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, Sections 23.1 and 23.2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective upon publication of a Notice of Adoption in the New York 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)

Section 23.2 is amended to read as follows:

Each health district shall provide adequate facilities either directly or through contract for the diagnosis and treatment, including prevention services, of persons living within its jurisdiction who are infected or [are suspected] at risk of being infected with an STD as specified in section 23.1 of this Part.

* * *

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 sexually transmissible diseases. 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, thereby improving their health and public health in New York State. Additionally, providing STD diagnosis and treatment is vital to protecting the health of newborn children whose mothers may have an STD.

Needs and Benefits:

This amendment adds Human Immunodeficiency Virus (HIV) to Group B of the existing list of sexually transmitted diseases (STDs). By doing so, STD clinics operated by LHDs or providing services through contractual arrangements will be required to provide diagnosis and treatment, including prevention services, to persons diagnosed or at risk for HIV, either directly or through referral. Further, minors will be able to consent to HIV treatment, including preventative antiretroviral medications for prophylaxis. Additionally, Sections 23.1 and 23.2 are amended to

clarify that preventive services are included in the services that STD clinics provide directly or by referral, for individuals who are at high risk for STD because of past exposure.

This amendment supports the Governor's plan to end the AIDS epidemic in New York State by 2020, by connecting persons diagnosed with HIV with treatment, including prevention services. After being diagnosed, young people currently face barriers that can prevent or delay access to care, including denial and fear of their HIV infection, misinformation, HIV-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 HIV 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 HIV related preventive services. Young people who have been exposed to STDs are at high risk for HIV. Under the amended regulation, such individuals will be able to consent to pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), just as they can for other reproductive or sexual health related services, so they can remain HIV 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 care.

Ensuring young people's right to the provision of confidential sexual health treatment is also essential to achieving federal goals. In particular, these amendments build on the goals of the National HIV/AIDS Strategy (NHAS) to reduce new infections by 25%, to increase access to care, to improve health outcomes for people living with HIV, and to reduce health disparities.

Costs to Regulated Parties:

LHDs diagnose patients for HIV by offering HIV testing, as required by PHL §2781-a. In regard to HIV 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 chronic conditions already listed in Group B, LHDs may fulfill their obligation to provide HIV 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 HIV may increase the use of HIV prophylactics, which may in turn initially increase the cost of the Medicaid program. However it is anticipated that any increase in the use of prophylactic services will decrease the number of people who become HIV positive, thereby greatly decreasing Medicaid program costs in the long run. Additionally, the amendments will lower the prevalence of HIV, thereby reducing the cost of providing care to individuals who are HIV positive.

In addition, LHDs and other providers that provide HIV 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 HIV treatment in New York, such as the HIV Uninsured Care Programs, which include: the AIDS Drug Assistance Program (ADAP), ADAP Plus, ADAP Plus Insurance Continuation (APIC), HIV Home Care Program, and the PrEP Assistance Program (PrEP-AP).

Local Government Mandates:

As discussed above, these amendments will require LHDs to provide HIV diagnosis and treatment, including prevention services, either directly or by referral. LHDs are not, however, required to provide HIV 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 offset the costs of providing HIV treatment services.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

The alternative is to continue not to list HIV as an STD in New York. However, to advance the goal of ending the AIDS epidemic by the end of 2020, HIV 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 HIV and the cost of providing care to HIV-positive individuals.

Federal Standards:

There are no Federal standards in this area.

Compliance Schedule:

The amendment will take effect when the Notice of Adoption is published 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 local health departments (LHDs), 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.

Compliance Requirements:

Pursuant to these amendments, LHDs must provide HIV 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 HIV 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.

Compliance Costs:

LHDs diagnose patients for HIV by offering HIV testing, as required by PHL §2781-a. In regard to HIV 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 chronic conditions already listed in Group B, LHDs may fulfill their obligation to provide HIV 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 HIV may increase the use of HIV prophylactics, which may in turn initially increase the cost of the Medicaid program. However it is anticipated that any increase in the use of prophylactic services will decrease the number of people who become HIV positive, thereby greatly decreasing Medicaid program costs in the long run. Additionally, the amendments will lower the prevalence of HIV, thereby reducing the cost of providing care to individuals who are HIV positive.

In addition, LHDs and other providers that provide HIV 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 HIV treatment in New York, such as the HIV Uninsured Care Programs, which include: the AIDS Drug Assistance Program (ADAP), ADAP Plus, ADAP Plus Insurance Continuation (APIC), HIV Home Care Program, and the PrEP Assistance Program (PrEP-AP).

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 HIV treatment must seek to offset any costs by billing insurance for rendered services. Remaining costs may be eligible for reimbursement other sources that fund HIV treatment in New York, such as the HIV Uninsured Care Programs, which include: the AIDS Drug Assistance Program (ADAP), ADAP Plus, ADAP Plus Insurance Continuation (APIC), HIV Home Care Program, and the PrEP Assistance Program (PrEP-AP).

Small Business and Local Government Participation:

Community stakeholders representative of regions and businesses across New York State have been engaged in the development of the proposed amendments. Specifically, the recommendation to amend regulations to assure minors have the right to consent to HIV treatment and prevention services was specifically addressed by the AIDS Advisory Council (AAC), the AAC Ending the Epidemic Subcommittee and the AAC ETE Subcommittee STD Workgroup. The recommendation to amend regulations to assure minors have the right to consent to HIV treatment and prevention services was also specifically identified through Ending the Epidemic regional discussions held in August through November of 2015 within each Ryan White Region, with over 800 New Yorkers having participated in these discussions.

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 Probability 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 the law. As stated, local health departments (LHDs) must provide HIV 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:

Rural health care providers are already required to offer HIV testing under PHL §2781-a. Some clinicians may experience up-front costs associated with providing HIV treatment services, including prevention services, to additional individuals. However, these regulations do not mandate health care providers to provide HIV treatment services. Any provider that does provide HIV 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 development of the proposed amendments. Specifically, the recommendation to amend regulations to assure minors have the right to consent to HIV treatment and prevention services was specifically addressed by the AIDS Advisory Council (AAC), the AAC Ending the Epidemic Subcommittee and the AAC ETE Subcommittee STD Workgroup. The recommendation to amend regulations to ensure minors have the right to consent to HIV treatment and prevention services was also specifically identified through Ending the Epidemic regional discussions held in August through November of 2015 within each Ryan White Region, with over 800 New Yorkers having participated in these discussions.

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.