

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF HIV, STD, AND TB SERVICES

HIV Infection Reporting

Proposed Recodification: N.J.A.C. 8:57-2 as 8:65

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

Proposed Repeals: N.J.A.C. 8:57-2.2, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, and 2.12, and 8:57-2 Appendices A through G

Proposed New Rules: N.J.A.C. 8:65-1.2, 1.4, 2.1 through 2.6, 3.1 and 3.3

Authorized By: Judith M. Persichilli, R.N., B.S., Commissioner, Department of Health, in consultation with the Public Health Council, and with the approval of the Health Care Administration Board.

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2021- .

Submit written comments by _____, 2021, electronically to <http://www.nj.gov/health/legal/ecomments.shtml>, or by postal mail postmarked by

_____, 2021, to:

Joy L. Lindo, Director

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Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

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The agency proposal follows:

Summary

N.J.A.C. 8:57 Communicable Diseases, establishes standards for reporting, investigating, and other activities attendant to the identification of, cases of certain communicable diseases. N.J.A.C. 8:57-2 establishes standards addressing “Reporting of Acquired Immunodeficiency Syndrome [(AIDS)] and Infection with Human Immunodeficiency Virus [(HIV)].” The Department of Health (Department), in consultation with the Public Health Council, proposes to recodify existing Subchapter 2 of N.J.A.C. 8:57, Reporting of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus, as N.J.A.C. 8:65, to be named HIV Infection Reporting, and proposes amendments, repeals, and new rules, described below.

I. Rulemaking History

Following is a summary of the rulemaking history of existing N.J.A.C. 8:57-2, as effected by changes over the years to New Jersey statutes.

The 1980s

The first cases of what eventually came to be known as HIV/AIDS were reported to the Centers for Disease Control and Prevention (CDC) of the United States

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Department of Health and Human Service in 1981. CDC, “*Pneumocystis Pneumonia* — Los Angeles,” *MMWR. Morbidity and Mortality Weekly Reports*, Vol. 30, No. 21, at 1–3 (June 5, 1981), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/june_5.htm and at <http://stacks.cdc.gov/view/cdc/1261> (first CDC article identifying “unusual” occurrence of cases of *Pneumocystis carinii* pneumonia in five otherwise healthy young men, who were unknown to each other and had no circumstances in common other than that they had sex with men).

In 1984, New Jersey enacted the “AIDS Assistance Act”, P.L. 1984, c. 126, *An Act concerning the treatment and diagnosis of acquired immune deficiency syndrome and making an appropriation* (effective August 8, 1984), codified at N.J.S.A. 26:5C-1 through 4 (Act). The Act requires the Commissioner (Commissioner) of the Department to establish programs for the education of the public and health care professionals about AIDS, and programs to support “early detection, counseling, social services, and referrals for those who suspect exposure to AIDS.” N.J.S.A. 26:5C-3 .

N.J.S.A. 26:1A-7 (f), authorizes the Public Health Council to promulgate rules (as part of the State Sanitary Code), “regulating the detection, reporting, prevention and control of communicable and preventable diseases.” In 1986, pursuant to the authority at N.J.S.A. 26:1A-7(f), the Public Health Council, with the Department, promulgated N.J.A.C. 8:57-1.14, Reporting of Acquired Immunodeficiency Syndrome and AIDS[-]Related Complex [(ARC)]. 18 N.J.R. 1245(a) (June 16, 1986), 18 N.J.R. 2011(a) (October 6, 1986). Until the promulgation of that rule, the Department had collected “AIDS data ... under the various infections and associated malignancies.” 18 N.J.R. at

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1246. N.J.A.C. 8:57-1.14 required physicians and the “superintendent ... of any institution” (including health care facilities and “penal institutions”) to report, with client identifiers, cases of persons having diagnoses of “AIDS or ARC” to the Department. N.J.A.C. 8:57-1.14 was to “unify data collection and ... include the ... associated opportunistic infections [that were] not [then] reportable.” *Id.*

In the mid-1980s, the Commissioner administratively reallocated the program that administers the Department’s HIV-related activities from within the Division of Epidemiology, Environmental and Occupational Health, which administers communicable disease reporting and oversees the State’s vaccine-preventable disease program, to the then-newly established Division of AIDS Services, within the Public Health Services Branch of the Department.

The 1990s

In 1990, the Public Health Council, with the Department, as part of the readoption of N.J.A.C. 8:57, and pursuant to the authority of N.J.S.A. 26:1A-7, repealed then-existing N.J.A.C. 8:57-1.14. 21 N.J.R. 3897(a) (December 18, 1989), 22 N.J.R. 1766(a) (June 4, 1990). The Public Health Council simultaneously established new rules at Subchapter 2, Reporting of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus, which became operative on June 4, 1990. 21 N.J.R. 3905(a) (December 18, 1989), 22 N.J.R. 1592(a) (May 21, 1990). The new rules at Subchapter 2 required physicians and institutional administrators to report, with client identifiers, diagnoses of persons who were “ill with AIDS,” and to report, without client identifiers, diagnoses of persons who had HIV infection and HIV-related laboratory test

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results indicative of HIV infection to the Department. 22 N.J.R. at 1594. The new rules also required clinical laboratories to quarterly report, without client identifiers, the number of HIV laboratory tests it performed and the number of laboratory results indicative of HIV infection it obtained. *Id.* The new rules at Subchapter 2 were to facilitate the Department's then-announced plan to identify, trace, and treat New Jersey residents infected with HIV, thus making New Jersey the first State to implement June 1989 CDC guidelines calling for the identification of, and provision of treatment to, persons infected with HIV. 21 N.J.R. at 3906. The Department also planned to use the data it would collect, by operation of the new rules at Subchapter 2, to "observe any ... changing nature of the epidemic, and to further plan the strategy for intervention." *Id.*

Also in 1990, following the proposal but before the adoption of the amendments described in the preceding paragraph, New Jersey supplemented the Act by the enactment of new sections mandating the reporting of diagnosed cases of AIDS and HIV infection, with patient identifiers, to the Department, and authorizing the Commissioner to establish anonymous counseling and testing sites, at which the results of testing performed on site would be reportable to the Department without client identifiers, unless tested persons consented to reporting of their identifying information. P.L. 1989, c. 303, *An Act concerning acquired immune deficiency syndrome and supplementing Title 26 of the Revised Statutes* (approved January 12, 1990), codified at N.J.S.A. 26:5C-5 through 14. In 1992, the Public Health Council, with the Department, pursuant to N.J.S.A. 26:1A-7 and 26:2-104 (relating to the State cancer registry) (and without referencing the Act as providing rulemaking authority), amended N.J.A.C. 8:57-2

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to discontinue aggregate quarterly reporting by clinical laboratories and to require clinical laboratories to report to the Department, with client identifiers, individuals' HIV-related laboratory test results indicative of HIV infection, and/or indicating low counts of CD4 T-lymphocytes (CD4 counts) (also known as "T-cells" or "T-helper cells"). 23 N.J.R. 3735(a) (December 16, 1991), 24 N.J.R. 1891 (May 18, 1992). (CD4 cells are white blood cells that trigger the body's immune response. HIV binds with CD4 cells to replicate itself and spread, and in so doing destroys the CD4 cells and lowers the body's overall CD4 count. Thus, the lower a person's CD4 count or percentage, the greater the person's susceptibility to other infections.) The proposed amendments were to assist the Department in planning and delivering services to clients, increase the accuracy of statistical data the Department generated, identify cases that were unreported by physicians, and provide clients access to services earlier upon their exposure to, or infection with, HIV. 23 N.J.R. at 3735.

N.J.S.A. 26:4-2, Powers of Department of Health and local boards; declaration of public health emergency, at paragraph a, authorizes the Department to declare what diseases are communicable and to require communicable disease reporting. In 1995, pursuant to N.J.S.A. 26:1A-7, 26:4-2, and the Act at 26:5C-5, Definitions, et seq., the Department and the Public Health Council readopted Subchapter 2 without change, as part of the readoption of N.J.A.C. 8:57 Communicable Diseases, pursuant to Executive Order No. 66 (Governor Byrne, 1978) (requiring readoption or expiration of agency rules every five years). 27 N.J.R. 420(a) (February 6, 1995), 1987(a) (May 15, 1995). In so doing, the Department noted that the reporting requirements at Subchapter 2 enable the

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Department to continue to take “appropriate actions to protect public health, to offer new and promising regimens of medication for prophylactic and therapeutic intervention, and to further plan for the continuing and significant impact” that HIV infection has on the health care system. 27 N.J.R. at 421.

In mid-1995, New Jersey enacted P.L. 1995, c. 174, *An Act requiring notification of pregnant women of the benefits of being tested for the presence of antibodies to the human immunodeficiency virus and supplementing Title 26 of the Revised Statutes* (approved July 7, 1995, effective September 5, 1995), codified at N.J.S.A. 26:5C-15 through 20.

2000 to the present

In 2000, pursuant to N.J.S.A. 26:1A-7, 26:1A-15, Additional powers of commissioner, 26:4-1, “Communicable disease,” defined, et seq. (governing communicable diseases), 26:5C-5, and 17:23A-13, Disclosure limitations and conditions (addressing disclosure by an insurance institution, agent, or insurance-support organization, of personal or privileged information about an individual collected or received in connection with an insurance transaction), the Department and the Public Health Council proposed to readopt Subchapter 2, with amendments, as part of the readoption of N.J.A.C. 8:57 Communicable Diseases, pursuant to Executive Order No. 66 (Governor Byrne, 1978). 32 N.J.R. 965(a) (March 20, 2000) (March 2000 proposal). The proposed amendments would add “insurance companies” to the types of institutions that were to report cases, with client identifiers, to the Department, pursuant to N.J.S.A. 17:23A-13.1 and 13.2; require clinical laboratories to report to the

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Department, with client identifiers, all HIV viral load (that is, the number of particles, also called copies, of the virus in a milliliter of blood) laboratory test findings, regardless of result; and require physicians and institutions to report to the Department, with client identifiers, cases of infants perinatally exposed to HIV. *Id.* The proposed amendment requiring viral load reporting was to acknowledge that viral load testing had “become a critical component of care ... in determining the course and type of therapeutic regimens for patients with HIV infection,” and to enable the Department to “monitor the epidemic and measure the availability and success of treatment for those infected with HIV.” *Id.* The proposed amendment requiring perinatal exposure reporting was to ensure timely identification, monitoring, prophylactic preventive efforts, and treatment of infants born to HIV-infected women. *Id.*

Pursuant to Executive Order No. 66 (Governor Byrne, 1978), N.J.A.C. 8:57 expired on April 12, 2000, before the Department had adopted the March 2000 proposal. Later in 2000, the Department and the Public Health Council adopted the expired rules as new rules at N.J.A.C. 8:57, and the proposed amendments at Subchapter 2 contained in the March 2000 proposal,. 32 N.J.R. 3463(a) (September 18, 2000).

In 2003, pursuant to N.J.S.A. 17:23A-13, 26:1A-7 and 15, 26:4-1 et seq., and 26:5C-5, the Department and the Public Health Council, as part of the readoption of N.J.A.C. 8:57 Communicable Diseases, readopted Subchapter 2 with amendments that added entities that “require HIV testing as part of an underwriting process,” in addition to “insurance companies,” to the types of entities that are to report cases to the

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Department, with client identifiers. 34 N.J.R. 3945(a) (November 18, 2002), 35 N.J.R. 4883(b) (September 25, 2003).

Reorganization Plan No. 003-2005 (Governor Codey, June 27, 2005), 37 N.J.R. 2735(a) (August 1, 2005), at §1, provides: “The functions, powers and duties of the Public Health Council under P.L. 1947, c. 177, as amended (C.26:1A-5 et seq.), other than the Council's advisory and consultative functions, are continued and are transferred to the Department of Health ... to be allocated within the Department as determined by the Commissioner.” Thus, the Commissioner assumed the power of the Public Health Council to promulgate rules comprising the State Sanitary Code, pursuant to N.J.S.A. 26:1A-7; however, in promulgating rules addressing the matters listed at N.J.S.A. 26:1A-7(a) through (p), the Commissioner continues to consult with the Public Health Council to secure its advisory recommendations.

In 2009, pursuant to N.J.S.A. 17:23A-13, 26:1A-7 and 15, 26:4-1 et seq., particularly 26:4-2, 26:5C-1, et seq., particularly 26:5C-6, Report of diagnosed cases of AIDS or HIV infection; anonymous testing, and 26:5C-20, Rules and regulations (addressing the Commissioner’s authority to promulgate rules addressing testing of pregnant women for HIV infection), the Department, in consultation with the Public Health Council, readopted Subchapter 2 with amendments, as part of the readoption of N.J.A.C. 8:57 Communicable Diseases. 40 N.J.R. 1962(a) (April 21, 2008), 41 N.J.R. 1419(a) (April 6, 2009). Significant substantive amendments relating to HIV reporting in that rulemaking established forms to be used for reporting HIV infection diagnoses and laboratory test results; added definitions of terms; and deleted references throughout

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the subchapter to the reporting obligations of “physicians,” and replaced them with references to the reporting obligations of “health care providers.” 40 N.J.R. at 1968-70. Other substantive amendments added a definition of the term, “responsible party,” to mean the person controlling or supervising an “institution,” and required responsible parties to report cases to the same extent as “health care providers.” *Id.*

The Department eventually merged its sexually transmitted disease (STD) and tuberculosis (TB) services into the Division of AIDS Services, and renamed the Division as it is now known, to be the Division of HIV, STD, and TB Services (Division).

On February 8, 2016, the Department, in consultation with the Public Health Council, readopted Subchapter 2 as part of the readoption without change of N.J.A.C. 8:57 Communicable Diseases. 48 N.J.R. 420(a) (March 7, 2016).

II. This Notice of Proposal

Recodification and Non-Substantial Changes

The Department, in consultation with the Public Health Council, proposes to recodify existing Subchapter 2 of N.J.A.C. 8:57, Reporting of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus, as a separate chapter, N.J.A.C. 8:65, bearing the chapter heading, HIV Infection Reporting. By removing the subchapter from N.J.A.C. 8:57 Communicable Diseases, the recodification would reflect the administrative reorganization of the Department some years ago that reallocated the Department’s HIV-related service units from within the Communicable Disease Service of the Division of Epidemiology, Environmental and Occupational Health, to the Division of HIV, STD, and TB Services. In addition, the

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Department, in consultation with the Public Health Council, proposes amendments, repeals, and new rules, described below.

The Department proposes amendments throughout the chapter to correct grammar, simplify sentence structure, delete descriptive text that is redundant of defined terms and add instead the defined terms, correct references to the Department to reflect the agency name change pursuant to N.J.S.A. 26:1A-2.1, reorganize rule text by means of sub codification, delete references to the “subchapter” and add in place thereof references to the “chapter,” and add or update contact information.

The Act contains terminology that reflects the understanding of HIV and AIDS when it was first enacted in 1984, and when in was amended in 1990, and again in 1995. Advances in scientific understanding have rendered this terminology inaccurate, imprecise, potentially stigmatizing or offensive, and/or otherwise inappropriate. For example, N.J.S.A. 26:5C-3 at subsection c refers to persons “who suspect exposure to AIDS.” “AIDS” is not an infectious agent; rather, it is a “syndrome of opportunistic infections and diseases that can develop as immunosuppression deepens along the continuum of HIV infection.” See Joint United Nations Programme on HIV/AIDS (UNAIDS), *UNAIDS Terminology Guidelines* (Geneva 2015) at 4, available at https://www.unaids.org/en/resources/documents/2015/2015_terminology_guidelines. Moreover, this overbroad phrase could be misconstrued to imply inaccurately, and potentially offensively, that one might obtain HIV infection by casual proximity to people who have HIV infection. A person’s exposure to HIV through a known virus transmission mode might result in a person obtaining HIV infection, which, depending

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on the care and treatment the person receives, might or might not progress to the most advanced stage of HIV infection known as AIDS. For another example, N.J.S.A. 26:5C-6 refers to reporting of “diagnosed cases of AIDS and ... diagnosed cases of HIV,” as if these were distinct illnesses. According to the CDC’s *Revised Surveillance Case Definition for HIV Infection — United States, 2014*, available at <http://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf> (“revised surveillance case definition”), HIV infection is classified by stage (from zero to three, or unknown stage), based on age-specific CD4+ T-lymphocyte count or percentage of total lymphocyte, as discussed more fully below. See also United States Department of Health and Human Services, *Glossary of HIV/AIDS-Related Terms, 9th Edition* (Rockville, MD, 20892-9840), available at <https://clinicalinfo.hiv.gov/en/glossary>.

The revised surveillance case definition, described above, modifies and combines “the surveillance case definitions for HIV infection into a single case definition for persons of all ages[, primarily] to adapt to recent changes in diagnostic criteria. Laboratory criteria for defining a confirmed case now accommodate new [multi-test] algorithms, including criteria for differentiating between HIV-1 and HIV-2 infection and for recognizing early HIV infection. A confirmed case can be classified in one of five HIV infection stages (0, 1, 2, 3, or unknown); early infection, recognized by a negative HIV test within 6 months of HIV diagnosis, is classified as stage 0, and ... AIDS ... is classified as stage 3[.] The [revised] surveillance case definition is intended primarily for monitoring the HIV infection burden and planning for prevention and care on a population level, not as a basis for clinical decisions for individual patients. [The] CDC

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and the Council of State and Territorial Epidemiologists recommend that all states and territories conduct case surveillance of HIV infection using this revised surveillance case definition.” Revised surveillance case definition at 1. The revised surveillance case definition classifies “stages 1 [to] 3 of HIV infection on the basis of the CD4+ T-lymphocyte count unless persons have had a stage-3-defining ‘opportunistic illness.’” *Id.* at 2, 7, and 10 (the Appendix to the revised surveillance case definition lists these opportunistic illnesses). Based on this guidance, the Department proposes to delete references throughout the chapter to “AIDS,” and to use instead references to “HIV,” for example, as in the phrases, “HIV infection” and “HIV-related laboratory test,” to reflect the revised surveillance case definition.

1. Proposed Amendments, Repeals, and New Rules

a. Subchapter 1. General Provisions

The Department proposes new Subchapter 1, General Provisions, at N.J.A.C. 8:65-1.

Existing N.J.A.C. 8:57-2.1, Purpose and scope, establishes the purpose and scope of N.J.A.C. 8:57-2. The Department proposes to recodify existing N.J.A.C. 8:57-2.1 as new N.J.A.C. 8:65-1.1, Purpose and scope. At existing subsection (a), the Department proposes to delete the reference to N.J.S.A. 26:5C-20, which establishes the Commissioner’s rulemaking authority with respect to HIV testing of pregnant women. Proposed new N.J.A.C. 8:65 would not address HIV testing of pregnant women. Existing N.J.A.C. 8:61-4 establishes rules governing HIV testing of pregnant women. In addition, at existing subsection (a), the Department proposes to delete the

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description of the chapter's purpose, and to add text stating that the chapter's purpose would be to establish standards for reporting HIV infection diagnoses and HIV-related laboratory test results, pursuant to N.J.S.A. 26:5C-1, et seq. The Department proposes to amend existing subsection (b) to indicate that the chapter establishes standards applicable to, at new subparagraph 1, health care providers and institutions that order HIV-related laboratory tests, diagnose persons as having HIV, and/or treat persons who have HIV; at new subparagraph 2, clinical laboratories that perform HIV-related laboratory tests; and at new subparagraph 3, counseling and testing sites. The Department proposes to delete existing subsection (c), because it would become unnecessary upon the adoption of the proposed recodification of existing N.J.A.C. 8:57-2 as N.J.A.C. 8:57-65.

The Department proposes to repeal existing N.J.A.C. 8:57-2.2, Incorporated documents, which lists forms and publications the subchapter incorporates by reference.

The Department proposes new N.J.A.C. 8:65-1.2, Publications incorporated by reference, would list publications to be incorporated by reference, as amended and supplemented. Proposed new subsection (a) would identify routinely updated web-based publications of, or administered by, the United States Department of Health and Human Services that the Department proposes to incorporate by reference, as amended and supplemented, specifically, the revised surveillance case definition, described above; *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate*

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Sharing and Use of Surveillance Data for Public Health Action; HIV Diagnostic Tests LOINC Map (2019); International Statistical Classification of Diseases and Related Health Problems, 10th revision, Clinical Modification; Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations; and 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens.

Proposed new subsection (b) would identify routinely updated web-based Directives of, or administered by, the Veterans Health Administration (VHA) of the United States Department of Veterans Affairs (VA), specifically, VHA Directive 1131(4), *Management of Infectious Diseases and Infection Prevention and Control Programs*, and VHA Directive 1304, *National Human Immunodeficiency Virus (HIV) Program*. Proposed new subsection (c) would identify routinely updated web-based publications of, or administered by, the Federal Bureau of Prisons (BOP) of the United States Department of Justice, specifically, *Clinical Guidance: HIV Management* (April 2021); and Program Statement Number 6190.04, *Infectious Disease Management*.

Existing N.J.A.C. 8:57-2.3, Definitions, establishes definitions of words and terms that existing N.J.A.C. 8:57-2 uses. The Department proposes to recodify existing N.J.A.C. 8:57-2.3 as new N.J.A.C. 8:65-1.3. The Department proposes to amend this section to add new subsection (a) at which it would incorporate by reference the definitions of the following words and terms that the Act establishes, particularly at N.J.S.A. 26:5C-5: “Commissioner,” “Department,” and “‘HIV infection,’ as amended and supplemented by the surveillance case definition.”

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The Department proposes to recodify the existing text at N.J.A.C. 8:57-2.3 as proposed new N.J.A.C. 8:65-1.3(b), and to add definitions of the following new words and terms: “adolescent,” “adult,” bio-analytical laboratory director,” “blood bank,” “Centers for Disease Control and Prevention” or “CDC,” “clinical laboratory,” “clinical laboratory director,” “confirmed positive,” “counseling and testing site,” “Division envelope,” “DNA,” “electronic laboratory reporting,” “Federal correctional institution,” “fourth generation HIV test,” “health benefits plan,” “health care facility,” “health care provider,” “HIV,” “HIV immunoassay,” “HIV-related laboratory test,” “HIV-related laboratory test result,” “limited purpose laboratory,” “Office of Information and Regulatory Affairs” or “OIRA,” “pediatric,” “perinatal,” “rapid HIV test,” “RNA,” “VHA laboratory,” and “VHA medical facility.”

The Department proposes to delete the following terms from existing N.J.A.C. 8:57-2.3, to be recodified as new N.J.A.C. 8:65-1.3, because N.J.A.C. 8:65 would no longer use these terms: “Acquired Immunodeficiency Syndrome” or “AIDS,” “Human Immunodeficiency Virus” or “HIV,” and “laboratory HIV results.” The Department proposes to amend the existing definition of the term, “audit,” to delete the description of patient records as “medical” records and to describe them more broadly as “health” records. The Department proposes to amend the existing term, “CD4 count,” to be “CD4 count or percentage,” and to amend the definition of the term to indicate that the term quantifies, by count or percentage, the presence of T-lymphocytes containing the CD4+ epitope, commonly referred to as the CD4, and to delete existing subparagraphs 1 and 2 , which provide unnecessary and redundant definitions of “absolute” and

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“relative” CD4 counts. The Department proposes to amend the existing definition of the term, “epidemiology investigations,” to put the term in the singular, and to describe more precisely the activities of the Division’s prevention and surveillance staff in reviewing patients’ health records. The Department proposes to amend the existing definition of the term, “institution,” to delete the undefined terms, “hospital,” “sanitarium,” “nursing home,” and “clinic,” to add the term, “health care facility”; to add references to facilities under the jurisdiction of various State and local governmental entities, typically of a custodial nature, because these might have occasion to diagnose a person in their custody as having, or treat a person in their custody for, HIV or HIV-related opportunistic illness; to exclude counseling and testing sites from the meaning of the term; to add a cross-reference to the statutory authority for blood bank licensure; to delete the undefined term, “insurance company”; and to add the term, “health benefits plan.” The Department proposes to amend the term, “perinatally exposed,” to be “perinatal exposure,” and to redefine the term as meaning exposure of a perinatal infant to HIV by having been born to a woman who has HIV infection at the infant’s delivery.

The Department proposes new N.J.A.C. 8:65-1.4, Forms and instructions, would establish the forms that entities with reporting obligations pursuant to the chapter are to submit to the Department, and the accompanying instructions.

44 U.S.C. at Chapter 35, commonly referred to as the “Paperwork Reduction Act of 1995,” requires Federal agencies to obtain the approval of the Office of Management and Budget (OMB) of the Executive Office of the President of the United States before requesting information from the public. The Office of Information and Regulatory Affairs

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(OIRA) of the OMB administers the information collection review process to implement the Paperwork Reduction Act pursuant to 5 CFR Part 1320. The OIRA assigns an OMB control number to each “information collection,” that is, each set of forms and instructions that a Federal agency promulgates to collect information. The OMB control numbers usually remain constant even as a Federal agency amends its forms and instructions or changes information collection vendors over time.

In accordance with the OIRA information collection review process, the National HIV Surveillance System (NHSS) of the CDC in the United States Department of Health and Human Services promulgates an OIRA-approved information collection of forms and associated instructions for adult and pediatric HIV case and perinatal HIV exposure reporting, and a separate OIRA-approved information collection of forms and associated instructions for rapid HIV test result reporting, which counseling and testing sites submit to the Department by electronic reporting through an NHSS-funded vendor. The Department proposes to incorporate by reference, as amended and supplemented, these two sets of NHSS forms, instructions, and procedures at proposed new N.J.A.C. 8:65-1.4(a)1 and 2, respectively. The proposed new rule would ensure that the Department’s collection of HIV case data remains consistent with NHSS’ information collection standards and requirements by use of forms and procedures that are subject to public notice and opportunity to be heard through the Federal information collection review process. This, in turn, would ensure the Department’s continuing compliance with terms and conditions of Federal grants that require adherence to NHSS HIV reporting standards. The Department would make the latest versions of the NHSS adult

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and pediatric case reporting forms, the perinatal HIV exposure reporting form, and the related instructions for completion thereof, entitled *Technical Guidance for HIV Surveillance Programs* (hereinafter referred to as *Technical Guidance*), available through its forms page on the Department's website and upon request to the Division. Forms, instructions, and procedures of the vendor with which the NHSS presently contracts for electronic laboratory test result reporting are available through the vendor's website, as proposed new N.J.A.C. 8:65-1.4(a)2 would indicate. If the NHSS changes its vendor, the incorporation of that NHSS information collection by reference to its OMB Control Number would ensure that the rule continues to refer to the latest OIRA-approved NHSS information collection, regardless of the change in vendor; however, the Department likely would need to change the vendor website to which the rule refers.

b. Subchapter 2. Reporting HIV Infection Diagnoses and HIV-related Laboratory Test Results

The Department proposes to establish new Subchapter 2, Reporting HIV Infection Diagnoses and HIV-related Laboratory Test Results.

The Department proposes new N.J.A.C. 8:65-2.1, Health care providers to report, and responsible parties to ensure reporting of, HIV infection diagnoses and HIV-related laboratory test results in adults and adolescents. Proposed new subsection (a) would require health care providers to submit, in accordance with the reporting procedure at proposed new N.J.A.C. 8:65-2.4, a fully completed Adult HIV Confidential Case Report Form (ACRF) to the Division within 24 hours of, with respect to an adult or

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an adolescent, obtaining an HIV-related laboratory test result, or diagnosing or treating HIV infection. Proposed new subsection (b) would require responsible parties to ensure that institution personnel comply with subsection (a). Proposed new subsection (c) would identify incomplete and untimely reporting as grounds upon which the Department might pursue enforcement action, in accordance with existing N.J.A.C. 8:57-2.12, as proposed for recodification with amendment at new N.J.A.C. 8:65-3.3. Proposed new subsection (d) would indicate that the Department would not pursue enforcement actions for untimely and incomplete reporting of the ACRF if the health care provider timely submits at least the fields that the NHSS has identified as “required” fields in the *Technical Guidance*.

The Department proposes new N.J.A.C. 8:65-2.2, Health care providers to report, and responsible parties to ensure reporting of, perinatal exposures to HIV, pediatric HIV-related laboratory test results, and pediatric HIV infection diagnoses. Proposed new subsections (a) and (b) would require health care providers to submit to the Division, in accordance with the reporting procedure at proposed new N.J.A.C. 8:65-2.4, the Perinatal HIV Exposure Reporting form (PHER) within 24 hours of identifying a case of perinatal exposure to HIV, and the Pediatric HIV Confidential Case Report Form (PCRFF) within 24 hours of obtaining an HIV-related laboratory test result performed on a pediatric diagnostic specimen (regardless of result), and/or diagnosing or treating a pediatric case of HIV infection. Proposed new subsection (c) would require responsible parties to ensure that institution personnel comply with subsections (a) and (b).

Proposed new subsection (d) would identify incomplete and untimely reporting as

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grounds upon which the Department might pursue enforcement action, in accordance with existing N.J.A.C. 8:57-2.12, as proposed for recodification with amendment at new N.J.A.C. 8:65-3.3. Proposed new subsection (e) would indicate that the Department would not pursue enforcement actions for untimely and incomplete reporting of the PHER or the PCRf if the health care provider timely submits at least the fields that the NHSS has identified as “required” fields in the *Technical Guidance*.

The Department proposes new N.J.A.C. 8:65-2.3, which would establish reporting responsibilities applicable to entities the Commissioner designates and funds as counseling and testing sites in accordance with the terms and conditions of a grant. These entities typically maintain Department licensure pursuant to N.J.A.C. 8:44-3 as limited purpose laboratories, which authorizes them to perform rapid HIV testing for adults and adolescents. Proposed new subsection (a) would require counseling and testing sites to report positive rapid HIV test results using the information collection process at OMB Control No. 0920-0696, which is presently a vendor-provided online electronic reporting system made available by the NHSS at its expense for use by grantees. In addition, proposed new N.J.A.C. 8:65-2.3(a)1 through 3 would require counseling and testing sites to specify, within the electronic reporting system, the name, date of birth, and street address of the adult or adolescent for whom the counseling and testing site obtains a positive result, and, if applicable, the dates of the adult or adolescent’s last negative and/or first positive result of a previous HIV test. Proposed new subsection (b) would require counseling and testing sites to report in compliance

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with the information collection at OMB Control No. 0920-0696 within 30 days of obtaining a negative rapid HIV test result in an adult or an adolescent.

The Department proposes to repeal existing N.J.A.C. 8:57-2.4, Reporting HIV Infection for health care providers and responsible parties.

The Department proposes new N.J.A.C. 8:65-2.4, Procedure to report to the Division by health care providers, responsible parties, and counseling and testing sites. Proposed new subsection (a) would establish the procedure by which health care providers and responsible parties, when required to do so pursuant to N.J.A.C. 8:65-2.1 or 2.2, would submit, or ensure the submission of, a PHER and/or a PCRf, and by which they, and counseling and testing sites, when required to do so pursuant to N.J.A.C. 8:65-2.3, would submit an ACCRF, to the Division. The proposed new rule would require submission of these forms by postal mail marked “confidential,” preferably using a Division envelope, or by secure electronic telefacsimile (“e-fax”). Proposed new subsection (b) would prohibit submission of required reports by electronic telefacsimile if the reporting entity does not use processes and equipment that are compliant with the *Data Security Guidelines*.

The Department proposes to repeal existing N.J.A.C. 8:57-2.5, Reporting HIV infection for clinical laboratories.

The Department proposes new N.J.A.C. 8:65-2.5, Clinical laboratories to report HIV-related laboratory test results. Proposed new subsections (a) and (b) would require clinical laboratory directors to submit to the Division, the information fields in the sections of the ACRF or PCRf, as applicable, labeled, “Patient Identification,” “Facility

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Providing Information” and “Laboratory Data.” Proposed new subsection (c) would indicate that the Department has collected the sections of the ACRF and PCRf that subsections (a) and (b) would require clinical laboratories to report and maintains these in a form entitled Confidential Laboratory Report, which is available on the Department’s website. Proposed new subsection (d) would require clinical laboratory directors to submit the fields of information that subsections (a) and (b) require by means of electronic laboratory reporting or by submitting that information using an ACRF or PCRf, as applicable, or the Confidential Laboratory Report, by postal mail marked “confidential,” preferably using a Division envelope. Proposed new subsection (e) would indicate that clinical laboratories, and their directors, remain responsible to ensure complete reporting to the Division of the results of HIV-related laboratory tests when they delegate or “refer” the performance of those tests to another clinical laboratory (“reference laboratory:”), regardless of whether the Department has jurisdiction over the reference laboratory. Proposed new subsection (f) would identify incomplete and untimely reporting as grounds upon which the Department might pursue enforcement action, in accordance with existing N.J.A.C. 8:57-2.12, as proposed for recodification with amendment at new N.J.A.C. 8:65-3.3. Proposed new subsection (g) would indicate that the Department would not pursue enforcement actions against a clinical laboratory and/or a clinical laboratory director for untimely and incomplete reporting if the clinical laboratory and the clinical laboratory director timely submit at least the fields in the form sections that subsections (a) and (b) require that the NHSS has identified in the *Technical Guidance* as “required” fields.

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The Department proposes to repeal existing N.J.A.C. 8:57-2.6, Reporting children perinatally exposed to HIV, 2.7, Reporting AIDS for health care providers and responsible parties, 2.8, Reporting AIDS for Clinical Laboratories, 2.9, Testing procedures, and 2.10, Specimen submission, because the Department no longer needs to maintain residual specimens of positive HIV-related laboratory test results.

Over the years, the Division has received from clinical laboratories many reports of HIV-related laboratory test results that contain incomplete or insufficient information by which to link the HIV-related laboratory test result to an identifiable patient, for whom a health care provider or a responsible party might have submitted an Adult or Pediatric HIV Confidential Case Report. The Division has limited personnel and resources with which to follow up with clinical laboratories to obtain the missing information. This incomplete reporting results in the abandonment and “loss to follow-up” of many cases that the Division could have processed further through case management and surveillance, had the patients been identifiable by the submission of complete reports of HIV-related laboratory test results.

The accurate identification of all patients with suspected or confirmed HIV infection is critical to the Division’s prevention and surveillance activities, including its ability to report cases to the NHSS. Just as the Federal government depends on the accuracy of the United States Census to determine the distribution of Federal funding to a state by the characteristics of its population, the Federal government allocates of Federal HIV-related funding based on a state’s HIV case reporting and the needs of its at-risk and HIV-infected population. Therefore, accurate and complete reports and case

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counts of persons who receive care in New Jersey or reside in the State are imperative to the Division's ability to continue to serve the needs of New Jerseyans who have HIV infection and/or are key to the dynamics of HIV and the State's prevention and response activities.

It appears that clinical laboratories are omitting required patient identifying information in their reports to the Division because health care providers ordering HIV-related laboratory tests might not be including this information in the HIV-related laboratory test orders and/or specimen submission forms they issue to clinical laboratories. Therefore, the Department proposes new N.J.A.C. 8:65-2.6 Mandatory content of HIV-related laboratory test order and specimen submission form, which would require health care providers and responsible parties to ensure that HIV-related laboratory test orders and specimen submission forms contain at least the patient identifying information that the *Technical Guidance* identifies as "required" fields that clinical laboratories must submit when reporting HIV-related laboratory test results. This will ensure that the Division will be able to link reports of HIV-related laboratory test results to identifiable patients, to ensure appropriate follow up and case management with patients, and to confirm that a corresponding ACRF or PCRf has been submitted to the Division regarding the patient by the applicable health care provider, institution, or counseling and testing site with reporting responsibilities. The Department would enforce complete compliance with reporting obligations by entities subject to the chapter pursuant to new N.J.A.C. 8:65-3.3.

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c. Subchapter 3. Reporting HIV Infection Diagnoses and HIV-related Laboratory Test Results

The Department proposes new Subchapter 3, Access to Records; Enforcement.

The Department proposes new N.J.A.C. 8:65-3.1, Records subject to Department examination. The proposed new rule would restate existing N.J.A.C. 8:57-2.4(d), 2.6(c), and 2.7(e), which are proposed for repeal, to articulate the responsibility of entities subject to the chapter, other than counseling and testing sites, to fully make available to the Department patient health records and information for inspection, audit, epidemiologic investigation, copying, and public health purposes. N.J.S.A. 26:5C-1, et seq, particularly 26:5C-8, and the terms and conditions of grants the Department issues to counseling and testing sites, address the Department's right of access to records of those sites.

The Department proposes to recodify existing N.J.A.C. 8:57-2.11, Access to information, as new N.J.A.C. 8:65-3.2, Access to information and records; confidentiality. The Department proposes to amend subsection (a) to add a reference to records held by or submitted to the Department, to delete an unnecessary description of the information and records to which the section applies, to indicate that the prohibition against public access and disclosure of information and records applies regardless of removal or redaction of personal and other identifiers therefrom; and to amend subsection (b) to add references to N.J.S.A. 26:1A-1 et seq., and 26:4-1, et seq. and a reference to the Department's right of access to records for public health purposes, which proposed new N.J.A.C. 8:65-3.1 would address.

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The Department proposes to repeal existing N.J.A.C. 8:57-2.12, Failure to comply with reporting requirements.

The Department proposes new N.J.A.C. 8:65-3.3 Noncompliance with chapter; enforcement; penalties. Proposed new subsection (a) would establish that the chapter is part of, and subject to the enforcement provisions and penalties applicable to noncompliance with, the State Sanitary Code. Proposed new subsection (b) would refer to provisions of the Act that establish private rights of action for improper disclosures of confidential information relating to a person's HIV status. Proposed new subsection (c) would identify, among other actions and remedies available to the Department to address noncompliance, the reporting by the Department of noncompliance with the chapter to applicable public and private credentialing, licensing, accrediting, privilege-granting, and/or health care payer entities with jurisdiction.

d. Subchapter Appendices

The Department proposes to repeal existing N.J.A.C. 8:57-2 Appendices A through G. The information collection at OMB Control No. 0920-0573, particularly the forms to which proposed new N.J.A.C. 1.4(a)1i and ii would refer, would take the place of existing N.J.A.C. 8:57-2 Appendices A, B, and C. The information collection at OMB Control No. 0920-0696, particularly the forms and instructions to which proposed new N.J.A.C. 8:65-1.4(a)2 refers, would take the place of existing N.J.A.C. 8:57-2 Appendix D. Consistent with the proposed repeal of existing N.J.A.C. 8:57-2.10, the Department likewise proposes to repeal existing N.J.A.C. 8:57-2 Appendices E and F, which provide instructions for submission of specimens yielding positive HIV laboratory test results.

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The incorporation by reference of the *HIV Diagnostic Tests LOINC Map (2019)* at proposed new N.J.A.C. 8:65-1.2(a)5 and the requirement at proposed new N.J.A.C. 8:65-2.6 that clinical laboratories report in accordance with the electronic laboratory reporting requirements at existing N.J.A.C. 8:57 would take the place of existing N.J.A.C. 8:57-2 Appendix G, which provides instructions for electronic laboratory reporting of HIV-related laboratory test results to the Division.

Social Impact

The rules proposed for recodification and the proposed amendments, repeals, and new rules would maintain the Department's compliance with rulemaking obligations at N.J.S.A. 26:5C-1 et seq., particularly at N.J.S.A. 26:5C-6 and 8, by establishing and updating the procedures for reporting HIV diagnoses.

HIV case diagnosis reporting serves several purposes. It facilitates the Department's identification of persons to whom the Department can offer various preventive, clinical, and social support services. It enables the Department to measure the prevalence of HIV Statewide, in local communities, and among various socioeconomic and demographic populations. These measurements enable the State to quantify and plan its financial and other resource needs; inform its allocation of prevention and response resources; identify emerging trends and best practices in prevention, mitigation, and response; and comply with data collection and reporting responsibilities in accordance with the terms of grant agreements with Federal partners, such as the CDC.

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HIV-related laboratory test result reporting serves the same beneficial purposes that case diagnosis reporting serves. In addition, it helps the Department to identify potential cases sooner because the Department receives laboratory test results before it receives health care provider reports. HIV-related laboratory test result reporting enables the Department to identify new cases among existing New Jersey residents and persons with existing HIV diagnoses who have relocated to New Jersey from other jurisdictions. This helps the Department to find persons who might be eligible for and need available services associated with a positive HIV infection diagnosis and who otherwise might have been lost to follow-up. In addition, laboratory test result reporting enables the Department to identify compliance deficiencies among health care providers who might require training in their reporting obligations, in furtherance of the Department's obligation to educate the healthcare community pursuant to N.J.S.A. 26:5C-2.

The proposed amendments identifying reportable HIV-related laboratory test results would enable the Division to identify the prevalence and progression in the State of HIV in each of its stages, in accordance with the surveillance case definition. The proposed amendments requiring reporting genotypic resistance test results would enable the Division to identify and respond to HIV transmission clusters and drug-resistant HIV infections.

The Department reports the HIV-related data it collects to the CDC in accordance with grant terms and conditions. The CDC describes the beneficial uses of HIV case, demographic incidence, prevalence, and stage data, as follows: "Diagnoses of HIV

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infection (including stage 3 classifications), and death data provide trends of the burden of disease and are useful for tracking the time from a diagnosis of HIV infection to a stage 3 classification or death. Disparities between populations in the time from HIV infection diagnoses to stage 3 classifications or time to death underscore inequities in access to testing and care; this knowledge can help direct resource allocation[.] Incidence estimates are useful for planning and for allocating of funds, as well as evaluating the impact of prevention programs[.] Prevalence is useful for planning and resource allocation, as it reflects the number of people currently needing care and treatment services for HIV infection. Prevalence rates are useful for comparing HIV disease between populations and for monitoring trends over time.” Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, *Terms, Definitions, and Calculations Used in CDC HIV Surveillance Publications* (December 2016), at 2, available at <https://www.cdc.gov/hiv/statistics/surveillance/terms.html> and <https://www.cdc.gov/hiv/pdf/statistics/systems/nhbs/cdc-hiv-terms-surveillance-publications-2014.pdf>.

The proposed amendments and new rules that would restate reporting procedures would inform entities that have reporting obligations of their role-specific reporting obligations with greater specificity; improve the completeness, timeliness, and usefulness of their reports; and enhance preservation of the confidentiality of case information from the point of recording to Department receipt. The proposed amendments to the standards for public access to Department records would provide

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greater protection of case confidentiality, in furtherance of the Department's confidentiality obligations pursuant to N.J.S.A. 26:5C-7 and other laws.

The proposed amendments and new rules establishing the Department's access rights and enforcement procedures would facilitate the ability of Department staff to obtain access to patient records held by health care providers, particularly those who are not subject to Department jurisdiction for licensure purposes (typically, health care providers who are under the licensure jurisdiction of the Professional Boards Section of the Division of Consumer Affairs of the Department of Law and Public Safety). Some of these health care providers have been resistant to supplying Department personnel access to patient records for public health surveillance and auditing purposes. These purposes can include obtaining missing patient information that is necessary for follow-up activities, and/or confirming health care providers' compliance with timely and accurate case reporting obligations. Some of these health care providers incorrectly believe that allowing Department access to patient records for public health purposes without patient consent would violate Federal and State privacy laws, such as the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). For a discussion of the exception that authorizes entities subject to HIPAA to disclose protected health information without patient authorization for public health purposes, see United States Department of Health and Human Services, *Disclosures for Public Health Activities*, (December 3, 2002; revised, April 3, 2003), available at <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-public-health-activities/index.html> (web version) and

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<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/publichealth/publichealth.pdf> (pdf version).

Economic Impact

The proposed repeal of N.J.A.C. 8:57-2.10, which requires laboratories to submit residual specimens to the Public Health and Environmental Laboratories of the Department, should result in laboratories saving incidental expenses associated with preserving, storing, assembling, and sending residual specimens. It would also save the Department the cost of associated courier services.

The rules proposed for recodification, and the proposed amendments, repeals, and new rules, would continue to subject health care providers, health care facilities, institutions, responsible persons, clinical laboratories and clinical laboratory directors that fail to comply with the chapter to enforcement proceedings, the imposition of associated penalties in accordance with applicable statutes, and, following Department reporting of noncompliance to applicable credentialing entities with jurisdiction, the imposition of additional civil monetary penalties and actions against their licenses by their respective credentialing bodies.

Except as thus indicated, the Department does not anticipate that the proposed recodification, amendments, repeals, and new rules would affect or change the costs that entities with reporting responsibilities incur to comply with existing N.J.A.C. 8:57-2. These costs are associated with healthcare and laboratory record data extraction, data entry into required reporting forms, and compliance with Department surveillance

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activities. The Department does not anticipate that entities with compliance obligations would need to retain the services of additional professionals to perform these tasks, because extracting and reporting healthcare data from patient records for care and treatment purposes, to consult with healthcare professionals, to fill patient requests for their records, and to comply with longstanding communicable disease reporting obligations, are functions that entities engaging in healthcare and clinical laboratory professions already perform, presumably through the use of existing personnel, as part of routine activities associated with patient health care record retention and management, and compliance with public health reporting obligations associated with preventable and/or communicable diseases.

The rules proposed for recodification, and the proposed amendments, repeals, and new rules would cause the Department to continue to incur costs associated with maintaining program personnel and equipment to receive and process reports, enter data, perform quality control activities, pursue report correction and completion by entities that submit inaccurate or incomplete reporting, and enforce noncompliance.

The rules proposed for recodification, and the proposed amendments, repeals, and new rules, would continue to enable the Department to report information to the appropriate Federal government agencies about new diagnoses, the prevalence of HIV in the State, that is, the number and location of existing and new cases of HIV infection in the State, and the progression of the disease among the people of New Jersey who have HIV infection. The Federal government uses this information to calculate each State's need for Federal funding. Department reporting of HIV-related data to Federal

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entities enables the Department to meet the terms and conditions of grants that fund the Department's various HIV prevention and care activities.

The Department routinely uses Federal grant funding, in addition to money from the State Treasury, to issue grants to local entities that provide HIV-related services to people in their communities who have HIV infection and/or are key to the dynamics of HIV and the State's response. Failure of the Department to report complete HIV-related data to Federal entities, and to demand complete reporting from entities with reporting obligations, undermines the usefulness of the State's data for national and international epidemiological research purposes, and jeopardizes the State's prospective eligibility to compete for Federal grant funding.

Thus, the Department's complete and accurate reporting of new HIV diagnoses and the prevalence of HIV in the State to the Federal government is critical to ensuring that the State and, through State disbursement of Federal funds to grantees, local providers receive all the Federal funding for which the State is eligible, to prevent and respond to HIV in New Jersey. Therefore, compliance with the chapter by members of the regulated community with reporting obligations is imperative to ensure the continued availability of Federal funds that enable these entities to serve the people of New Jersey.

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."

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Consistent with this mandate to adhere to the Federal definition in implementing its rulemaking obligations under the AIDS Assistance Act, the Department proposes to define the term, “HIV infection,” 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 proposed definition thus meets but does not exceed this State statute that incorporates and refers to Federal law, standards, or requirements.

As described in the Economic Impact, above, the rules proposed for recodification, and the proposed 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 propose 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.

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Jobs Impact

The rules proposed for recodification, and the proposed amendments, repeals, and new rules, would maintain, but not increase or decrease, existing demand for personnel in positions that facilitate reporting of HIV-related diagnoses and laboratory test results, because a change in demand for these personnel is likely to depend more on the extent of disease prevalence in the State and not on the existence of reporting obligations.

Agriculture Industry Impact

The rules proposed for recodification, and the proposed amendments, repeals, and new rules, would have no impact on the State agriculture industry.

Regulatory Flexibility Analysis

The rules proposed for recodification, and the proposed amendments, repeals, and new rules, would impose reporting, recordkeeping, and other compliance requirements on health care facilities, health care professionals, clinical laboratories, institutions and their administrators, and health benefits plans. The Summary, above, describes these requirements. Among these entities, health care professionals and clinical laboratories may be small businesses within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16, et seq.

The compliance costs that small businesses would incur are the same as those that entities that are not small businesses incur, if they have reporting obligations. The

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Economic Impact, above, describes these costs. As the Economic Impact, above, indicates, entities with compliance obligations would not need to retain the services of professionals to comply. The burden of reporting that the chapter would impose on entities that are small businesses is self-scaling to correspond to the number of persons that the entity treats, diagnoses, and/or tests for HIV infection or HIV-related illnesses.

The Department has determined that the rules proposed for recodification, and the proposed amendments, repeals, and new rules, would impose the minimum standards necessary to ensure the universal and uniform reporting of complete and accurate HIV-related information, in compliance with applicable State law and Federal standards, to support the Department's public health surveillance and funding activities that rely on that data. Therefore, the Department proposes no lesser or differing standards based on business size.

Housing Affordability Impact

The rules proposed for recodification, and the proposed amendments, repeals, and new rules would have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing, because they would establish standards for HIV case reporting to the Department and would have no bearing on housing costs.

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Smart Growth Development Impact Analysis

The rules proposed for recodification, and the proposed amendments, repeals, and new rules would have an insignificant impact on smart growth, and there is an extreme unlikelihood that the rules would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey, because they would establish standards for HIV case reporting to the Department and would have no bearing on housing or development.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the rules proposed for repeal and recodification may be found at N.J.A.C. 8:57-2 and at N.J.A.C. 8:57-2 Subchapter Appendices A through G.

Full text of the rules proposed for recodification with amendments, and the proposed amendments and new rules, follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

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TITLE 8

HEALTH

CHAPTER 57

COMMUNICABLE DISEASES

SUBCHAPTER 1. (No change.)

SUBCHAPTER 2. (RESERVED)

SUBCHAPTER 3. – SUBCHAPTER 8. (No change.)

CHAPTER 65

[(RESERVED)]

HIV INFECTION REPORTING

SUBCHAPTER [2. REPORTING OF ACQUIRED IMMUNODEFICIENCY SYNDROME AND INFECTION WITH HUMAN IMMUNODEFICIENCY VIRUS] **1. GENERAL PROVISIONS**

[8:57-2.1] **8:65-1.1** Purpose and scope

(a) The purpose of this [subchapter] **chapter** is to establish [a framework] **standards** for the reporting of **cases of infection with** Human Immunodeficiency Virus (HIV) [infection and Acquired Immunodeficiency Syndrome (AIDS) so that] **and HIV-related laboratory test results to** the Department [of Health and Senior Services can take action to protect the public health and set standards for maintaining confidentiality in accordance with] **pursuant to N.J.S.A. 26:1A-1 et seq., especially 26:1A-7; 26:4-1, et seq., and 26:5C-1, et seq., particularly 26:5C-6 [and 20].**

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(b) This [subchapter] **chapter** applies to [health]:

1. Health care providers and institutions that [order diagnostic]:

i. Order, or obtain the results of, HIV-related laboratory tests [for HIV or AIDS, diagnose individuals with];

ii. Diagnose persons as having HIV [or AIDS,] infection; and/or [provide treatment for individuals diagnosed with]

iii. Treat persons for HIV [or AIDS,] infection; and [to clinical]

2. Clinical laboratories that perform **HIV-related laboratory** tests [indicative of HIV or AIDS and covers reporting standards]; **and**

3. Counseling and testing sites.

[(c) The provisions of N.J.A.C. 8:57-1 shall not apply to any case of AIDS or infection with HIV.]

8:65-1.2 Publications incorporated by reference

(a) The following web-based publications of, or administered by, the United States Department of Health and Human Services, are incorporated herein by reference, as amended and supplemented:

1. CDC, *Revised Surveillance Case Definition for HIV Infection — United States, 2014*, MMWR 2014; 63 (No. RR-3) (April 11, 2014), as amended and supplemented (hereinafter referred to as “surveillance case definition”), available at <https://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf>,

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<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>, and

<https://www.cdc.gov/hiv/guidelines/reporting.html>;

2. CDC, *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action* (2011) (hereinafter referred to as the “*Data Security Guidelines*”), available at

<https://www.cdc.gov/hiv/guidelines/reporting.html> and

<https://www.cdc.gov/nchhstp/programintegration/docs/pcsidatasecurityguidelines.pdf>;

3. CDC, *HIV Diagnostic Tests LOINC Map* (2021), available at

<https://www.cdc.gov/hiv/guidelines/reporting.html>;

4. CDC, National Center for Health Statistics, under authorization by the World Health Organization, *International Statistical Classification of Diseases and Related Health Problems, 10th revision, Clinical Modification* (2021 release) (hereinafter referred to as the “ICD-10-CM,”) available at

<https://www.cdc.gov/nchs/icd/icd10cm.htm>;

5. CDC and Association of Public Health Laboratories, *Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations* (June 27, 2014) (hereinafter referred to as the “*Laboratory Testing Recommendations*”), available

at <http://dx.doi.org/10.15620/cdc.23447>; and

The official versions of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* and/or the *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

6. CDC, *2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens* (2018) (hereinafter referred to as the “testing algorithm”), available at <https://stacks.cdc.gov/view/cdc/50872>.

(b) The following web-based publications of, or administered by, the Veterans Health Administration (VHA) of the United States Department of Veterans Affairs (VA) are incorporated herein by reference, as amended and supplemented:

1. VHA Directive 1131(4), *Management of Infectious Diseases and Infection Prevention and Control Programs* (November 7, 2017, amended March 26, 2021) (hereinafter referred to as “VHA Directive 1131(4)”), available at https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=5616, (see particularly Appendix E *Infectious Disease Reporting*); and

2. VHA Directive 1304, *National Human Immunodeficiency Virus (HIV) Program* (August 15, 2019) (hereinafter referred to as “VHA Directive 1304”) available at https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3056, (see particularly Part 5, *Responsibilities, §f VA Medical Facility Director*, at subsection (11)).

(c) The following web-based publications of, or administered by, the Federal Bureau of Prisons (BOP) of the United States Department of Justice are incorporated herein by reference, as amended and supplemented:

1. BOP, *Clinical Guidance: HIV Management* (April 2021) (hereinafter referred to as *BOP HIV Management Guidance*, available at

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https://www.bop.gov/resources/pdfs/hiv_infection_management_20210427.pdf;

and

2. BOP, Program Statement Number 6190.04, *Infectious Disease Management* (June 3, 2014) (hereinafter referred to as “BOP PS 6190.04”) available at https://www.bop.gov/policy/progstat/6190_004.pdf.

[8:57-2.3] 8:65-1.3 Definitions

(a) The following words and terms, as used in this chapter, have the meanings that N.J.S.A. 26:5C-1, et seq., establishes, particularly at 26:5C-5:

“Commissioner”;

“Department”; and

“HIV infection,” as amended and supplemented by the surveillance case definition.

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

[“Acquired Immunodeficiency Syndrome” or “AIDS” means a condition affecting an individual who has a reliably diagnosed disease that meets the criteria for AIDS specified by the Centers for Disease Control and Prevention of the United States Public Health Services in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Review (MMWR) published on December 18, 1992 and in Volume 43 No. RR-17 of the MMWR published on September 30, 1994 and updated in Volume 48 No. RR-13 of the MMWR published on December 10, 1999.]

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“Adolescent” means a person who is 13 years of age or older, and under 18 years of age.

“Adult” means a person who is 18 years of age or older.

“Audit” means the review of [medical] health records to determine the type and dates of services related to HIV infection provided by a health care provider, responsible party, or institution, and to verify compliance with this [subchapter] chapter.

“Bio-analytical laboratory director” means a person to whom the State Board of Medical Examiners, within the Division of Consumer Affairs of the New Jersey Department of Law and Public Safety, issues a license pursuant to the Bio-analytical Laboratory and Laboratory Directors Act (1953), N.J.S.A. 45:9-42 through 42.25.

“Blood bank” means an entity that the Department licenses as a blood bank pursuant to N.J.S.A. 26:2A-1 through 16 and N.J.A.C. 8:8.

“CD4 count or percentage” means a count or percentage of [lymphocytes] T-lymphocytes containing the [CD4] CD4+ epitope [as], determined [by the] as a result of lymphocyte phenotyping.

[1. An absolute CD4 count means the number of lymphocytes containing the CD4 epitope per cubic millimeter.

2. A relative CD4 count means the number of such cells expressed as a percentage of total lymphocytes.]

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“Centers for Disease Control and Prevention” or “CDC” means the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

“Clinical laboratory” means:

- 1. A laboratory that the Department licenses as a clinical laboratory pursuant to the New Jersey Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.26 through 42.45, excluding a limited purpose laboratory; and**
- 2. A VHA laboratory.**

“Clinical laboratory director” means a bio-analytical laboratory director in charge of a clinical laboratory.

“Confirmed case” means a case that is positive for HIV in accordance with the criteria for a confirmed case established in the surveillance case definition, obtained in accordance with the *Laboratory Testing Recommendations* and the testing algorithm.

“Counseling and testing site” means a facility the Department designates to provide counseling and rapid HIV testing without charge pursuant to the terms and conditions of a Department grant.

“Division” means the Division of HIV[/AIDS], STD, and TB Services [located in] for which the contact information is The New Jersey Department of Health, Division of HIV, STD and TB Services, HIV/AIDS Surveillance, , PO Box 363, Trenton, NJ 08625-0360, telephone (609) 984-5940.

The official versions of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* and/or the *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

“Division envelope” means a postage-prepaid envelope that is addressed to the Division and marked “confidential,” for use in submission of HIV reports to the Division.

1. Supplies of Division envelopes are available at no charge to health care providers, responsible parties, and clinical laboratories upon telephone request to the Division at (609) 984-5940.

“DNA” means deoxyribonucleic acid.

“Electronic laboratory reporting” means electronic laboratory reporting as N.J.A.C. 8:57 defines that term and in accordance with the electronic laboratory reporting procedures that N.J.A.C. 8:57 establishes.

“Epidemiologic investigation[s]” means the [review] analysis of [medical] health records and laboratory test results to [determine] confirm cases, evaluate and identify disease progression, confirm treatments and co-morbidities [of other diseases with HIV or AIDS, treatments prescribed, laboratory test results], and ascertain other characteristics of [individuals diagnosed] persons exposed to or living with HIV infection [or AIDS].

[“Human Immunodeficiency Virus” or “HIV” means the virus that causes AIDS and that meets the case definition of HIV specified by the Centers for Disease Control and Prevention of the United States Public Health Services in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Review (MMWR) published on December 18, 1992 and in Volume 43 No. RR-17 of the MMWR published on September 30, 1994 and updated in Volume 48 No. RR-13 of the MMWR published on December 10, 1999.]

The official versions of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* and/or the *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

“Federal correctional institution” means a hospital, clinic, laboratory service, or other provider of health care or laboratory services, which is:

- 1. Operated by, or under the jurisdiction of, the Federal Bureau of Prisons of the United States Department of Justice;**
- 2. Subject to BOP *HIV Management Guidance* and BOP PS 6190.04;**
and
- 3. Located:**
 - i. In New Jersey; or**
 - ii. In any State or Territory of the United States and providing health care or laboratory services to a New Jersey resident.**

“Fourth generation HIV test” means a test that detects the presence of HIV-1 antigens and HIV-1/2 antibodies.

"Health benefits plan" means a public or private plan that pays or provides hospital and medical expense benefits for covered services, and is delivered or issued for delivery in this State by or through a carrier, but does not include the following plans, policies, or contracts: Medicaid, Medicare, Medicare Advantage, accident only, credit, disability, long-term care, TRICARE supplement coverage, coverage arising out of a workers' compensation or similar law, automobile medical payment insurance, personal injury protection insurance issued pursuant to N.J.S.A. 39:6A-1 et seq., a dental plan as defined pursuant to N.J.S.A. 26:2S-26, and hospital confinement indemnity coverage.

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“Health care facility” means health care facility as N.J.S.A. 26:2H-1 et seq., particularly N.J.S.A. 26:2H-2, defines that term.

“Health care provider” means a physician, a physician assistant, and/or an advanced practice nurse whom the applicable professional board within the Division of Consumer Affairs of the Department of Law and Public Safety licenses pursuant to Title 45 of the New Jersey Revised Statutes.

“HIV” means the condition identified in the surveillance case definition, designated by the following ICD-10-CM codes:

- 1. B20 Human immunodeficiency virus (HIV) disease; and**
- 2. Z21 Asymptomatic human immunodeficiency virus (HIV) infection.**

“HIV immunoassay” means one of the following laboratory tests:

- 1. HIV 1 antibody differentiation assay;**
- 2. HIV 2 antibody differentiation assay;**
- 3. HIV-1 Western blot;**
- 4. HIV-2 Western blot; and**
- 5. HIV-1 immunofluorescent assay.**

“HIV-related laboratory test” means a test that the *HIV Diagnostic Tests LOINC Map* lists.

“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**

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result, and the results of all supplemental differential HIV immunoassays performed on the same specimen as part of the testing algorithm, regardless of whether the results of the supplemental HIV immunoassays are positive (reactive), non-reactive (negative for HIV), or indeterminate;

2. That is an HIV immunoassay performed on a specimen taken from a pediatric person, regardless of whether the results are positive (reactive), non-reactive (negative for HIV), or indeterminate;

3. That is an HIV nucleic acid (RNA or DNA) polymerase chain reaction (PCR) test:

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

ii. Yielding a quantitative result (copies per milliliter and/or logarithm value).

4. For CD4 counts and/or percentages, unless the test is ordered to assess a condition that is known not to be HIV, such as cancer;

5. For HIV subtype and antiviral resistance, which is to be reported by nucleotide sequence, as determined through genotypic resistance testing;

6. That is a positive or reactive result of an HIV detection culture or a P24 antigen test;

7. That is a positive or reactive result of a fourth-generation test for HIV; and

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8. That is a result of an HIV-related laboratory test conducted as part of the testing algorithm, including negative and indeterminate results, when any HIV-related test conducted as part of the testing algorithm contains a positive or reactive result.

“Institution” means [a hospital, sanitarium, nursing home, correctional facility, clinic,] **any of the following, but does not include a counseling and testing site:**

- 1. A health care facility;**
- 2. A facility under the jurisdiction of the Division of Mental Health and Addiction Services of the Department;**
- 3. A facility under the jurisdiction of the New Jersey:**
 - i. Department of Children and Families;**
 - ii. Department of Corrections;**
 - iii. Department of Human Services;**
 - iv. Juvenile Justice Commission; or**
 - v. Office of the Secretary of Higher Education;**
- 4. A correctional or juvenile detention facility under the jurisdiction of any New Jersey county or municipality;**
- 5. A Federal correctional institution;**
- 6. A VHA medical facility;**
- 7. A VHA laboratory;**

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8. A blood bank[, insurance company, or facility for HIV counseling and testing]; and

9. A health benefits plan.

["Laboratory HIV results" means clinical laboratory results showing the presence of HIV or components of HIV, or laboratory results showing the presence of antibodies to HIV, or results from viral load laboratory tests.]

"Limited purpose laboratory" means an entity that the Department licenses pursuant to N.J.A.C. 8:44-3.

"Office of Information and Regulatory Affairs" or "OIRA" means an office that is part of the Office of Management and Budget of the Executive Office of the President of the United States for which the contact information is Office of Information and Regulatory Affairs, Regulatory Information Service Center (MVE), General Services Administration, 1800 F Street, NW, Washington, DC 20405, (202) 482-7340, website <http://www.reginfo.gov>.

"Pediatric" means under 13 years of age and includes perinatal.

"Perinatal" means under 18 months of age.

"[Perinatally exposed] Perinatal exposure" means [that a child is] exposure of a perinatal infant to HIV by reason of the infant being born to a woman who [is known to be] has HIV [infected] infection at the time of delivery[, either through HIV testing prior to or during her pregnancy, or diagnosed by a health care provider].

"Rapid HIV test" means a test used to screen for HIV infection that detects, in under 30 minutes, the presence, in blood or oral fluid, of HIV:

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- 1. Antibodies; or**
- 2. Antibodies and antigens.**

“Responsible party” means the individual having control or supervision [over any] **of an** institution, such as a chief administrator.

“RNA” means ribonucleic acid.

“VHA laboratory” means a pathology and laboratory medicine service that **is:**

- 1. Operated by, or under the jurisdiction of, the Veterans Health Administration of the United States Department of Veterans Affairs; and**

- 2. Subject to VHA Directives 1131(4) and 1304; and**

- 3. Located:**

- i. In New Jersey; or**

- ii. In any State or Territory of the United States and providing laboratory services to New Jersey residents.**

“VHA medical facility” means a hospital, clinic, pathology and laboratory medicine service, or other provider of health care services, that **is:**

- 1. Operated by, or under the jurisdiction of, the Veterans Health Administration of the United States Department of Veterans Affairs;**

- 2. Subject to VHA Directives 1131(4) and 1304; and**

- 3. Located:**

- i. In New Jersey; or**

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ii. In any State or Territory of the United States and providing health care or pathology and laboratory medicine services to New Jersey residents.

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. Adult HIV Confidential Case Report Form (ACRF), CDC Form 50.42A (Revised November 2019);**
- ii. The instructions for completion of the ACRF, entitled the Technical Guidance for HIV Surveillance Programs: Adult HIV Confidential Case Report Form (revised November 2019) (“ACRF Technical Guidance”);**
- ii. Pediatric HIV Confidential Case Report Form (PCRF), CDC Form 50.42B (revised November 2019);**
- iii. Perinatal HIV Exposure Reporting form (PHER), CDC Form 50.42D ((revised November 2019); and**

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iv. 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”); and

2. The information collection bearing OMB Control No. 0920-0696, which is accessible by users of the website, <http://www.evaluationweb.com>, and available for review at <https://help.lutherconsulting.com/index.html>, particularly:

i. The 2019 EvaluationWeb® HIV Test Template and EvaluationWeb® HIV Test Template Guidance (revised January 18, 2019); and

ii. CDC, *National HIV Prevention Program Monitoring and Evaluation: NHM&E Data Variables and Values* (February 21, 2019).

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

8:65-2.1 Health care providers to report, and responsible parties to ensure reporting of, HIV infection diagnoses and HIV-related laboratory test results in adults and adolescents

(a) With respect to an adult and/or an adolescent who receives health care and/or resides in the State, health care providers shall complete all fields of an ACRF and submit it to the Division pursuant to N.J.A.C. 8:65-2.4 within 24 hours of:

1. Obtaining an HIV-related laboratory test result performed on the adult or adolescent;

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2. Making a diagnosis of a confirmed case of HIV infection in the adult or adolescent; and/or

3. Providing the adult or adolescent treatment for HIV infection.

(b) Responsible parties shall ensure that institution personnel comply with (a) above.

(c) Subject to (d) below, the Department may take enforcement action pursuant to N.J.A.C. 8:65-3 against health care providers, responsible parties, and institutions that fail to comply with (a) and/or (b) above, as applicable.

(d) The Department will refrain from enforcement action against a health care provider, a responsible party, or an institution that fails to comply with (a) and/or (b) above, as applicable, if the health care provider, responsible party, or institution completes and timely submits to the Division, and/or ensures the completion and timely submission to the Division of, an ACRF in which the fields that the ACRF Technical Guidance identifies as “required” are fully completed.

8:65-2.2 Health care providers to report, and responsible parties to ensure reporting of, perinatal exposures to HIV, pediatric HIV-related laboratory test results, and pediatric HIV infection diagnoses in perinatal or pediatric cases

(a) A health care provider shall complete a PHER and a PCRF and submit them to the Division pursuant to N.J.A.C. 8:65-2.4 within 24 hours of identifying a patient as a case of perinatal exposure to HIV if:

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1. The health care provider is providing health care to the patient in the State; and/or

2. The patient is a resident of the State.

(b) With respect to a pediatric patient to whom a health care provider is providing health care in the State, and/or who is a resident of the State, a health care provider shall complete a PCRf and submit it to the Division pursuant to N.J.A.C. 8:65-2.4 within 24 hours of:

1. Obtaining an HIV-related laboratory test result performed on a diagnostic specimen taken from the pediatric patient;

2. Diagnosing a confirmed case of HIV infection in the pediatric patient in accordance with the criteria for a confirmed case; and/or

3. Providing treatment for HIV infection to the pediatric patient.

(c) Responsible parties shall ensure that institution personnel comply with (a) and (b) above.

(d) Subject to (e) below, the Department may take enforcement action pursuant to N.J.A.C. 8:65-3 against health care providers, responsible parties, and institutions that fail to comply with (a), (b), and/or (c) above.

(e) The Department will refrain from enforcement action against a health care provider, a responsible party, or an institution that fails to comply with (a), (b), and/or (c) above, as applicable, if the health care provider, responsible party, or institution completes and timely submits to the Division, and/or ensures the completion and timely submission to the Division of, a PCRf and/or a PHER, as

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applicable, in which the fields that the PCRF and PHER Technical Guidance identifies as “required” are fully completed.

8:65-2.3 Counseling and testing sites to report rapid HIV test results

(a) Within 24 hours of obtaining a positive rapid HIV test result for an adult or an adolescent, regardless of whether the adult or adolescent is a resident of the State, a counseling and testing site shall:

1. Submit information relating to the result in accordance with the content and procedural requirements of the information collection at OMB Control No. 0920-0696;

2. Submit within the information collection form the name, date of birth, and street address of the adult or adolescent; and

3. Specify the responses of the adult or adolescent to the following inquiries:

i. Whether the adult or adolescent had previous negative HIV test result, and, if so, the date of the last test that yielded a negative result; and

ii. Whether the adult or adolescent had previous positive HIV test result, and, if so, the date of the first test that yielded a positive result.

(b) Within 30 days of obtaining a negative rapid HIV test result for an adult or an adolescent, a counseling and testing site shall submit information relating to the result in accordance with the content and procedural requirements of the information collection at OMB Control No. 0920-0696.

The official versions of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* and/or the *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

8:65-2.4 Procedure to report to the Division by health care providers, responsible parties, and counseling and testing sites

(a) Health care providers, responsible parties, and counseling and testing sites with reporting obligations pursuant to N.J.A.C. 8:65-2.1, 2.2, or 2.3 shall submit, or ensure submission of, required reports to the Division:

1. By postal mail marked “confidential,” preferably using a Division envelope; or

2. By secure electronic facsimile (e-fax) to (609) 984-2455, subject to (b) below.

(b) Health care providers, responsible parties, and counseling and testing sites, having reporting obligations pursuant to this chapter, shall not transmit reports, and shall ensure that reports are not submitted, by e-fax pursuant to (a)2 above unless the sending entity does so using processes and equipment that are compliant with the *Data Security Guidelines*.

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

(a) A clinical laboratory director shall report to the Division the accession number, the CLIA code, and the following sections of the ACRF, in accordance with (b) below, within five working days of obtaining an HIV-related laboratory test result performed on a specimen taken from an adult or adolescent person who is receiving health care in, or is a resident of, the State:

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1. The section labeled, “Patient Identification”;
2. The section labeled, “Facility Providing Information”;
3. The section labeled, “Patient Demographics”; and
4. The section labeled, “Laboratory Data.”

(b) A clinical laboratory director shall report to the Department the accession number, the CLIA code, and the following sections of the PCRf, in accordance with (b) below, within five working days of obtaining an HIV-related laboratory test result performed on a specimen taken from a pediatric person who is receiving health care in, or is a resident of, the State:

1. The section labeled, “Patient Identification”;
2. The section labeled, “Facility Providing Information”;
3. The section labeled, “Patient Demographics”; and
4. The section labeled, “Laboratory Data.”

(c) The Department establishes and maintains a form of “Confidential Laboratory Report” that captures the sections of the ACRf and the PCRf that clinical laboratories are to report pursuant to (a) and (b) above, and makes this form available on the Department’s forms page at <http://www.nj.gov/health/forms> or upon request to the Division.

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

1. Electronic laboratory reporting;

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2. By secure electronic facsimile (e-fax) to (609) 984-2455, subject to (b) below;

3. 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.

(e) A clinical laboratory director and a clinical laboratory shall not transmit reports, and shall ensure that reports are not submitted, by e-fax pursuant to (d)2 above, unless the sending entity does so using processes and equipment that are compliant with the *Data Security Guidelines*.

(f) If a clinical laboratory sends or “refers” a specimen (a “referring clinical laboratory”) to another clinical laboratory (a “reference laboratory”) to perform an HIV-related laboratory test, the referring clinical laboratory and the laboratory director thereof remain responsible to report, and to ensure the complete reporting, to the Division in accordance with this section, of HIV-related laboratory test results that the reference laboratory obtains, regardless of whether the Department has independent jurisdiction over the reference laboratory.

(g) Subject to (h) below, the Department may take enforcement action pursuant to N.J.A.C. 8:65-3 against a clinical laboratory and/or a clinical laboratory director that fails to comply with this section.

(h) The Department will refrain from enforcement action against clinical laboratories and clinical laboratory directors that fail to comply with this section

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if the clinical laboratory and the clinical laboratory director timely submit to the Division, and/or ensure the timely submission to the Division of, the sections listed at (a) and (b) above of an ACRF or a PCRf, as applicable, as to which all fields that the ACRF Technical Guidance or the PCRf and PHER Technical Guidance, as applicable, identifies as “required,” are fully completed.

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. The specimen collection date;**
- 2. The health care provider’s:**
 - i. Name;**
 - ii. Hospital, office, or practice name;**
 - iii. Street address, municipality, ZIP Code™, and county; and**
 - iv. Telephone number; and**
- 2. The patient’s:**
 - i. Full name (first name, all middle names, and last name);**
 - ii. Street address, municipality, ZIP Code™, and county;**
 - iii. Telephone number;**
 - iv. Sex;**

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v. Date of birth;

viii. The identifying number assigned to the patient by the health care provider ordering the laboratory test, and

ix. Pregnancy status, if applicable.

(b) A responsible party shall ensure that institution personnel comply with (a) above.

(c) The Department may take enforcement action pursuant to N.J.A.C. 8:65-3 against health care providers and responsible parties that fail to ensure that all of the information required pursuant to (a) above are included within the order or specimen submission form.

SUBCHAPTER 3. ACCESS TO RECORDS; ENFORCEMENT

8:65-3.1 Records subject to Department examination

(a) Health care providers, responsible parties, and clinical laboratory directors shall make available to the Department on request, for inspection, audit, epidemiologic investigation, copying, scanning, and/or public health purposes, the complete health records, including identifying information, of:

1. Persons who have a confirmed diagnosis of HIV infection and who receive care or reside in the State;

2. Persons who receive care or reside in the State for whom an HIV-related laboratory test result is ordered or obtained;

3. Infants who have perinatal exposure; and

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4. Women who give birth, and/or have given birth, to infants who have perinatal exposure.

[8:57-2.11] **8:65-3.2** Access to information **and records; confidentiality**

(a) [The] **Information, forms, and records** submitted to **or obtained by** the Department pursuant to this [subchapter] **chapter** [contain demographic and medical information related to the Department's investigations and epidemiologic studies of HIV and AIDS and shall] **are not** [be considered] "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq., **or under the common law, regardless of whether personal or other identifiers are removed or redacted,** and [shall be] **are deemed to be:**

1. - 3. (No change.)

(b) [As provided by N.J.S.A. 26:4-2 and 26:5C-5 through 14, the information] **Information reported and records held by or submitted** to the Department [shall] **pursuant to N.J.S.A. 26:1A-1, et seq., especially 26:1A-7, 26:4-1, et seq., 26:5C-1, et seq., and this chapter, are not** [be] subject to public **access or** inspection[, but shall be subject to access only by the Department for public health purposes].

(c) (No change.)

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8:65-3.3 Noncompliance with chapter; enforcement; penalties

(a) This chapter is part of the State Sanitary Code and persons who are noncompliant herewith are subject to the penalties for noncompliance with the State Sanitary Code at N.J.S.A. 26:1A-10, and 26:4-129 and 130.

(b) Persons who are noncompliant with this chapter are subject to N.J.S.A. 26:5C-14 and 18.

(c) In addition to other available actions and remedies:

1. Health care providers who are noncompliant with this chapter are subject to Department reporting of their noncompliance to applicable professional licensing boards with jurisdiction established pursuant to Title 45 of the Revised Statutes within the Division of Consumer Affairs of the Department of Law and Public Safety, to credentialing and accrediting entities, health care facilities and other institutions at which they are employed or hold privileges, and health care plans and Federal payers from which they might seek compensation or reimbursement for health care services;

2. Responsible parties and/or institutions that are noncompliant with this chapter are subject to Department reporting of their noncompliance to credentialing and accrediting entities, Federal and State licensing entities with jurisdiction over the responsible party and/or the institution, and health care plans and Federal payers from which they might seek compensation or reimbursement for health care services; and

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3. Clinical laboratory directors and/or clinical laboratories that are noncompliant with this chapter are subject to Department reporting of their noncompliance to credentialing and accrediting entities, Federal and State clinical laboratory director and clinical laboratory licensing authorities with jurisdiction, health care facilities and other institutions at which they are employed, hold privileges, or provide services, and health care plans and Federal payers from which they might seek compensation or reimbursement for health care services.

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