

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:

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)

Mpox

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 mpox to Group B of the existing list of STDs. County LHDs already have an obligation to control the spread of mpox 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 mpox, either directly or through

referral. Further, minors will be able to consent to their own mpox testing, prevention services (including vaccine), and treatment.

This amendment supports the Department's plan to control the current and future mpox outbreaks by connecting persons diagnosed with, exposed to, or at risk of mpox 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 mpox infection, misinformation, mpox-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 mpox 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 mpox related preventive services, including those who have been exposed to STDs or who are at high risk for mpox. Under the amended regulation, such individuals will be able to obtain mpox vaccine so they can remain mpox 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 mpox by offering mpox testing. In regard to mpox 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 mpox treatment by referring the patient to another provider; they are not required to pay for treatment.

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

Generally, LHDs and other providers that provide mpox treatment must seek to offset any costs by billing insurance for rendered services. At this time, treatment for mpox, 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 mpox, 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 mpox diagnosis and treatment, including prevention services, either directly or by referral. LHDs are not, however, required to provide mpox 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 mpox 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 mpox 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 mpox.

Alternatives:

The alternative is to continue not to list mpox as an STD in New York. However, to advance the goal of controlling mpox outbreaks, mpox 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 mpox and the cost of providing care to mpox-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.

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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 mpox 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 mpox. Therefore, this regulation adding mpox to the list of STDs will not create any unfunded mandate for local government.

Increasing vaccination rates will decrease the number of mpox cases and will reduce Medicaid costs to care for Medicaid recipients with mpox, 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 mpox 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 mpox 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 mpox by offering mpox testing. In regard to mpox 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 mpox 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 mpox may increase the use of mpox vaccine. It is anticipated that any increase in the use of prophylactic services will decrease the number of people who become mpox positive, thereby greatly reducing the cost of providing care to individuals who are mpox positive.

In addition, LHDs and other providers that provide mpox 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 mpox 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 mpox 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 mpox 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 mpox outbreak, including ensuring that minors have the right to consent to mpox treatment and prevention services. The recommendation to amend regulations to ensure minors have the right to consent to mpox 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 mpox vaccine, which will result in cost savings, because less money will need to be spent on treatment. LHDs are already providing mpox vaccine. The reason minors should be permitted to access mpox vaccine is that it will prevent minors from getting mpox, 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 mpox 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 mpox treatment services, including prevention services, to additional individuals. However, these regulations do not mandate health care providers to provide mpox treatment services. Any provider that does provide mpox 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 mpox outbreak, including ensuring that minors have the right to consent to mpox treatment and prevention services. The recommendation to amend regulations to ensure minors have the right to consent to mpox 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.

Assessment of Public Comments

The New York State Department of Health (NYSDOH) received one comment, expressing support for the proposed amendments to 10 NYCRR Section 23.1. The comment was submitted by an association representing local health departments.

Comment:

The association supports the amendment to 10 NYCRR Section 23.1 and its immediate adoption.

Response:

NYSDOH appreciates the support. NYSDOH also notes that the final rule uses the term “mpox” instead of “monkeypox virus” or “MPV” – consistent with the updated terminology adopted by the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and NYSDOH.