

Pursuant to the authority vested in the Commissioner of Health by Sections 2139 and 2786 of the Public Health Law (PHL), Sections 63.2 and 63.4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended to read as follows, to be effective upon publication of a Notice of Adoption in the New York State Register:

Section 63.2 is amended to read as follows:

63.2 Application. These regulations apply to physicians and other persons authorized by law to order laboratory tests or to make medical diagnoses, laboratories, blood banks, tissue banks and organ procurement organizations, to persons who receive confidential HIV-related information in the course of providing any health or social service and to persons who receive confidential HIV-related information pursuant to a release. These regulations do not apply to information which was received by the Commissioner under Subpart 24-1 of this Title and protected from disclosure pursuant to Public Health Law section 206(1)(j). [These regulations do not apply to insurance institutions and insurance support organizations, except as noted in section 63.6(a)(9), (10) and (12) of this Part. Health] Insurance institutions, insurance support organizations, and health care providers associated with or under contract to a health maintenance organization or other medical services plan are subject to these regulations.

Paragraph (1) of subdivision (a) of section 63.4 is amended to read as follows:

(a)(1) All determinations or diagnoses of Human Immunodeficiency Virus (HIV) infection, HIV-related illness, and Acquired Immune Deficiency Syndrome (AIDS) shall be reported to the

commissioner by physicians and other persons authorized to order diagnostic tests or make medical diagnoses or their agents as soon as possible but no later than [14] seven (7) days after the provider's receipt of a positive laboratory result or after diagnosis, whichever is sooner.

Physicians and other persons authorized to order diagnostic tests or make medical diagnoses, or their agents, shall report any determination or diagnosis of acute HIV infection, including primary HIV infection, acute retroviral syndrome, and early HIV infection, within one day (24 hours) of such determination or diagnosis. Acute HIV infection is the earliest stage of HIV disease, and it precedes the development of detectable antibodies to HIV resulting from the viral infection. A report of acute HIV infection must include the basis for the determination or diagnosis, which is: (i) laboratory testing results demonstrating the presence of p24 antigen and HIV virus (RNA or DNA), in the absence of HIV antibodies; and/or (ii) clinical evidence of documented negative testing history which includes previous negative or indeterminate test results within 180 days before the first confirmed positive HIV test result of any type.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) §2139 gives the Commissioner of Health (Commissioner) the authority to promulgate regulations to effectuate the purposes of PHL Article 21, Title 3 (Control of Acute Communicable Diseases – Human Immunodeficiency Virus). PHL §2786 gives the Commissioner the authority to promulgate regulations concerning the implementation of PHL Article 27-F (HIV and AIDS Related Information).

Legislative Objectives:

Title 3 of PHL Article 21 and PHL 27-F were enacted, *inter alia*, to permit the Department of Health (Department) to conduct epidemiologic surveillance for HIV/AIDS: to record, monitor and evaluate the progression of the HIV/AIDS epidemic in the state. By providing for confidential reporting, these laws permit the Department to assess the spread of the disease in various localities and among risk group, thereby enabling focused prevention efforts and the targeting of scarce health resources where they can be most effective.

Needs and Benefits:

Under PHL §2784, PHL Article 27-F does not apply to insurance institutions, except for the provisions of PHL Article 27-F regarding re-disclosure of confidential HIV-related information. Insurance institutions are not, however, exempt from the reporting requirement in PHL Article 21, Title 3. Under PHL §2130, the duty to report AIDS and HIV infection cases and

data applies to every physician or other person authorized by law to order diagnostic tests or make a medical diagnosis, including such persons doing so for insurance institutions.

Under PHL Article 21, Title 3, AIDS and HIV infection cases are reported to the New York State AIDS Case Surveillance Registry (also known as the AIDS Surveillance Case Registry, the AIDS Registry or the HIV/AIDS Registry). Under PHL §2135, the data can be used to carry out the provisions of PHL Article 21, Title 3, including contact tracing.

In 2014, New York State began a series of initiatives to end the AIDS epidemic. L. 2014, Ch. 60, Part A, §3, amended PHL §2135 to effect this objective by allowing data reported under PHL Article 21, Title 3, to be used for the purpose of linking individuals with diagnosed HIV to care and/or ensuring that they are retained in care.

These amendments to 10 NYCRR sections 63.2 and 63.4: (1) clarify that HIV-testing conducted in the context of insurance institution underwriting decisions is required to be reported to the Department by clinicians under whose medical license the HIV testing is ordered; (2) reduce the time within which HIV diagnoses must be reported from 14 days to 7 days; and, (3) add a provision to 10 NYCRR Part 63.4 requiring that clinicians also report any case of acute HIV infection (i.e., primary HIV infection, acute retroviral syndrome, or early HIV infection) within one day (24 hours) of such determination or diagnosis.

Acute HIV infection is the earliest stage of HIV infection, lasting for approximately three to four weeks and often accompanied by flu-like symptoms. Acute infection precedes seroconversion – that is, the development of detectable antibodies to HIV resulting from the viral infection. Typically, it takes four weeks after infection occurs for HIV antibodies to develop and

be measurable through conventional laboratory tests. Antigen and virus are detectable within the first 2-3 weeks of HIV infection.

The risk of HIV transmission from persons with acute and early infection is much higher than that from persons with established infection. Extremely high levels of infectious virus become detectable in serum and genital secretions during acute HIV infection and persist for 10–12 weeks. Models based on data from cohort studies suggest that the rate of sexual transmission during acute infection is 2-6 times as high as that during established HIV infection. Acute HIV infection, despite its short duration, can account for 10%–50% of all new HIV transmissions, especially in persons who have multiple concurrent sex partners or high rates of partner change. Computer modeling of the HIV epidemic in New York State suggests that >40% of new HIV transmissions occurring in the State in 2020 originated from persons with acute or early HIV infection.

Medical providers who order diagnostic HIV testing, including those in insurance institutions, are trained to identify acute infection based on symptomology and laboratory test results. As the diagnostic clinician, they are uniquely able to rapidly alert NYSDOH of a person with acute or early infection.

The proposed amendments to 10 NYCRR Parts 63.2 and 63.4 will enable NYSDOH to identify persons in the most infectious stage of HIV infection earlier, with the public health aim of preventing onward transmission. It is a public health priority that persons with diagnosed acute or early HIV infection are offered timely partner services (see PHL §2133, 10 NYCRR §63.1(m)) to ensure the patient is linked to HIV treatment, and his/her sexual or needle-sharing contacts are tested/treated for HIV to prevent transmissions and outbreaks. Initiation of antiretroviral therapy (ART) during the early stage of HIV infection can benefit patients and

reduce HIV transmission. Treatment of acute and early HIV infection with combination ART improves laboratory markers of disease progression. Data also suggest that treatment of acute HIV infection might decrease the severity of acute disease, lower the viral set point, slow disease progression rates in the event therapy is stopped, reduce the size of the viral reservoir, and decrease the rate of viral mutation by suppressing viral replication and preserving immune function. Because very high levels of virus in blood and genital secretions increase infectiousness during and immediately after acute HIV infection, initiating treatment during acute infection can also reduce the risk of HIV transmission substantially.

The purpose of this regulation change is to mandate clinician and laboratory reporting of acute HIV infection (primary HIV infection, acute retroviral syndrome and early HIV infection) within one day (24 hours) of determination or diagnosis. This amendment defines acute HIV infection. Acute HIV infection is the earliest stage of HIV disease. It is defined based on (1) laboratory testing results demonstrating the presence of p24 antigen and HIV virus (RNA or DNA), in the absence of HIV antibodies; and/or (2) clinical evidence of documented negative testing history which includes previous negative or indeterminate test results within 180 days before the first confirmed positive HIV test result of any type. Negative or indeterminate testing immediately prior to confirmed HIV diagnosis allows for the identification of the exposure period in which the person became infected. The Centers for Disease Control and Prevention established the 180 day window in its definition of early HIV infection.

Further, 10 NYCRR §63.4 currently requires the reporting of persons with diagnosed HIV infection and AIDS to NYSDOH “as soon as possible but no later than 14 days” after diagnosis. The proposed amendment to 10 NYCRR §63.4 reduces the amount of time to report to “as soon as possible but no later than seven (7) days.” The Department has determined that it is

possible to make the reports within seven (7) days, so this is more of a clarification than a substantive change.

Finally, clarifying language is needed to specify within 10 NYCRR 63.2 that HIV-testing conducted in the context of insurance institution underwriting decisions is required to be reported to NYSDOH by clinicians under whose medical license the HIV-testing is ordered. Reporting is the crucial first step in triggering the rapid deployment of state Partner Services to interrupt forward transmission and facilitate linkage to care and early treatment.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

Mandating the reporting of acute and early HIV-infection is expected to carry minimal cost. Currently, there are other diseases, such as hemorrhagic fever, measles or Hepatitis in a food handler, which require notice to DOH within 24 hours. Adding diagnoses of acute HIV infection to the list of diseases requiring 24-hour reporting should not be burdensome under existing clinician reporting processes.

Costs to State and Local Governments:

There is no impact on costs to state and local governments associated with this proposed rule change.

Costs to the Department of Health:

There are minimal costs to the Department of Health associated with this proposed rule change that shall be met within existing resources.

Local Government Mandates:

There is no impact on local government mandates associated with this proposed rule change.

Paperwork:

No new paperwork is necessitated by the proposed regulation.

Duplication:

These regulatory amendments do not duplicate any New York State or federal rules.

Alternatives:

NYSDOH is not required to move forward with these regulations, but NYSDOH believes the regulations are needed for the reasons stated in the Needs and Benefits section of this Regulatory Impact Statement.

An alternative would be to make no changes to the regulations.

Federal Standards:

These regulations do not exceed any minimum standard of the federal government.

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.