

## SUBCHAPTER 2. REPORTING OF ACQUIRED IMMUNODEFICIENCY SYNDROME AND INFECTION WITH HUMAN IMMUNODEFICIENCY VIRUS

### 8:57-2.1 Purpose and scope

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

(b) This subchapter applies to health care providers and institutions that order diagnostic tests for HIV or AIDS, diagnose individuals with HIV or AIDS, or provide treatment for individuals diagnosed with HIV or AIDS, and to clinical laboratories that perform tests indicative of HIV or AIDS and covers reporting standards.

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

### 8:57-2.2 Incorporated documents

(a) The Department incorporates by reference, as amended and supplemented, in this subchapter the Centers for Disease Control and Prevention of the United States Public Health Services case definitions of HIV and AIDS available in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Report (MMWR) published on December 18, 1992 and in Volume 43 No RR-17 of the MMWR published on September 30, 1994 and updates found at [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr).

(b) The Department incorporates by reference the following forms and instructions in this subchapter.

1. Adult HIV/AIDS Confidential Case Report (DHAS-44) (Appendix A) is a form required for health care providers and responsible parties to report adult cases of HIV and AIDS;
  2. HIV/AIDS Laboratory Report (DHAS-43) (Appendix B) is a form required for clinical laboratory directors to report tests defined in this subchapter;
  3. Pediatric HIV/AIDS Confidential Case Report (DHAS-45) (Appendix C) is a form required for health care providers and responsible parties to report pediatric cases of HIV, AIDS and pediatric exposures to HIV;
  4. The HIV Test Form (OMB No. 0920-0696) Exp. Date: 08/31/2010, as amended and supplemented, produced by the Centers for Disease Control and Prevention (Appendix D) is required for health care providers or responsible parties using the State Public Health and Environmental Laboratories to perform HIV testing in order to report adult cases of HIV and AIDS;
- i. Instructions for HIV Reporting using the HIV Test Form (Appendix E ) are to be used by health care providers or responsible parties testing individuals as part of the New Jersey HIV Counseling and Testing System and using the New Jersey Public Health and Environmental Laboratories; and

5. The Instructions for Submission of Positive HIV Diagnostic Specimens (Appendix F) is a set of instructions to be used by health care providers, responsible parties and clinical laboratory directors for sending specimens to the New Jersey Public Health and Environmental Laboratories.

(c) The Department's reporting forms and instructions described in (b)1 through 5 above are available using the following methods:

1. Electronically at the Department's "Forms" webpage <http://web.doh.state.nj.us/forms/> or the Division's webpage at [www.state.nj.us/health/aids](http://www.state.nj.us/health/aids); or

2. By contacting the Division of HIV/AIDS Services at (609) 984-5940.

(d) Completed forms shall be addressed to "Surveillance" and mailed to the Division of HIV/AIDS Services at PO Box 363, Trenton, New Jersey 08625-0363 in an envelope marked "Confidential."

1. Health care providers, responsible parties or clinical laboratory directors may contact the Division of HIV and AIDS Services at (609) 984-\*[6940]\*\***5940\*** to request pre-addressed envelopes.

(e) The Department incorporates by reference the Instructions for Electronic Submission of Laboratory Results Indicative of HIV Infection (Appendix G) in this subchapter, which details the requirements for clinical laboratory directors to report tests defined in this subchapter and is available on the Division's webpage at [www.state.nj.us/health/aids](http://www.state.nj.us/health/aids).

### 8:57-2.3 Definitions

The following words and terms, when used in this subchapter shall 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.

"Audit" means the review of medical 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.

"CD4 count" means a count of lymphocytes containing the CD4 epitope as determined by the results 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.

"Division" means the Division of HIV/AIDS Services located in the Department.

"Epidemiologic investigations" means the review of medical records to determine disease progression, co-morbidities of other diseases with HIV or AIDS, treatments prescribed, laboratory test results, and other characteristics of individuals diagnosed 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.

"Institution" means a hospital, sanitarium, nursing home, correctional facility, clinic, blood bank, insurance company or facility for HIV counseling and testing.

"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 \*[conducted to measure the quantitative presence of HIV ribonucleic acid (RNA) (viral load tests), such as quantitative polymerase chain reaction (PCR) tests, or tests used only for HIV infected individuals]\*.

"Perinatally exposed" means that a child is born to a woman who is known to be HIV infected at the time of delivery, either through HIV testing prior to or during her pregnancy, or diagnosed by a health care provider.

"Responsible party" means the individual having control or supervision over any institution, such as a chief administrator.

#### 8:57-2.4 Reporting HIV Infection for health care providers and responsible parties

(a) A health care provider or responsible party for an institution providing services to an individual found to be infected with HIV, or ordering a test resulting in the diagnosis of HIV, shall, within 24 hours of receipt of a laboratory report indicating such a condition, or within 24 hours of making a diagnosis of HIV infection, report in writing to the Department using the Adult HIV/AIDS Confidential Case Report Form, available at subchapter Appendix A.

(b) A health care provider or responsible party testing individuals as part of the New Jersey HIV Counseling and Testing System and using the New Jersey Public Health and Environmental Laboratories shall, within 24 hours of receipt of a laboratory report indicating such a condition, [page=1443] report in writing such condition directly to the Department using the HIV Test Form, available at subchapter Appendix D.

i. The health care provider or responsible party shall use the Instructions for HIV Reporting using the HIV Test Form, available at subchapter Appendix E.

(c) A health care provider or responsible party, may delegate this reporting activity

to a member of the staff, but this delegation does not relieve the health care provider or responsible party of the ultimate reporting responsibility.

(d) A health care provider or responsible party who provides medical services to an individual found to be infected with HIV, or orders tests resulting in the diagnosis of HIV, shall make the names of the individuals infected with HIV along with their medical records available to the Department for audit or epidemiologic investigation.

#### 8:57-2.5 Reporting HIV infection for clinical laboratories

(a) A clinical laboratory director shall, within five working days of completion of a quantitative\*[, Polymerase Chain Reaction (PCR) also known as a]\* **HIV** viral load test regardless of test result, or any other laboratory test, which has results indicative of infection with HIV, report in writing such results to the Department using one of the following two methods:

1. An electronic file in accordance with the Instructions for Electronic Submission of Laboratory Results Indicative of HIV Infection, available at subchapter Appendix G; or
2. The HIV/AIDS Laboratory Report Form (DHAS-43), available at subchapter Appendix B.

(b) The clinical laboratory director shall only report specimens sent to the clinical laboratory from a healthcare provider or institution located in New Jersey, or obtained from residents of New Jersey.

#### 8:57-2.6 Reporting children perinatally exposed to HIV

(a) A health care provider or responsible party for an institution providing care to a child known to be perinatally exposed to HIV, or ordering a test resulting in the diagnosis of perinatally exposed to HIV, shall, within 24 hours of receipt of a laboratory report indicating such a condition, report in writing such condition directly to the Department using the Pediatric HIV/AIDS Case Report Form (DHAS-45), available at subchapter Appendix C.

(b) The health care provider or responsible party of the institution may delegate this reporting activity to a member of the staff, but this delegation does not relieve the health care provider or responsible party of the ultimate reporting responsibility.

(c) A health care provider attending a child who was exposed perinatally to HIV or the responsible party at an institution in which any child is determined to have been perinatally exposed to HIV shall make the medical records of the mother and child available to the Department for audit or epidemiologic purposes.

#### 8:57-2.7 Reporting AIDS for health care providers and responsible parties

(a) A health care provider or responsible party for an institution providing services to an individual determined to be diagnosed with AIDS shall, within 24 hours of the time AIDS is diagnosed, report in writing such condition directly to the Department using the Adult HIV/AIDS Confidential Case Report Form (DHAS-44), available at subchapter Appendix A.

(b) The health care provider or responsible party may delegate this reporting activity to a member of the staff, but this delegation does not relieve the health care provider or responsible party of the ultimate reporting responsibility.

(c) A health care provider or responsible party shall complete the required report established at (a) above regardless of whether the patient previously had been reported as having HIV infection.

(d) The report of AIDS will be deemed to also be a report of HIV infection.

(e) A health care provider attending an individual found to be diagnosed with AIDS or the health care provider or responsible party at any institution shall make the names of the individuals diagnosed with AIDS along with their medical records available to the Department for audit or epidemiologic purposes.

#### 8:57-2.8 Reporting AIDS for Clinical Laboratories

(a) A clinical laboratory director shall, within five working days of completion of a CD4 count, which has absolute or relative results below a level specified by the Centers for Disease Control and Prevention as criteria for defining AIDS, report such results to the Department using one of the following methods:

1. An electronic file in accordance with the Instructions for Electronic Submission of Laboratory Results indicative of HIV infection, available in subchapter Appendix G; or
2. The HIV/AIDS Laboratory Report Form (DHAS-43), available in subchapter Appendix B.

(b) The clinical laboratory director shall only report specimens sent to the clinical laboratory from a health care provider or institution located in New Jersey, or obtained from residents of New Jersey.

#### 8:57-2.9 Testing procedures

(a) No health care provider or responsible party may direct a person to be tested for HIV, a component of HIV, or antibodies to HIV, unless the name and address of the person whose specimen is being tested is known and recorded by the health care provider or \*[administrator]\* **\*responsible party and provided to the testing laboratory\***, except that the Commissioner may designate facilities, which are permitted to test for antibodies to HIV without obtaining the name and address of the person being tested.

1. The Department does not require a health care provider or responsible party to report the name or address of any individual that requests testing at a facility designated by the Commissioner to test for HIV anonymously.

#### 8:57-2.10 Specimen submissions

(a) A health care provider, responsible party or clinical laboratory director shall, within \*[24 hours]\* **\*one week\*** of completion of a confirmatory diagnostic test indicative of HIV infection, send the residual specimen of such test to the State's Public Health and Environmental Laboratories (PHEL), except as noted in (b) below.

1. The specimen must contain identifying information so that the Department can link the specimen to the identifying information contained in the reports required at [N.J.A.C. 8:57-2.5](#) and [2.8](#).

2. The specimen shall be sent in accordance with the Instructions for Submission of Positive HIV Diagnostic Specimens, available at subchapter Appendix F.

(b) A health care provider or responsible party shall not send a specimen to the PHEL if they obtained the specimen from an individual without identifying information at a facility designated by the Commissioner to test for HIV anonymously.

#### 8:57-2.11 Access to information

(a) The forms submitted to the Department pursuant to this subchapter contain demographic and medical information related to the Department's investigations and epidemiologic studies of HIV and AIDS and shall not be considered "government records" subject to public access or inspection within the meaning of [N.J.S.A. 47:1A-1](#) et seq. and shall be deemed:

1. "Information relating to medical . . . history, diagnosis, treatment, or evaluation" within the meaning of Executive Order 26, §4(b)1 (McGreevey, August 13, 2002);

2. "Records concerning morbidity, mortality and reportable diseases of named individuals required to be made, maintained or kept by any State or local governmental agency" within the meaning of Executive Order 9, §2(c) (Hughes, September 30, 1963); and/or

3. Information "for use in the field of forensic pathology or for use in medical or scientific education or research" pursuant to [N.J.S.A. 47:1A-1.1](#).

(b) As provided by [N.J.S.A. 26:4-2](#) and [26:5C-5](#) through 14, the information reported to the Department shall not be subject to public inspection, but shall be subject to access only by the Department for public health purposes.

(c) The Department may release data in summary format without identifying information in the form of reports and epidemiologic profiles.

#### [page=1444] 8:57-2.12 Failure to comply with reporting requirements

(a) The Department shall provide written notification to health care providers that fail to fulfill the reporting requirements of this subchapter.

1. Health care providers failing to meet these reporting requirements, despite warning, shall be subject to fines, as allowed by [N.J.S.A. 26:4-129](#) and 1.30.

2. Health care providers shall be subject to other actions, including notification of the Board of Medical Examiners of the Department of Law and Public Safety, and appropriate hospital medical directors or administrators.

(b) The Department shall provide written notification to the responsible party for an institution, who fails to fulfill the reporting obligations of this subchapter.

1. A responsible party failing to meet these reporting requirements, despite warning,

shall be subject to a fine, as allowed by [N.J.S.A. 26:4-129](#) and 1.30.

2. The responsible party shall be subject to other actions, including notification of the Department's Health Facilities Evaluation and Licensing Division, other appropriate licensing review organizations, and other appropriate agencies.

(c) The Department shall provide written notification to clinical laboratory directors that fail to fulfill the aforementioned reporting obligations.

1. Clinical laboratory directors failing to meet these requirements, despite warning, shall be subject to fines as allowed by [N.J.S.A. 26:4-129](#) and 1.30.

2. The clinical laboratory director shall be subject to other actions, including notification of the Department's Clinical Laboratory Improvement Service.