HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF HIV, STD, AND TB SERVICES

HIV Infection Reporting

Adopted Recodification with Amendments: N.J.A.C. 8:57-2.1, 2.3, and 2.11 as 8:65-1.1, 1.3, and 3.2, Respectively

Adopted New Rules: N.J.A.C. 8:65-1.2, 1.4, 2, 3.1, and 3.3

Adopted Repeals: N.J.A.C. 8:57-2.2, 2.4 through 2.10, and 2.12 and 8:57-2 Appendices A through G

Proposed: September 7, 2021, at 53 N.J.R. 1440(a).

Adopted: June 16, 2022, by Judith M. Persichilli, R.N., B.S.N., M.A., Commissioner, Department of Health, in consultation with the Public Health Council, and with the approval of the Health Care Administration Board.

Filed: June 16, 2022, as R.2022 d.090, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:1A-7; 26:4-1 et seq., particularly 2, 15, 19, 129, and 130; and 26:5C-1 et seq., particularly 26:5C-6 and 8.

Effective Date: July 18, 2022.

Expiration Date: February 8, 2023.

Summary of Public Comment and Agency Response:

No comments were received.

Summary of Agency-initiated changes:

The Department of Health (Department) is making non-substantial changes on adoption as follows:

1. At N.J.A.C. 8:65-1.3, Definitions, at subsection (b), the Department is changing the definition of the term, “HIV-related laboratory test result”:

i. At paragraph 1, to delete the phrase, “supplemental differential,” and add in its place the term “additional,” to include reporting of the results of tests performed by a laboratory that is not using a recommended testing algorithm;

ii. At paragraph 3, to require reporting of the results of quantitative test types that do not yield a quantitative result, that is, to require reporting of all HIV nucleic acid detection test results, both qualitative and quantitative; and

iii. At paragraph 7, to require reporting of the results of tests that detect the presence of antibodies of HIV-1 and antigens of HIV-1 and HIV-2 antigens. The Department is making a corresponding deletion of the definition of the term, “fourth-generation HIV test,” the content of which would be expressly stated within the definition of “HIV-related laboratory test result” at paragraph 7.

2. At N.J.A.C. 8:65-1.4, Forms and instructions, at subparagraph (a)1v, the Department is adding a revision date for the referenced technical guidance, for consistency with a comparable provision at (a)1ii.

3. At N.J.A.C. 8:65-2.5, Clinical laboratories, to report HIV-related laboratory test results, the Department is providing additional mechanisms by which clinical laboratories may comply with mandatory reporting of HIV-related laboratory test results, that is, at new (d)2, by secure email, and at new (d)5, by secure file transfer protocol.

4. At N.J.A.C. 8:65-2.6, Mandatory content of laboratory order and specimen submission forms, the Department is qualifying subparagraph (a)3iv to require identification of a patient's sex at birth and current gender identity, for consistency with CDC reporting requirements.

Federal Standards Statement

N.J.S.A. 26:5C-3 defines AIDS as "acquired immune deficiency syndrome as defined by the Centers for Disease Control of the United States Public Health Service." Consistent with this mandate to adhere to the Federal definition in implementing its rulemaking obligations under the AIDS Assistance Act, the Department is defining the term, "HIV," through the incorporation by reference, as amended and supplemented, of the CDC's revised surveillance case definition, and the CDC's ICD-10-CM, which establishes the diagnostic coding of HIV-related conditions. The adopted definition, thus meets, but does not exceed, this State statute that incorporates and refers to Federal law, standards, or requirements.

The adopted recodification with amendments, repeals, and new rules would continue to require entities with HIV reporting obligations to report the information that Federal reporting forms request, and thereby would meet, but not exceed, these Federal standards. The Department requires reporting consistent with these Federal standards to ensure that the Department maintains compliance with applicable terms and conditions of its existing Federal HIV grant funding agreements and remains eligible to compete for new Federal grant funding.

Except as described above, the Department does not adopt this rulemaking under the authority of, or in order to implement, comply with, or participate in any program established under Federal law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, a Federal standards analysis is not required.

Full text of the adopted recodification with amendments and new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 1. GENERAL PROVISIONS

8:65-1.3 Definitions

(a) (No change from proposal.)

(b) The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

…

["Fourth generation HIV test" means a test that detects the presence of HIV-1 antibodies and antigens of HIV-1 and HIV-2.]

…

"HIV-related laboratory test result" means the result of an HIV-related laboratory test:

1. That is an HIV immunoassay performed on a specimen taken from an adult or adolescent and having a positive (reactive) or indeterminate result, and the results of all *[supplemental differential]* ***additional*** HIV immunoassays performed on the same specimen as part of the testing algorithm, regardless of

whether the results of the *[supplemental]* ***additional*** HIV immunoassays are positive (reactive), non-reactive (negative for HIV), or indeterminate;

2. (No change from proposal.)

3. That is an HIV nucleic acid (RNA or DNA) *[polymerase chain reaction (PCR)]* ***qualitative and quantitative*** test*[:

i. Yielding a positive (reactive) qualitative result; and/or

ii. Yielding a quantitative result (copies per milliliter and/or logarithm value)]* ***, including quantitative test types that do not yield a quantitative result***;

4.–6. (No change from proposal.)

7. That is a positive or reactive result of *[a fourth-generation]* ***an HIV-1 or HIV-2 immunoassay*** test *[for]* ***that can detect both*** HIV ***antigens and antibodies***; and

8. (No change from proposal.)

…

8:65-1.4 Forms and instructions

(a) The Department incorporates herein by reference the following forms and instructions for information collection, as amended and supplemented, promulgated by the National HIV Surveillance System of the CDC in accordance with procedures of the OIRA:

1. The information collection bearing OMB Control No. 0920-0573, particularly the following forms, and the instructions for completion thereof, which are available from

the Department's forms page at http://www.nj.gov/health/forms or upon request to the Division:

i.-iv. (No change from proposal.)

v. The instructions for completion of the PCRF and the PHER, entitled the Technical Guidance for HIV Surveillance Programs: Pediatric HIV Confidential Case Report Form and Perinatal HIV Exposure Reporting Form (PCRF and PHER Technical Guidance) ***(revised November 2019)***; and

2. (No change from proposal.)

SUBCHAPTER 2. REPORTING HIV INFECTION DIAGNOSES AND HIV-RELATED LABORATORY TEST RESULTS

8:65-2.5 Clinical laboratories to report HIV-related laboratory test results

(a)-(c) (No change from proposal.)

(d) A clinical laboratory director shall comply with (a) and (b) above , in the following order of preference***, by***:

1. (No change from proposal.)

2. *[By secure]* ***Secure email to episervices@doh.nj.gov;***

3. Secure electronic facsimile (e-fax) to (609) 984-2455, subject to (b) *[below]****above***;

*[3.]****4.*** Submitting a completed form of ACRF or PCRF, as applicable, or Confidential Laboratory Report, to the Division by postal mail marked "confidential," preferably using a Division envelope***; or***

5. Submitting by use of a Secure File Transfer Protocol (SFTP) through the website at https://njgov.moveitcloud.com/*.

i. Entities electing to submit through SFTP should submit an email to episervices@doh.nj.gov to obtain access credentials.

(e)-(h) (No change from proposal.)

8:65-2.6 Mandatory content of laboratory order and specimen submission forms

(a) A health care provider that issues an order or submits a specimen to a clinical laboratory for HIV-related laboratory testing shall provide, and/or ensure the provision of, at least the following information in the order or specimen submission form:

1.-2. (No change from proposal.)

3. The patient's:

i.-iii. (No change from proposal.);

iv. Sex ***assigned at birth and current gender identity***;

v.-vii. (No change from proposal.)

(b)-(c) (No change from proposal.)