement

Statutory Authority:

Pursuant to sections 225(4), 2304, 2305 and 2311 of the Public Health Law (PHL), the Commissioner of Health and the Public Health and Health Planning Council have the authority to adopt regulations that list the sexually transmitted diseases (STDs) for which PHL Article 23 is applicable and, in particular, that establish requirements for local health departments (LHDs) concerning STD services.

Legislative Objectives:

PHL section 2311 requires the Commissioner of Health to promulgate a list of STDs. The purpose of Article 23 of the PHL, and its associated regulations, is to ensure that persons at risk for or diagnosed with an STD have access to diagnosis and treatment, including prevention services, thereby improving their health and public health in New York State. Additionally, providing STD diagnosis and treatment, including prevention services, is vital to protecting the health of newborn children whose mothers may have an STD.

Needs and Benefits:

This amendment adds monkeypox virus to Group B of the existing list of STDs. County LHDs already have an obligation to control the spread of monkeypox under PHL Article 6 communicable disease guidance. Consistent with such guidance, this regulation requires STD clinics operated by LHDs or providing services through contractual arrangements to provide diagnosis and treatment, including prevention services, to persons diagnosed or at risk for

monkeypox, either directly or through referral. Further, minors will be able to consent to their own monkeypox testing, prevention services (including vaccine), and treatment.

This amendment supports the Department's plan to control the current and future monkeypox outbreaks by connecting persons diagnosed with, exposed to, or at risk of monkeypox with testing, vaccine, treatment, and prevention services. Young people currently face barriers that can prevent or delay access to care, including denial and fear of their monkeypox infection, misinformation, monkeypox-related stigma, low self-esteem, lack of insurance, homelessness, substance use, mental health issues, and lack of adequate support systems. Because of these factors, many young people need the ability to consent to monkeypox diagnosis and treatment, including prevention services.

These regulations will help ensure that more young people have optimal health outcomes and do not transmit the virus to others. In addition, young people will have the ability to consent to monkeypox related preventive services, including those who have been exposed to STDs or who are at high risk for monkeypox. Under the amended regulation, such individuals will be able to obtain monkeypox vaccine so they can remain monkeypox negative. These amendments are necessary to provide appropriate health care rights and protections to minors and remove the barriers that can prevent or delay access to diagnosis and treatment, including prevention services.

Costs to Regulated Parties:

LHDs may diagnose patients for monkeypox by offering monkeypox testing. In regard to monkeypox treatment, including prevention services, some LHDs may experience up-front costs

associated with providing treatment to additional individuals. However, these regulations do not mandate that an LHD provide treatment directly. As with the other conditions already listed in Group B, LHDs may fulfill their obligation to provide monkeypox treatment by referring the patient to another provider; they are not required to pay for treatment.

Providing diagnosis and treatment, including monkeypox vaccine, to persons diagnosed or at risk for monkeypox may increase the use of monkeypox vaccine. It is anticipated that any increase in monkeypox vaccination will decrease the number of people who become monkeypox positive, thereby greatly decreasing the cost of providing care to individuals who are monkeypox positive. The monkeypox vaccine is provided by the federal government at no cost to the State.

Generally, LHDs and other providers that provide monkeypox treatment must seek to offset any costs by billing insurance for rendered services. At this time, treatment for monkeypox, including Tecovirimat (also known as TPOXX or ST-246), is provided under an expanded access Investigational New Drug (EA-IND) protocol, which allows for the use of TPOXX for primary or early empiric treatment of non-variola orthopoxvirus infections, including monkeypox, in adults and children of all ages. The treatment is provided at no cost.

Costs to State Government:

There are no direct costs to the State or the Department. The Department will continue to work with LHDs using existing resources to provide guidance regarding the control of communicable diseases using STD clinics and other methods as required by the PHL Article 6 State aid rules and these regulations.

Local Government Mandates:

As discussed above, these amendments will require STD clinics operated by LHDs to provide monkeypox diagnosis and treatment, including prevention services, either directly or by referral. LHDs are not, however, required to provide monkeypox treatment directly; they may refer patients to other providers for treatment.

Paperwork:

LHDs will be required to bill public and commercial third-party payers to the extent practicable to offset the costs of providing monkeypox treatment services.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that conflict with this rule. Like other STDs (syphilis, gonorrhea, etc.), since MPV will be listed on both the state communicable disease list and the STD list, two sets of Article 6 guidance documents for LHDs will apply to MPV.

Alternatives:

The alternative is to continue not to list monkeypox as an STD in New York. However, to advance the goal of controlling monkeypox outbreaks, monkeypox should be listed as an STD. This will not only reduce morbidity and mortality, but will also decrease health care costs statewide by lowering the prevalence of monkeypox and the cost of providing care to monkeypox-positive individuals.

Federal Standards:

There are no Federal standards in this area.

Compliance Schedule:

The amendment will take effect when it is filed with the Secretary of State. The Department will assist affected entities in compliance efforts.

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Regulatory Flexibility Analysis
for Small Businesses and Local Governments

Effect of the Rule:

The proposed amendments to 10 NYCRR Part 23 will impact the 58 local health departments (LHDs) and the New York City Department of Health and Mental Hygiene, which are required to provide STD services as a condition of State Aid pursuant to Article 6 of the Public Health Law. In addition, local governments are responsible for the local share of the cost of the Medicaid program. The amendments will not impact small businesses (i.e., small private practices or clinics) any differently from other health care providers.

This mandate does not create new costs for local government. Currently, since monkeypox is listed as a communicable disease in 10 NYCRR §2.1, and since LHDs are responsible for controlling the spread of communicable diseases, LHDs are already required to treat monkeypox. Therefore, this regulation adding monkeypox to the list of STDs will not create any unfunded mandate for local government.

Increasing vaccination rates will decrease the number of monkeypox cases and will reduce Medicaid costs to care for Medicaid recipients with monkeypox, thereby reducing the local share of the cost of the Medicaid program. Since the vaccine is provided for free, this regulation implements a public health measure that will save money for local governments that are supported by property taxpayers.

Compliance Requirements:

Pursuant to these amendments, LHDs must provide monkeypox diagnosis and treatment, including prevention services, either directly in an STD clinic, or by making a written or electronic prescription or referral to another health care provider. Implementation of this rule will require recordkeeping and reporting by LHDs.

Professional Services:

Those LHDs that provide monkeypox treatment services directly or through contract may be required to ensure the development or updating of billing systems to comply with the obligation to seek payment from insurance providers to the extent practicable.

Compliance Costs:

LHDs diagnose patients for monkeypox by offering monkeypox testing. In regard to monkeypox treatment, including prevention services, some LHDs may experience up-front costs associated with providing treatment to additional individuals. However, these regulations do not mandate that an LHD provide treatment directly. As with the other conditions already listed in Group B, LHDs may fulfill their obligation to provide monkeypox treatment by referring the patient to another provider; they are not required to pay for treatment.

Providing diagnosis and treatment, including prevention services, to persons diagnosed or at risk for monkeypox may increase the use of monkeypox vaccine. It is anticipated that any increase in the use of prophylactic services will decrease the number of people who become monkeypox positive, thereby greatly reducing the cost of providing care to individuals who are monkeypox positive.

In addition, LHDs and other providers that provide monkeypox treatment must seek to offset any costs by billing insurance for rendered services to the extent practicable. Remaining costs may be eligible for reimbursement from other sources that fund monkeypox treatment in New York.

Economic and Technological Feasibility:

The requirement to seek insurance recovery and the availability of other funding sources make this requirement economically feasible. There are no new technology requirements. The Department will also provide technical advice and support as needed.

Minimizing Adverse Impact:

LHDs and other providers that provide monkeypox treatment must seek to offset any costs by billing insurance for rendered services. Remaining costs may be eligible for reimbursement from other sources that fund monkeypox treatment in New York.

Small Business and Local Government Participation:

Community stakeholders, representative of regions and businesses across New York State, have been engaged in the response to the monkeypox outbreak, including ensuring that minors have the right to consent to monkeypox treatment and prevention services. The recommendation to amend regulations to ensure minors have the right to consent to monkeypox treatment and prevention services has been supported by community stakeholders. The Department sought and received input from local health departments, including the New York City Department of Health and Mental Hygiene.

This regulation does not have the effect of imposing a mandate. Rather, it permits local governments to expand access to monkeypox vaccine, which will result in cost savings, because less money will need to be spent on treatment. LHDs are already providing monkeypox vaccine. The reason minors should be permitted to access monkeypox vaccine is that it will prevent minors from getting monkeypox, which furthers the Department's mission to decrease morbidity and mortality.

Cure Period:

Chapter 524 of the Law of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

The proposed amendments to 10 NYCRR Part 23 will impact clinicians in rural areas no differently than throughout New York State.

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

This rule imposes no mandates upon entities in rural areas outside those entities noted in Article 23 of the Public Health Law. As stated, local health departments (LHDs) must provide monkeypox treatment, including prevention services, either directly in an STD clinic, or by making a written or electronic prescription or referral to another health care provider. Implementation of this rule will require recordkeeping and reporting by LHDs.

Costs:

Some clinicians may experience up-front costs associated with providing monkeypox treatment services, including prevention services, to additional individuals. However, these regulations do not mandate health care providers to provide monkeypox treatment services. Any provider that does provide monkeypox treatment for additional patients can offset any costs by billing for services rendered.

Minimizing Adverse Impact:

As discussed above, the ability to recover costs will minimize the impact of these regulations.

Rural Area Participation:

Community stakeholders, representative of regions and businesses across New York State, including those in rural areas, have been engaged in the response to the monkeypox outbreak, including ensuring that minors have the right to consent to monkeypox treatment and prevention services. The recommendation to amend regulations to ensure minors have the right to consent to monkeypox treatment and prevention services has been supported by community stakeholders in rural areas.

Statement in Lieu of
Job Impact Statement

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendments, that it will not have an adverse impact on jobs and employment opportunities.

Emergency Justification

Compliance with the requirements of the State Administrative Procedure Act for filing of a 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.

Monkeypox virus is a rare, viral infection that does not usually cause serious illness. However, it can result in hospitalization or death. Monkeypox can result in individuals experiencing severe pain requiring isolation and significant life disruptions as well as stigma. Health officials in New York State, the federal government, and in countries around the world are monitoring cases of monkeypox in areas that do not usually report monkeypox infections, including in New York State. Monkeypox spreads through close, physical contact between people. This means anyone can get monkeypox. However, based on the current outbreak, certain populations are being affected by monkeypox more than others, including gay/bisexual men and other men who have sex with men, transgender individuals, and non-binary individuals, among others.

As of August 26, 2022, there are 47,652 confirmed cases of monkeypox reported to the World Health Organization from 99 countries, of which 92 have not historically reported monkeypox.

On July 23, 2022, the World Health Organization designated monkeypox a public health emergency of international concern.

On August 4, 2022, the Secretary of Health and Human Services determined that as a result of the consequences of an outbreak of monkeypox cases across multiple states in the United States, a public health emergency exists nationwide. As of August 22, 2022, there are

17,432 confirmed monkeypox cases across all 50 states, the District of Columbia, and Puerto Rico.

On July 28, 2022, with the increase in monkeypox cases in New York State and more counties reporting cases, the New York State Commissioner of Health determined that monkeypox is communicable, rapidly emergent and a significant threat to the public health. Further, as one in five monkeypox cases in the country are in New York State, Governor Hochul declared a State Disaster Emergency on July 29, 2022. As of August 26, 2022, New York State reports 3,124 cases.

This emergency regulation is necessary to confirm the Commissioner's designation of monkeypox as a sexually transmitted disease and to permit the Department to take necessary and appropriate action to prevent the spread of this communicable disease.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 225(4), 2304, 2305 and 2311 of the Public Health Law, Section 23.1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the State Register, to read as follows:

Group B of Section 23.1 is amended to read as follows:

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<u>Monkeypox Virus (MPV)</u>

Regulatory Impact Statement

Statutory Authority:

Pursuant to sections 225(4), 2304, 2305 and 2311 of the Public Health Law (PHL), the Commissioner of Health and the Public Health and Health Planning Council have the authority to adopt regulations that list the sexually transmitted diseases (STDs) for which PHL Article 23 is applicable and, in particular, that establish requirements for local health departments (LHDs) concerning STD services.

Legislative Objectives:

PHL section 2311 requires the Commissioner of Health to promulgate a list of STDs. The purpose of Article 23 of the PHL, and its associated regulations, is to ensure that persons at risk for or diagnosed with an STD have access to diagnosis and treatment, including prevention services, thereby improving their health and public health in New York State. Additionally, providing STD diagnosis and treatment, including prevention services, is vital to protecting the health of newborn children whose mothers may have an STD.

Needs and Benefits:

This amendment adds monkeypox virus to Group B of the existing list of STDs. County LHDs already have an obligation to control the spread of monkeypox under PHL Article 6 communicable disease guidance. Consistent with such guidance, this regulation requires STD clinics operated by LHDs or providing services through contractual arrangements to provide diagnosis and treatment, including prevention services, to persons diagnosed or at risk for

monkeypox, either directly or through referral. Further, minors will be able to consent to their own monkeypox testing, prevention services (including vaccine), and treatment.

This amendment supports the Department's plan to control the current and future monkeypox outbreaks by connecting persons diagnosed with, exposed to, or at risk of monkeypox with testing, vaccine, treatment, and prevention services. Young people currently face barriers that can prevent or delay access to care, including denial and fear of their monkeypox infection, misinformation, monkeypox-related stigma, low self-esteem, lack of insurance, homelessness, substance use, mental health issues, and lack of adequate support systems. Because of these factors, many young people need the ability to consent to monkeypox diagnosis and treatment, including prevention services.

These regulations will help ensure that more young people have optimal health outcomes and do not transmit the virus to others. In addition, young people will have the ability to consent to monkeypox related preventive services, including those who have been exposed to STDs or who are at high risk for monkeypox. Under the amended regulation, such individuals will be able to obtain monkeypox vaccine so they can remain monkeypox negative. These amendments are necessary to provide appropriate health care rights and protections to minors and remove the barriers that can prevent or delay access to diagnosis and treatment, including prevention services.

Costs to Regulated Parties:

LHDs may diagnose patients for monkeypox by offering monkeypox testing. In regard to monkeypox treatment, including prevention services, some LHDs may experience up-front costs

associated with providing treatment to additional individuals. However, these regulations do not mandate that an LHD provide treatment directly. As with the other conditions already listed in Group B, LHDs may fulfill their obligation to provide monkeypox treatment by referring the patient to another provider; they are not required to pay for treatment.

Providing diagnosis and treatment, including monkeypox vaccine, to persons diagnosed or at risk for monkeypox may increase the use of monkeypox vaccine. It is anticipated that any increase in monkeypox vaccination will decrease the number of people who become monkeypox positive, thereby greatly decreasing the cost of providing care to individuals who are monkeypox positive. The monkeypox vaccine is provided by the federal government at no cost to the State.

Generally, LHDs and other providers that provide monkeypox treatment must seek to offset any costs by billing insurance for rendered services. At this time, treatment for monkeypox, including Tecovirimat (also known as TPOXX or ST-246), is provided under an expanded access Investigational New Drug (EA-IND) protocol, which allows for the use of TPOXX for primary or early empiric treatment of non-variola orthopoxvirus infections, including monkeypox, in adults and children of all ages. The treatment is provided at no cost.

Costs to State Government:

There are no direct costs to the State or the Department. The Department will continue to work with LHDs using existing resources to provide guidance regarding the control of communicable diseases using STD clinics and other methods as required by the PHL Article 6 State aid rules and these regulations.

Local Government Mandates:

As discussed above, these amendments will require STD clinics operated by LHDs to provide monkeypox diagnosis and treatment, including prevention services, either directly or by referral. LHDs are not, however, required to provide monkeypox treatment directly; they may refer patients to other providers for treatment.

Paperwork:

LHDs will be required to bill public and commercial third-party payers to the extent practicable to offset the costs of providing monkeypox treatment services.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that conflict with this rule. Like other STDs (syphilis, gonorrhea, etc.), since MPV will be listed on both the state communicable disease list and the STD list, two sets of Article 6 guidance documents for LHDs will apply to MPV.

Alternatives:

The alternative is to continue not to list monkeypox as an STD in New York. However, to advance the goal of controlling monkeypox outbreaks, monkeypox should be listed as an STD. This will not only reduce morbidity and mortality, but will also decrease health care costs statewide by lowering the prevalence of monkeypox and the cost of providing care to monkeypox-positive individuals.

Federal Standards:

There are no Federal standards in this area.

Compliance Schedule:

The amendment will take effect upon publication of a Notice of Adoption in the State Register.

The Department will assist affected entities in compliance efforts.

Contact Person: Katherine Ceroalo
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Regulatory Flexibility Analysis
for Small Businesses and Local Governments

Effect of the Rule:

The proposed amendments to 10 NYCRR Part 23 will impact the 58 local health departments (LHDs) and the New York City Department of Health and Mental Hygiene, which are required to provide STD services as a condition of State Aid pursuant to Article 6 of the Public Health Law. In addition, local governments are responsible for the local share of the cost of the Medicaid program. The amendments will not impact small businesses (i.e., small private practices or clinics) any differently from other health care providers.

This mandate does not create new costs for local government. Currently, since monkeypox is listed as a communicable disease in 10 NYCRR §2.1, and since LHDs are responsible for controlling the spread of communicable diseases, LHDs are already required to treat monkeypox. Therefore, this regulation adding monkeypox to the list of STDs will not create any unfunded mandate for local government.

Increasing vaccination rates will decrease the number of monkeypox cases and will reduce Medicaid costs to care for Medicaid recipients with monkeypox, thereby reducing the local share of the cost of the Medicaid program. Since the vaccine is provided for free, this regulation implements a public health measure that will save money for local governments that are supported by property taxpayers.

Compliance Requirements:

Pursuant to these amendments, LHDs must provide monkeypox diagnosis and treatment, including prevention services, either directly in an STD clinic, or by making a written or electronic prescription or referral to another health care provider. Implementation of this rule will require recordkeeping and reporting by LHDs.

Professional Services:

Those LHDs that provide monkeypox treatment services directly or through contract may be required to ensure the development or updating of billing systems to comply with the obligation to seek payment from insurance providers to the extent practicable.

Compliance Costs:

LHDs diagnose patients for monkeypox by offering monkeypox testing. In regard to monkeypox treatment, including prevention services, some LHDs may experience up-front costs associated with providing treatment to additional individuals. However, these regulations do not mandate that an LHD provide treatment directly. As with the other conditions already listed in Group B, LHDs may fulfill their obligation to provide monkeypox treatment by referring the patient to another provider; they are not required to pay for treatment.

Providing diagnosis and treatment, including prevention services, to persons diagnosed or at risk for monkeypox may increase the use of monkeypox vaccine. It is anticipated that any increase in the use of prophylactic services will decrease the number of people who become monkeypox

positive, thereby greatly reducing the cost of providing care to individuals who are monkeypox positive.

In addition, LHDs and other providers that provide monkeypox treatment must seek to offset any costs by billing insurance for rendered services to the extent practicable. Remaining costs may be eligible for reimbursement from other sources that fund monkeypox treatment in New York.

Economic and Technological Feasibility:

The requirement to seek insurance recovery and the availability of other funding sources make this requirement economically feasible. There are no new technology requirements. The Department will also provide technical advice and support as needed.

Minimizing Adverse Impact:

LHDs and other providers that provide monkeypox treatment must seek to offset any costs by billing insurance for rendered services. Remaining costs may be eligible for reimbursement from other sources that fund monkeypox treatment in New York.

Small Business and Local Government Participation:

Community stakeholders, representative of regions and businesses across New York State, have been engaged in the response to the monkeypox outbreak, including ensuring that minors have the right to consent to monkeypox treatment and prevention services. The recommendation to amend regulations to ensure minors have the right to consent to monkeypox treatment and prevention services has been supported by community stakeholders. The Department sought and

received input from local health departments, including the New York City Department of Health and Mental Hygiene.

This regulation does not have the effect of imposing a mandate. Rather, it permits local governments to expand access to monkeypox vaccine, which will result in cost savings, because less money will need to be spent on treatment. LHDs are already providing monkeypox vaccine. The reason minors should be permitted to access monkeypox vaccine is that it will prevent minors from getting monkeypox, which furthers the Department's mission to decrease morbidity and mortality.

Cure Period:

Chapter 524 of the Law of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

The proposed amendments to 10 NYCRR Part 23 will impact clinicians in rural areas no differently than throughout New York State.

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

This rule imposes no mandates upon entities in rural areas outside those entities noted in Article 23 of the Public Health Law. As stated, local health departments (LHDs) must provide monkeypox treatment, including prevention services, either directly in an STD clinic, or by making a written or electronic prescription or referral to another health care provider. Implementation of this rule will require recordkeeping and reporting by LHDs.

Costs:

Some clinicians may experience up-front costs associated with providing monkeypox treatment services, including prevention services, to additional individuals. However, these regulations do not mandate health care providers to provide monkeypox treatment services. Any provider that does provide monkeypox treatment for additional patients can offset any costs by billing for services rendered.

Minimizing Adverse Impact:

As discussed above, the ability to recover costs will minimize the impact of these regulations.

Rural Area Participation:

Community stakeholders, representative of regions and businesses across New York State, including those in rural areas, have been engaged in the response to the monkeypox outbreak, including ensuring that minors have the right to consent to monkeypox treatment and prevention services. The recommendation to amend regulations to ensure minors have the right to consent to monkeypox treatment and prevention services has been supported by community stakeholders in rural areas.

Statement in Lieu of
Job Impact Statement

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendments, that it will not have an adverse impact on jobs and employment opportunities.