Appendix: Revised Surveillance Case Definition for HIV Infection*

This revised definition of HIV infection, which applies to any HIV (e.g., HIV-1 or HIV-2), is intended for public health surveillance only. It incorporates the reporting criteria for HIV infection and AIDS into a single case definition. The revised criteria for HIV infection update the definition of HIV infection implemented in 1993 (18); the revised HIV criteria apply to AIDS-defining conditions for adults (18) and children (17,19), which require laboratory evidence of HIV. This definition is not presented as a guide to clinical diagnosis or for other uses (17,18).

I. In adults, adolescents, or children aged greater than or equal to 18 months**, a reportable case of HIV infection must meet at least one of the following criteria:

**Laboratory Criteria**

- Positive result on a screening test for HIV antibody (e.g., repeatedly reactive enzyme immunoassay), followed by a positive result on a confirmatory (sensitive and more specific) test for HIV antibody (e.g., Western blot or immunofluorescence antibody test)

or

- Positive result or report of a detectable quantity on any of the following HIV virologic (nonantibody) tests:
  - HIV nucleic acid (DNA or RNA) detection (e.g., DNA polymerase chain reaction [PCR] or plasma HIV-1 RNA)***
  - HIV p24 antigen test, including neutralization assay
  - HIV isolation (viral culture)

**OR**

**Clinical or Other Criteria (if the above laboratory criteria are not met)**

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician

or
II. In a child aged less than 18 months, a reportable case of HIV infection must meet at least one of the following criteria:

**Laboratory Criteria**

**Definitive**

- Positive results on two separate specimens (excluding cord blood) using one or more of the following HIV virologic (nonantibody) tests:
  - HIV nucleic acid (DNA or RNA) detection
  - HIV p24 antigen test, including neutralization assay, in a child greater than or equal to 1 month of age
  - HIV isolation (viral culture)

**Presumptive**

A child who does not meet the criteria for definitive HIV infection but who has:

- Positive results on only one specimen (excluding cord blood) using the above HIV virologic tests and no subsequent negative HIV virologic or negative HIV antibody tests

**OR**

**Clinical or Other Criteria (if the above definitive or presumptive laboratory criteria are not met)**

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician

**OR**

- Conditions that meet criteria included in the 1987 pediatric surveillance case definition for AIDS (17,19)

III. A child aged less than 18 months born to an HIV-infected mother will be categorized for surveillance purposes as "not infected with HIV" if the child does not meet the criteria for HIV infection but meets the following criteria:
Laboratory Criteria

Definitive

- At least two negative HIV antibody tests from separate specimens obtained at greater than or equal to 6 months of age

  or

- At least two negative HIV virologic tests* from separate specimens, both of which were performed at greater than or equal to 1 month of age and one of which was performed at greater than or equal to 4 months of age

  AND

No other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)

  or

Presumptive

A child who does not meet the above criteria for definitive "not infected" status but who has:

- One negative EIA HIV antibody test performed at greater than or equal to 6 months of age and NO positive HIV virologic tests, if performed

  or

- One negative HIV virologic test* performed at greater than or equal to 4 months of age and NO positive HIV virologic tests, if performed

  or

- One positive HIV virologic test with at least two subsequent negative virologic tests****, at least one of which is at greater than or equal to 4 months of age; or negative HIV antibody test results, at least one of which is at greater than or equal to 6 months of age

  AND

No other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition).

OR

Clinical or Other Criteria (if the above definitive or presumptive laboratory criteria are not met)
• Determined by a physician to be "not infected", and a physician has noted the results of the preceding HIV diagnostic tests in the medical record

AND

NO other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)

II. A child aged less than 18 months born to an HIV-infected mother will be categorized as having perinatal exposure to HIV infection if the child does not meet the criteria for HIV infection (II) or the criteria for "not infected with HIV" (III).

* Draft revised surveillance criteria for HIV infection were approved and recommended by the membership of the Council of State and Territorial Epidemiologists (CSTE) at the 1998 annual meeting (11). Draft versions of these criteria were previously reviewed by state HIV/AIDS surveillance staffs, CDC, CSTE, and laboratory experts. In addition, the pediatric criteria were reviewed by an expert panel of consultants. [External Pediatric Consultants: C. Hanson, M. Kaiser, S. Paul, G. Scott, and P. Thomas.
CDC staff: J. Bertolli, K. Dominguez, M. Kalish, M.L. Lindegren, M. Rogers, C. Schable, R.J. Simonds, and J. Ward]

** Children aged greater than or equal to 18 months but less than 13 years are categorized as "not infected with HIV" if they meet the criteria in III.

*** In adults, adolescents, and children infected by other than perinatal exposure, plasma viral RNA nucleic acid tests should NOT be used in lieu of licensed HIV screening tests (e.g., repeatedly reactive enzyme immunoassay). In addition, a negative (i.e., undetectable) plasma HIV-1 RNA test result does not rule out the diagnosis of HIV infection.

**** HIV nucleic acid (DNA or RNA) detection tests are the virologic methods of choice to exclude infection in children aged less than 18 months. Although HIV culture can be used for this purpose, it is more complex and expensive to perform and is less well standardized than nucleic acid detection tests. The use of p24 antigen testing to exclude infection in children aged less than 18 months is not recommended because of its lack of sensitivity.

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1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults

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1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults

Summary

CDC has revised the classification system for HIV infection to emphasize the clinical importance of the CD4+ T-lymphocyte count in the categorization of HIV-related clinical conditions. This classification system replaces the system published by CDC in 1986 (1) and is primarily intended for use in public health practice. Consistent with the 1993 revised classification system, CDC has also expanded the AIDS surveillance case definition to include all HIV-infected persons who have less than 200 CD4+ T-lymphocytes/uL, or a CD4+ T-lymphocyte percentage of total lymphocytes of less than 14. This expansion includes the addition of three clinical conditions

- pulmonary tuberculosis, recurrent pneumonia, and invasive cervical cancer -- and retains the 23 clinical conditions in the AIDS surveillance case definition published in 1987 (2); it is to be used by all states for AIDS case reporting effective January 1, 1993.

REVISED HIV CLASSIFICATION SYSTEM FOR ADOLESCENTS AND ADULTS

The etiologic agent of acquired immunodeficiency syndrome (AIDS) is a retrovirus designated human immunodeficiency virus (HIV). The CD4+ T-lymphocyte is the primary target for HIV infection because of the affinity of the virus for the CD4 surface marker (3). The CD4+ T-lymphocyte coordinates a number
of important immunologic functions, and a loss of these functions results in progressive impairment of the immune response. Studies of the natural history of HIV infection have documented a wide spectrum of disease manifestations, ranging from asymptomatic infection to life-threatening conditions characterized by severe immunodeficiency, serious opportunistic infections, and cancers (4-13). Other studies have shown a strong association between the development of life-threatening opportunistic illnesses and the absolute number (per microliter of blood) or percentage of CD4+ T-lymphocytes (14-21). As the number of CD4+ T-lymphocytes decreases, the risk and severity of opportunistic illnesses increase.

Measures of CD4+ T-lymphocytes are used to guide clinical and therapeutic management of HIV-infected persons (22). Antimicrobial prophylaxis and antiretroviral therapies have been shown to be most effective within certain levels of immune dysfunction (23-28). As a result, antiretroviral therapy should be considered for all persons with CD4+ T-lymphocyte counts of less than 500/uL, and prophylaxis against Pneumocystis carinii pneumonia (PCP), the most common serious opportunistic infection diagnosed in men and women with AIDS, is recommended for all persons with CD4+ T-lymphocyte counts of less than 200/uL and for persons who have had prior episodes of PCP. Because of these recommendations, CD4+ T-lymphocyte determinations are an integral part of medical management of HIV-infected persons in the United States.

The classification system for HIV infection among adolescents and adults has been revised to include the CD4+ T-lymphocyte count as a marker for HIV-related immunosuppression. This revision establishes mutually exclusive subgroups for which the spectrum of clinical conditions is integrated with the CD4+ T-lymphocyte count. The objectives of these changes are to simplify the classification of HIV infection, to reflect current standards of medical care for HIV-infected persons, and to categorize more accurately HIV-related morbidity.

The revised CDC classification system for HIV-infected adolescents and adults * categorizes persons on the basis of clinical conditions associated with HIV infection and CD4+ T-lymphocyte counts. The system is based on three ranges of CD4+ T-lymphocyte counts and three clinical categories and is represented by a matrix of nine mutually exclusive categories (Table 1). This system replaces the classification system published in 1986, which included only clinical disease criteria and which was developed before the widespread use of CD4+ T-cell testing (1).

- Criteria for HIV infection for persons ages greater than 13 years:
  a. repeatedly reactive screening tests for HIV antibody (e.g., enzyme immunoassay) with specific antibody identified by the use of supplemental tests (e.g., Western blot, immunofluorescence assay);
  b. direct identification of virus in host tissues by virus isolation; c) HIV antigen detection; or d) a positive result on any other highly specific licensed test for HIV.

CD4+ T-Lymphocyte Categories

The three CD4+ T-lymphocyte categories are defined as follows:

- Category 1: greater than or equal to 500 cells/mL
- Category 2: 200-499 cells/uL
- Category 3: less than 200 cells/uL
These categories correspond to CD4+ T-lymphocyte counts per microliter of blood and guide clinical and therapeutic actions in the management of HIV-infected adolescents and adults (22-28). The revised HIV classification system also allows for the use of the percentage of CD4+ T-cells (Appendix A).

HIV-infected persons should be classified based on existing guidelines for the medical management of HIV-infected persons (22). Thus, the lowest accurate, but not necessarily the most recent, CD4+ T-lymphocyte count should be used for classification purposes.

Clinical Categories

The clinical categories of HIV infection are defined as follows: Category A

Category A consists of one or more of the conditions listed below in an adolescent or adult (greater than or equal to 13 years) with documented HIV infection. Conditions listed in Categories B and C must not have occurred.

- Asymptomatic HIV infection
- Persistent generalized lymphadenopathy
- Acute (primary) HIV infection with accompanying illness or history of acute HIV infection (29,30)

Category B consists of symptomatic conditions in an HIV-infected adolescent or adult that are not included among conditions listed in clinical Category C and that meet at least one of the following criteria: a) the conditions are attributed to HIV infection or are indicative of a defect in cell-mediated immunity; or b) the conditions are considered by physicians to have a clinical course or to require management that is complicated by HIV infection. Examples of conditions in clinical Category B include, but are not limited to:

- Bacillary angiomatosis
- Candidiasis, oropharyngeal (thrust)
- Candidiasis, vulvovaginal; persistent, frequent, or poorly responsive to therapy
- Cervical dysplasia (moderate or severe)/cervical carcinoma in situ
- Constitutional symptoms, such as fever (38.5 C) or diarrhea lasting greater than 1 month
- Hairy leukoplakia, oral
- Herpes zoster (shingles), involving at least two distinct episodes or more than one dermatome
- Idiopathic thrombocytopenic purpura
- Listeriosis
- Pelvic inflammatory disease, particularly if complicated by tubo-ovarian abscess
- Peripheral neuropathy
For classification purposes, Category B conditions take precedence over those in Category A. For example, someone previously treated for oral or persistent vaginal candidiasis (and who has not developed a Category C disease) but who is now asymptomatic should be classified in clinical Category B.

Category C

Category C includes the clinical conditions listed in the AIDS surveillance case definition (Appendix B). For classification purposes, once a Category C condition has occurred, the person will remain in Category C.

EXPANSION OF THE CDC SURVEILLANCE CASE DEFINITION FOR AIDS

In 1991, CDC, in collaboration with the Council of State and Territorial Epidemiologists (CSTE), proposed an expansion of the AIDS surveillance case definition. This proposal was made available for public comment in November 1991 and was discussed at an open meeting on September 2, 1992. Based on information presented and reviewed during the public comment period and at the open meeting, CDC, in collaboration with CSTE, has expanded the AIDS surveillance case definition to include all HIV-infected persons with CD4+ T-lymphocyte counts of less than 200 cells/uL or a CD4+ percentage of less than 14. In addition to retaining the 23 clinical conditions in the previous AIDS surveillance definition, the expanded definition includes pulmonary tuberculosis (TB), recurrent pneumonia, and invasive cervical cancer.* This expanded definition requires laboratory confirmation of HIV infection in persons with a CD4+ T-lymphocyte count of less than 200 cells/uL or with one of the added clinical conditions. This expanded definition for reporting cases to CDC becomes effective January 1, 1993.

- Diagnostic criteria for AIDS-defining conditions included in the expanded surveillance case definition are presented in Appendix C and Appendix D.

In the revised HIV classification system, persons in subcategories A3, B3, and C3 meet the immunologic criteria of the surveillance case definition, and those persons with conditions in subcategories C1, C2, and C3 meet the clinical criteria for surveillance purposes (Table 1).

COMMENTARY Revised Classification System

The revised classification system for HIV infection is based on the recommended clinical standard of monitoring CD4+ T-lymphocyte counts, since this parameter consistently correlates with HIV-related immune dysfunction and disease progression and provides information needed to guide medical management of persons infected with HIV (14-18, 22-28). The classification system also allows for use of the percentage of CD4+ T-cells instead of absolute CD4+ T-lymphocyte counts (Appendix A). Other markers of immune status — such as serum neopterin, beta-2 microglobulin, HIV p24 antigen, soluble interleukin-2 receptors, immunoglobulin A, and delayed-type hypersensitivity (DTH) skin-test reactions — may be useful in the evaluation of individual patients but are not as strongly predictive of disease progression or as specific for HIV-related immunosuppression as measures of CD4+ T-lymphocytes (14-21, 31). DTH skin-test reactions are often used in conjunction with the Mantoux tuberculin skin test to evaluate HIV-infected patients for TB infection and anergy (31-33).

Other systems have been proposed for classification and staging of HIV infection (1, 31, 34-39). In 1990, the World Health Organization (WHO) published an interim proposal for a staging system for HIV infection and diseases that was based primarily on clinical criteria and included the use of CD4+ T-lymphocyte determinations (34). The WHO system incorporates a performance scale and total lymphocyte counts to be used in lieu of CD4+ T-lymphocyte determinations in countries where CD4+ T-lymphocyte testing is not available.

The accuracy of CD4+ T-lymphocyte counts is important for medical care of individual patients. To assure reliability, laboratories conducting CD4+ T-lymphocyte measurements should be experienced with test procedures, have established quality assurance methods, and participate in proficiency testing programs conducted by CDC or other organizations (22, 40). CDC has published guidelines for the performance of CD4+ T-cell determinations for HIV-
infected persons (41). To assure that test results are indicative of a patient’s medical condition, the health-care provider should evaluate the results with those of earlier tests and with the patient’s clinical condition. In clinical practice, repeat CD4+ testing may be judged necessary in guiding therapeutic decisions for individual patients. For surveillance purposes, however, a requirement for repeat CD4+ determinations is impractical for population-based monitoring.

The revised classification system of the clinical and immunologic manifestations of HIV infection provides a framework for categorizing HIV-related morbidity and immunosuppression and will assist efforts to evaluate the overall impact of the HIV epidemic. Knowledge of the spectrum of clinical conditions and the extent of immunosuppression that may occur during the course of HIV infection is important for prompt evaluation and for provision of appropriate health services. Clinicians should be aware of the clinical conditions suggestive of HIV infection and the need for prophylactic and therapeutic interventions.

This revised HIV classification system should be used by state and territorial health departments that conduct HIV infection surveillance. Because AIDS surveillance data will continue to represent only a portion of the total morbidity caused by HIV, surveillance for HIV infection may be particularly useful in depicting the total impact of HIV on health-care and social services (42). More accurate reporting and analysis of CD4+ T-lymphocyte counts, together with HIV-related clinical conditions, should facilitate efforts to evaluate health-care and referral needs for persons with HIV infection and to project future needs for these services.

Expanded AIDS Surveillance Case Definition

The population of HIV-infected persons with CD4+ T-lymphocyte counts of less than 200/uL is substantially larger than the population of persons with AIDS-defining clinical conditions (43). The inclusion in the AIDS surveillance definition of persons with a CD4+ T-lymphocyte count of less than 200 cells/uL or a CD4+ percentage less than 14 will enable AIDS surveillance to reflect more accurately the number of persons with severe HIV-related immunosuppression and those at highest risk for severe HIV-related morbidity. Since the AIDS surveillance case definition was last revised in 1987, the increasing use of prophylaxis against PCP and antiretroviral therapy for persons infected with HIV has slowed the rate at which HIV-infected persons develop AIDS-defining clinical conditions (2,22-25). For example, among homosexual/bisexual men with AIDS reported to CDC, the proportion with PCP decreased from 62% in 1988 to 46% in 1990 (44). This trend is expected to continue.

The ability of clinicians to report HIV-infected persons on the basis of CD4+ T-lymphocyte counts may also simplify the case-reporting process. A simplified AIDS surveillance case definition will be particularly important for outpatient clinics in which the availability of staff to conduct surveillance is limited and from which an increasing proportion of AIDS cases are being reported. For example, from pre-1985 to 1988, the proportion of AIDS cases reported from outpatient sites in the state of Washington increased from 6% (9/155) to 25% (55/219) (45). A similar increase occurred in Oregon (25% {44/171} before 1987 to 38% {40/105} in the first half of 1989) (46).

Pulmonary Tuberculosis

Throughout the world, pulmonary TB is the most common type of TB in persons with HIV infection (47). The addition of pulmonary TB to the list of AIDS-indicator diseases is based on the strong epidemiologic link between HIV infection and the development of TB (48-50). Persons co-infected with HIV and TB have a substantially increased risk of developing active TB compared with persons without HIV infection (48, 49). In a prospective evaluation of injecting-drug users (IDUs) with positive tuberculin skin tests, the estimated annual incidence of active TB among 49 HIV-infected IDUs was 7.9 cases/100 person-years; however, no cases of active TB occurred among 62 tuberculin-positive but HIV-seronegative IDUs followed for as long as 30 months (48).
There is also a substantial immunologic association between HIV-infected persons and pulmonary TB when compared with HIV-infected persons with extrapulmonary TB (a condition included in the 1987 surveillance definition). In a recent review, median CD4+ T-lymphocyte counts in HIV-infected patients with pulmonary TB ranged from 250 to 500 cells/ul (51). In comparison, the median CD4+ lymphocyte count was 242 cells/ul in one study of persons with localized extrapulmonary TB and ranged from 70 to 79 cells/ul in two studies of patients with disseminated or miliary TB (51-53). In CDC’s Adult and Adolescent Spectrum of HIV Disease (ASD) Project, 69% of HIV-infected persons with pulmonary TB had CD4+ T-lymphocyte counts of less than 200/ul, compared with 77% of persons with extrapulmonary TB (CDC, unpublished observations).

The addition of pulmonary TB to AIDS surveillance criteria will require continued collaboration between state and local TB and HIV/AIDS programs. Knowledge of a patient’s HIV status is important for the proper medical management of TB because longer courses of therapy and prophylaxis are recommended for HIV-infected patients with TB (54). Furthermore, HIV-infected TB patients should be a priority for epidemiologic investigation because these persons are more likely to have HIV-infected contacts than are seronegative TB patients. TB contact follow-up among HIV-infected persons will help to ensure delivery of a full course of preventive therapy to these contacts, who are at greatly increased risk of developing active TB themselves.

Recurrent Pneumonia

With the exception of conditions included in the 1987 AIDS surveillance case definition, pneumonia, with or without a bacteriologic diagnosis, is the leading cause of HIV-related morbidity and death (55, 56). In addition, several studies have shown that persons with HIV-related immunosuppression are at an increased risk of bacterial pneumonia (57-59). For example, one study found that the yearly incidence rate of bacterial pneumonia among HIV-infected IDUs without AIDS was five times that found in non-HIV-infected IDUs (58). Recurrent episodes of pneumonia (two or more episodes within a 1-year period) are required for AIDS case reporting because pneumonia is a relatively common diagnosis and multiple episodes of pneumonia are more strongly associated with immunosuppression than are single episodes. For example, data from the ASD Project indicate that the risk of an HIV-infected person having had one episode of pneumonia in a 12-month period is approximately five times higher among infected persons with CD4+ T-lymphocyte counts of less than 200/ul (320/2,411) than among those with higher CD4+ T-lymphocyte counts (90/2,792). In contrast, data from the same study indicate that the risk for multiple episodes of pneumonia in a 12-month period is approximately 20 times higher among HIV-infected persons with CD4+ T-lymphocyte counts of less than 200/ul (67/2,411) than among those with higher CD4+ T-cell counts (4/2,792) (CDC, unpublished observations).

Invasive Cervical Cancer

Several studies have found an increased prevalence of cervical dysplasia, a precursor lesion for cervical cancer, among HIV-infected women (60, 61). In a study of 310 HIV-infected women attending methadone maintenance and sexually transmitted disease clinics in New York City and Newark, New Jersey, cervical dysplasia was confirmed by biopsy and/or colposcopy in approximately 22%, a prevalence rate 10 times greater than that found among women attending family planning clinics in the United States (Wright TC, personal communication; 62). Several studies have documented that a higher prevalence of cervical dysplasia among HIV-infected women is associated with greater immunosuppression (Wright TC, personal communication; 61,63). In addition, HIV infection may adversely affect the clinical course and treatment of cervical dysplasia and cancer (64-69).

Invasive cervical cancer is a more appropriate AIDS-indicator disease than is either cervical dysplasia or carcinoma in situ because these latter cervical lesions are common and frequently do not progress to invasive disease (70). Also, cervical dysplasia or carcinoma in situ among women with severe cervicovaginal infections, which are common in HIV-infected women, can be difficult to diagnose. In contrast, the diagnosis of invasive cervical cancer is generally unequivocal.
Invasive cervical cancer is preventable by the proper recognition and treatment of cervical dysplasia. Thus, the occurrence of invasive cervical cancer among all women — including those who are HIV-infected — represents missed opportunities for disease prevention. The addition of invasive cervical cancer to the list of AIDS-indicator diseases emphasizes the importance of integrating gynecologic care into medical services for HIV-infected women.

Impact on AIDS Case Reporting

The expanded AIDS surveillance case definition is expected to have a substantial impact on the number of reported cases. The immediate increase in case reporting will be largely attributable to the addition of severe immunosuppression to the definition; a smaller impact is expected from the addition of pulmonary TB, recurrent pneumonia, and invasive cervical cancer, since many persons with these diseases will also have CD4+ T-lymphocyte counts of less than 200 cells/uL. If all of the approximately 1,000,000 persons in the United States with HIV infection were diagnosed and their immune status were known, it is estimated that 120,000-190,000 persons who do not have AIDS-indicator diseases would be found to have CD4+ T-lymphocyte counts of less than 200 cells/uL (71). However, not all of these persons are aware of their HIV infection and of those who know their HIV infection status, not all have had an immunologic evaluation; thus, the immediate impact on the number of AIDS cases will be considerably less than 120,000-190,000. If AIDS surveillance criteria were unchanged, approximately 50,000-60,000 reported AIDS cases would be expected in 1993. Based on current levels of HIV and CD4+ testing, CDC estimates that the expanded definition could increase cases reported in 1993 by approximately 75%. Early effects of expanded surveillance will be greater than long-term effects because prevalent as well as incident cases of immunosuppression will be reported following implementation of the expanded surveillance case definition. In subsequent years, the effect on the number of reported cases is expected to be much smaller.

Uses of the HIV Classification System or AIDS Surveillance Case Definition

The revised HIV classification system and the AIDS surveillance case definition are intended for use in conducting public health surveillance. The CDC’s AIDS surveillance case definition was not developed to determine whether statutory or other legal requirements for entitlement to Federal disability or other benefits are met. Consequently, this revised surveillance case definition does not alter the criteria used by the Social Security Administration in evaluating claims based on HIV infection under the Social Security disability insurance and Supplemental Security Income programs. Other organizations and agencies providing medical and social services should develop eligibility criteria appropriate to the services provided and local needs.

Confidentiality

The confidentiality of AIDS case reports — including laboratory reports of HIV test results, CD4+ T-lymphocyte test results, and medical records under review by health department staff — is of critical importance to maintaining effective HIV/AIDS surveillance. CDC and state health departments have implemented procedures and policies to maintain confidentiality and security of HIV/AIDS surveillance data (72). CDC’s efforts include a federal assurance of confidentiality, the removal of names before encrypted records are transmitted to CDC, strict guidelines for the release of aggregate data, and the inclusion of confidentiality and security safeguards as evaluation criteria for federal funding of state HIV/AIDS surveillance activities (73). These strict criteria will continue to apply to cases reported under the expanded definition. CDC funding of surveillance cooperative agreements is dependent on the recipient’s ability to ensure the physical security of case reports and on state policies or laws to protect the confidentiality of persons reported with AIDS. Failure to ensure the security and confidentiality of personal identifying information collected as part of AIDS or HIV surveillance activities will jeopardize federal surveillance funding.

CD4+ T-lymphocyte test results reported by laboratories will be an important adjunct to medical record review and provider-initiated reporting in order to increase completeness, timeliness, and efficiency of AIDS surveillance. Information from a laboratory-initiated report of a CD4+ T-lymphocyte count is insufficient for reporting a case of
AIDS. Confirmation of HIV infection status and receipt of other surveillance information from the health-care provider or from medical or public health records will remain necessary.

Every effort should be made by health-care providers, laboratories, and public health agencies to protect the confidentiality of CD4+ T-lymphocyte test results, including the review of record-keeping practices in laboratories and health-care settings. Some states have considered additional means to assure the confidentiality of CD4+ T-lymphocyte test results. For example, a proposal in Oregon would allow health-care providers to send specimens to laboratories for CD4+ T-lymphocyte testing with a unique code for each person being tested. If the test result indicates a CD4+ T-lymphocyte count of less than 200 cells/uL, the health department would notify the health-care provider that an AIDS case report is required if the person is HIV infected, the CD4+ T-lymphocyte count is valid, and the case has not been previously reported. Informed consent for CD4+ T-lymphocyte testing should be obtained in accordance with local laws or regulations. CD4+ T-lymphocyte test results alone should not be used as a surrogate marker for HIV or AIDS. A low CD4+ T-lymphocyte count without a positive HIV test result will not be reportable since other conditions may result in a low CD4+ T-lymphocyte count. Health-care providers must ensure that persons who have a CD4+ T-lymphocyte count of less than 200/uL are HIV infected before initiating treatment for HIV disease or reporting those persons as cases of AIDS.

CONCLUSION

The revised HIV classification system provides uniform and simple criteria for categorizing conditions among adolescents and adults with HIV infection and should facilitate efforts to evaluate current and future health-care and referral needs for persons with HIV infection. The addition of a measure of severe immunosuppression, as defined by a CD4+ T-lymphocyte count of less than 200 cells/uL or a CD4+ percentage of less than 14, reflects the standard of immunologic monitoring for HIV-infected persons and will enable AIDS surveillance data to more accurately represent those who are recognized as being immunosuppressed, who are in greatest need of close medical follow-up, and who are at greatest risk for the full spectrum of severe HIV-related morbidity. The addition of three clinical conditions — pulmonary TB, recurrent pneumonia, and invasive cervical cancer — to AIDS surveillance criteria reflects the documented or potential importance of these diseases in the HIV epidemic. Two of these conditions (pulmonary TB and cervical cancer) are preventable if appropriate screening tests are linked with proper follow-up. The third, recurrent pneumonia, reflects the importance of pulmonary infections not included in the 1987 definition as leading causes of HIV-related morbidity and mortality. Successful implementation of expanded surveillance criteria will require the extension of existing safeguards to protect the security and confidentiality of AIDS surveillance information.

APPENDIX A. Equivalences for CD4+ T-lymphocyte count and percentage of total lymphocytes

Compared with the absolute CD4+ T-lymphocyte count, the percentage of CD4+ T-cells of total lymphocytes (or CD4+ percentage) is less subject to variation on repeated measurements (18,74). However, data correlating natural history of HIV infection with the CD4+ percentage have not been as consistently available as data on absolute CD4+ T-lymphocyte counts (14-16,18,19,21,31). Therefore, the revised classification system emphasizes the use of CD4+ T-lymphocyte counts but allows for the use of CD4+ percentages.

Equivalences (Table A1) were derived from analyses of more than 15,500 lymphocyte subset determinations from seven different sources: one multistate study of diseases in HIV-infected adolescents and adults (59) and six laboratories (two commercial, one research, and three university-based). The six laboratories are involved in proficiency testing programs for lymphocyte subset determinations. In the analyses, concordance was defined as the proportion of patients classified as having CD4+ T-lymphocyte counts in a particular range among patients with a given CD4+ percentage. A threshold value of the CD4+ percentage was calculated to obtain optimal concordance with each stratifying value of the CD4+ T-lymphocyte counts (i.e., less than 200/uL and greater than or equal to 500/uL). The thresholds for the CD4+ percentages that best correlated with a CD4+ T-lymphocyte count of less than 200/uL varied minimally among the
seven data sources (range, 13%-14%; median, 13%; mean, 13.4%). The average concordance for a CD4+ percentage of less than 14 and a CD4+ T-lymphocyte count of less than 200/uL was 90.2%. The threshold for the CD4+ percentages most concordant with CD4+ T-lymphocyte counts of greater than or equal to 500/uL varied more widely among the seven data sources (range, 22.5%-35%; median, 29%; mean, 29.1%). This wide range of percentages optimally concordant with greater than or equal to 500/uL CD4+ T-lymphocytes makes the concordance at this stratifying value less certain. The average concordance for a CD4+ percentage of greater than or equal to 29 and a CD4+ T-lymphocyte count of greater than or equal to 500/uL was 85% (CDC, unpublished data). Clinicians and other practitioners must recognize that these suggested equivalences may not always correspond with values observed in individual patients.

APPENDIX B. Conditions included in the 1993 AIDS surveillance case definition

- Candidiasis of bronchi, trachea, or lungs
- Candidiasis, esophageal
- Cervical cancer, invasive *
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (greater than 1 month’s duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV-related
- Herpes simplex: chronic ulcer(s) (greater than 1 month’s duration); or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (greater than 1 month’s duration)
- Kaposi’s sarcoma
- Lymphoma, Burkitt’s (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
- Mycobacterium tuberculosis, any site (pulmonary * or extrapulmonary)
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis carinii pneumonia
- Pneumonia, recurrent *
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain
- Wasting syndrome due to HIV
- Added in the 1993 expansion of the AIDS surveillance case definition.

APPENDIX C. Definitive diagnostic methods for diseases indicative of AIDS

Cryptosporidiosis, Isosporiasis, Kaposi’s sarcoma, Lymphoma, Pneumocystis carinii pneumonia, Progressive multifocal leukoencephalopathy, Toxoplasmosis, Cervical cancer

Microscopy (histology or cytology)

Candidiasis
Gross inspection by endoscopy or autopsy or by microscopy (histology or cytology) on a specimen obtained directly from the tissues affected (including scrapings from the mucosal surface), not from a culture

Coccidioidomycosis, Cryptococcosis, Cytomegalovirus, Herpes simplex virus, Histoplasmosis
Microscopy (histology or cytology), culture, or detection of antigen in a specimen obtained directly from the tissues affected or a fluid from those tissues

Tuberculosis, Other mycobacteriosis, Salmonellosis
Culture

HIV encephalopathy (dementia)
Clinical findings of disabling cognitive or motor dysfunction interfering with occupation or activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection that could explain the findings. Methods to rule out such concurrent illness and conditions must include cerebrospinal fluid examination and either brain imaging (computed tomography or magnetic resonance) or autopsy.

HIV wasting syndrome
Findings of profound involuntary weight loss of greater than 10% of baseline body weight plus either chronic diarrhea (at least two loose stools per day for greater than or equal to 30 days), or chronic weakness and documented fever (for greater than or equal to 30 days, intermittent or constant) in the absence of a concurrent illness or condition other than HIV infection that could explain the findings (e.g., cancer, tuberculosis, cryptosporidiosis, or other specific enteritis).

Pneumonia, recurrent
Recurrent (more than one episode in a 1-year period), acute (new x-ray evidence not present earlier) pneumonia diagnosed by both: a) culture (or other organism-specific diagnostic method) obtained from a clinically reliable specimen of a pathogen that typically causes pneumonia (other than Pneumocystis carinii or Mycobacterium tuberculosis), and b) radiologic evidence of pneumonia; cases that do not have laboratory confirmation of a causative organism for one of the episodes of pneumonia will be considered to be presumptively diagnosed.

APPENDIX D. Suggested guidelines for presumptive diagnosis of diseases indicative of AIDS

Candidiasis of esophagus
a. Recent onset of retrosternal pain on swallowing; AND

b. Oral candidiasis diagnosed by the gross appearance of white patches or plaques on an erythematous base or by the microscopic appearance of fungal mycelial filaments from a noncultured specimen scraped from the oral mucosa.

Cytomegalovirus retinitis
A characteristic appearance on serial ophthalmo-scoptic examinations (e.g., discrete patches of retinal whitening with distinct borders, spreading in a centrifugal manner along the paths of blood vessels, progressing...
over several months, and frequently associated with retinal vasculitis, hemorrhage, and necrosis). Resolution of active
disease leaves retinal scarring and atrophy with retinal pigment epithelial mottling.

Mycobacteriosis Microscopy of a specimen from stool or normally sterile body fluids or tissue from a site other than
lungs, skin, or cervical or hilar lymph nodes that shows acid-fast bacilli of a species not identified by culture.

Kaposi’s sarcoma A characteristic gross appearance of an erythematous or violaceous plaque-like lesion on skin or
mucous membrane. (Note: Presumptive diagnosis of Kaposi’s sarcoma should not be made by clinicians who have seen
few cases of it.)

Pneumocystis carinii pneumonia

a. A history of dyspnea on exertion or nonproductive cough of recent onset (within the past 3 months); AND

b. Chest x-ray evidence of diffuse bilateral interstitial infiltrates or evidence by gallium scan of diffuse bilateral
pulmonary disease; AND

c. Arterial blood gas analysis showing an arterial pO(2) of less than 70 mm Hg or a low respiratory diffusing
capacity (less than 80% of predicted values) or an increase in the alveolar-arterial oxygen tension gradient; AND

d. No evidence of a bacterial pneumonia.

Pneumonia, recurrent Recurrent (more than one episode in a 1-year period), acute (new symptoms, signs, or x-ray
evidence not present earlier) pneumonia diagnosed on clinical or radiologic grounds by the patient’s physician.

Toxoplasmosis of brain

a. Recent onset of a focal neurologic abnormality consistent with intracranial disease or a reduced level of
consciousness; AND

b. Evidence by brain imaging (computed tomography or nuclear magnetic resonance) of a lesion having a mass
effect or the radiographic appearance of which is enhanced by injection of contrast medium; AND

c. Serum antibody to toxoplasmosis or successful response to therapy for toxoplasmosis.

Tuberculosis, pulmonary When bacteriologic confirmation is not available, other reports may be considered to be
verified cases of pulmonary tuberculosis if the criteria of the Division of Tuberculosis Elimination, National Center for
Prevention Services, CDC, are used. The criteria in use as of January 1, 1993, are available in MMWR 1990;39(No.

References

1. CDC. Classification system for human T-lymphotropic virus type III/lymphadenopathy-associated virus
infections. MMWR 1986;35:334-

2.

3. CDC. Revision of the CDC surveillance case definition for acquired immunodeficiency syndrome. MMWR
1987;36:1-15S.

4. McDougal JS, Kennedy MS, Sligh JM, et al. Binding of the HTLV-III/LAV to T4+ T cells by a complex of the


ADULT HIV/AIDS CONFIDENTIAL CASE REPORT

(Patients ≥13 years of age at time of diagnosis)

II. HEALTH DEPARTMENT USE ONLY

DATE FORM COMPLETED:

REPORT SOURCE:

SOUNDEX

REPORT STATUS:

REPORTING HEALTH DEPARTMENT:

DATE AT BIRTH:

AGE AT BIRTH:

CURRENT STATUS:

STATE/TERRITORY OF DEATH:

DIAGNOSTIC INFORMATION

DIAGNOSIS AT REPORT: (check one):

1. HIV infection (not AIDS)

2. AIDS

SEX:

1. Male

2. Female

RACE:

1. White

2. Black

3. Native American

4. Other

5. (Specify):

6. Native Hawaiian or Other Pacific Islander

7. Asian

8. Other (specify):


RESIDENCE AT DIAGNOSIS:

CITY

STATE

ZIP CODE

COUNTRY

COUNTY

OCCUPATION

V. PATIENT HISTORY

AFTER 1977 AND PRECEDING THE FIRST POSITIVE HIV ANTIBODY TEST OR AIDS DIAGNOSIS, THIS PATIENT HAD

1. Sex with male

2. Sex with female

3. Injected nonprescription drugs

4. Received clotting factor for hemophilia/coagulation disorder

5. HIV and/or AIDS

6. HETEROSEXUAL relations with any of the following:

   - Bisexual male

   - Person with hemophilia/coagulation disorder

   - Transfusion recipient with documented HIV infection

   - Transplant recipient with documented HIV infection

   - Person with AIDS or documented HIV infection, risk not specified

   - Received transfusion of blood/blood components (other than clotting factor)

   - Worked in a healthcare or clinical laboratory setting

   - Worked in a healthcare or clinical laboratory setting

6. Other (specify):

VI. LABORATORY DATA

1. HIV TESTS AT DIAGNOSIS:

   (Indicate first test)

   - HIV-1 test

   - HIV-2 test

   - Other test

   - Date of last documented negative HIV test

   - If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician?

   - If yes, please provide date of documentation by physician

2. POSITIVE HIV DETECTION TEST:

   - Culture

   - Antigen

   - PCR, DNA or RNA probe

   - Other

3. DETECTABLE VIRAL LOAD TEST:

   - (Indicate most recent test)

   - Type

   - Value

   - Other

IV. FACILITY OF DIAGNOSIS

FACILITY TYPE:

1. Public

2. Private

3. Federal

4. Unk.

FACILITY ADDRESS:

1. Physician.

2. Hospital, Inpatient

3. Other (specify):

CITY

STATE

ZIP CODE

COUNTRY

COUNTY

VI. LABORATORY DATA

4. IMMUNOLOGIC LAB TESTS:

   - AT OR CLOSEST TO CURRENT DIAGNOSTIC STATUS

   - CD4 Count

   - CD4 Percent

   - CD4 Count

   - CD4 Percent

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ADULT HIV/AIDS CONFIDENTIAL CASE REPORT
### VIII. CLINICAL STATUS

<table>
<thead>
<tr>
<th>AIDS INDICATOR DISEASES</th>
<th>Asymptomatic</th>
<th>Symptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial Diagnosis</td>
<td>Initial Date</td>
</tr>
<tr>
<td>Candidiasis, bronchi, trachea, or lungs</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Candidiasis, esophagitis</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Carcinoma, invasive cervical</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Coccidioidomycosis, disseminated or extrapulmonary</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Cryptococcosis, extrapulmonary</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Cryptosporidiosis, chronic intestinal (&lt;1 mo. duration)</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Cryptosporidiosis (other than in intestine, spleen, or colon)</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Cytomegalovirus (with less than vision)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Hepatitis B, inactive</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Hepatitis B, acute</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Herpes simplex, chronic ulcer (&gt;1 mo. duration) or bronchitis, pneumonitis or esophagitis</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Herpes simplex, disseminated or extrapulmonary</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Isosporiasis, chronic intestinal (&gt;1 mo. duration)</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Kaposi's sarcoma</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Def.** = definitive diagnosis  **Pres.** = presumptive diagnosis

### IX. TREATMENT/SERVICES REFERRALS

This patient is receiving or has been referred for:
- HIV-related medical services [ ] Yes [ ] No [ ] Unknown
- Substance abuse treatment services [ ] Yes [ ] No [ ] Unknown

This patient's medical treatment is primarily reimbursed by:
- Medicaid [ ]
- Private insurance/HMO [ ]
- Other Public Funding [ ]
- Other [ ]

### X. COMMENTS:

...
§64-64-1. General.

1.1. Scope. -- This legislative rule establishes specific standards and procedures concerning AIDS-related medical testing; record confidentiality and disclosure; consent for testing by a legal representative; exclusion from schools; reporting requirements for physicians, laboratories and other health care providers; the approval of laboratories for HIV testing; and other matters pertinent and necessary for the implementation of the AIDS-Related Medical Testing and Records Confidentiality Act, W. Va. Code §16-3C-1 et seq.

This rule supplements the AIDS-Related Medical Testing and Records Confidentiality Act, W. Va. Code §16-3C-1 et seq., and should be read in conjunction with the Act.


1.3. Filing Date. -- April 13, 2000.

1.4. Effective Date. -- May 15, 2000.

1.5. Supersession and Repeal of Former Rules - This rule repeals and replaces “AIDS-Related Medical Testing and Confidentiality,” 64 CSR 64, effective April 26, 1996.


2.1. Application. -- This rule applies to:

2.1.a. Health facilities;

2.1.b. Health care providers;

2.1.c. Funeral service providers and personnel;

2.1.d. Persons issuing marriage licenses;

2.1.e. Persons with access to or in charge of medical records or other sources of information regarding AIDS-related testing information;

2.1.f. Laboratories seeking approval to conduct AIDS-related tests to be utilized in this State;

2.1.g. Medical or emergency responders and their employers; and

2.1.h. Spouses, sexual contacts and intravenous (IV) drug contacts who may be at risk of having acquired the HIV infection as a result of the possible exchange of body fluids.

2.2. Enforcement. -- This rule is enforced by the commissioner of the bureau of public health or his or her lawful designee.


The following definitions of terms are in addition to the definitions of terms in W. Va. Code §16-3C-1.

3.1. Anonymous HIV Testing. -- HIV testing performed on a voluntary patient by a health provider with no knowledge of the person's identity.

3.2. Body Fluids. -- Substances that have been implicated in the transmission of HIV that include:

3.2.a. Blood, semen, vaginal secretions or other body fluids contaminated with visible blood; and

3.2.b. Cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids, which have an undetermined risk for transmitting HIV.


3.4. CLIA-88. -- Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) to Section 353 of the Public Health Service Act (Title 42 United States Code, Section 2621).
States Code Section 263a).

3.5. Commissioner of the Bureau of Public Health. -- Director of the division of health.

3.6. Confidential HIV Testing. -- HIV testing performed by a health provider identifying the patient by name. The use of test results is limited by law.

3.7. Contact. --When used as a noun, a sexual or needle-sharing partner.

3.8. Convicted. -- Pleas of guilty and pleas of nolo contendere accepted by the court having jurisdiction of the criminal prosecution, a finding of guilty following a jury trial to a court, and a juvenile delinquent or status offender as defined in W. Va. Code §49-1-4.

3.9. Director. -- The director of the division of health of the department of health and human resources or his or her lawful designee.

3.10. Division. -- The division of health of the state department of health and human resources.

3.11. Funeral Director. -- Any person engaged, or holding himself or herself out as engaged, in the business of funeral directing as defined in W. Va. Code §30-6-4, and who uses in connection with his or her name or business the words or terms "funeral director," "undertaker," "mortician," or any other word, term, or title to imply or designate himself or herself as a funeral director, undertaker, or mortician.

3.12. Funeral Establishment. -- A place of business maintained and operated by a person, partnership, association, corporation, or other organization, conducted in a building, or series of buildings, or a separate portion of a building having a specific street address or location, and devoted to activities incident, convenient, or related to the preparation and arrangements, financial and otherwise, for the embalming, funeral, transportation, burial or other disposition of dead human bodies.

3.13. HIV-Infected Person. -- A person who has been diagnosed with AIDS or ARC or who has a positive confirmatory test for HIV.

3.14. Legal Representative. -- A person from whom substituted consent may be obtained as provided for in W. Va. Code §16-3C-4 for HIV-related testing or for the authorization of the release of test results.


3.16. Post-Exposure Care. -- Care including an initial HIV test following exposure and United States centers for disease control and prevention currently recommended follow-up HIV testing, counseling, medical evaluation and provision for post-exposure prophylactic treatment.

3.17. Source Patient. -- Any person whose body fluids have been the source of a significant exposure to a medical or emergency responder or other person.

§64-64-4. Testing.

4.1. Voluntary Consent.

4.1.a. The HIV-related testing provided for in W. Va. Code §§16-3C-2(a) through (d) may also be requested by a health care provider acting within the scope of his or her professional license.

4.1.b. The provisions of W. Va. Code §§16-3C-2(b) through (d) shall also be followed when a patient, without a request from a physician, dentist, other health care provider acting within the scope of his or her professional license, or the division, voluntarily seeks an HIV test from any physician, dentist, other health care provider, or from the division.

4.1.c. Nothing in this rule shall be construed to provide grounds for any physician, dentist, other health care provider or the director to refuse to treat a patient, nor shall the testing provisions of this rule be used by health care providers to screen patients.

4.2. Consent Not Required.

4.2.a. No consent for testing is required and the provisions of W. Va. Code §16-3C-2(b) and Subsection 4.1 of this rule do not apply for the performance of an HIV test:

4.2.a.1. On a human body part as provided in W. Va. Code §16-3C-2(e)(1). If a test is required of the donor or recipient of the human body part, reasonable efforts shall be made to obtain consent and otherwise follow the procedures of W. Va. Code §§16-3C-2(b)
4.2.a.1.A. All confidentiality restrictions contained in Section 9 of this rule and in W. Va. Code §16-3C-3 apply to information obtained through the testing of human body parts, tissue, blood, blood products, or semen; Consent for HIV-related testing is required for donors of routine blood transfusions, and the provisions of W. Va. Code §16-3C-2(e)(1) do not apply to those transfusions;

4.2.a.2. In documented bona fide medical emergencies as provided for in W. Va. Code §16-3C-2(e)(2) and as determined by a treating physician taking into account the nature and extent of the exposure to another person, whether the source patient’s blood is to be obtained or is already available: Provided, That:

4.2.a.2.A. The source patient is unable or unwilling to grant or withhold consent, and if the source patient is unable to grant or withhold consent, substituted consent is not obtained after a reasonable attempt (such as telephoning or personal contact) is made to obtain consent from a legal representative of the source patient in accordance with W. Va. Code §16-3C-4;

4.2.a.2.B. The test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment, and the HIV testing for a source patient is conducted only after a health care provider, as qualified in Subsection 8.1 of this rule, documents in the medical record of a medical or emergency responder or another person who has come into contact with a source patient that there has been a significant exposure of the responder or person and that in the medical judgement of the above described health care provider the results are medically necessary to determine the course of treatment for the exposed responder or person; and

4.2.a.2.B.1. Attempts to counsel the source patient for obtaining consent for the performance of the test and release of the results are documented on a form provided by the division and reported to the division in a confidential envelope;

4.2.a.2.B.2. A reasonable attempt, such as telephoning or personal contact, is made to contact the source patient, or the source patient’s legal representative if the source patient is unable to grant or withhold consent, to inform him or her that the test will be performed using a pseudonym;

4.2.a.2.B.3. The test results are offered to the source patient, and any refusal of acceptance is documented only in the medical record of the exposed medical or emergency responder or other exposed person;

4.2.a.2.B.4. Post-test counseling is provided in accordance with W. Va. Code §16-3C-2(d). Necessary treatment shall not be withheld pending HIV test results; and

4.2.a.2.B.5. None of the activities set forth in this Subsection are documented in the source patient’s medical record. Confidentiality shall be maintained by the health care facility and the medical or emergency responder. If any improper disclosure occurs, the source patient may invoke the remedies and penalties of W.Va. Code §16-3C-5; and

4.2.a.3. For the purpose of research in accordance with W. Va. Code §16-3C-2(e)(3).

4.2.b. For a test performed under the authority of W. Va. Code §16-3C-2(f)(9), the director may, at his or her discretion, release the test result to the physician or other health care provider who requested the test: Provided, That the provisions of Section 9 of this rule and W. Va. Code §16-3C-3 regarding confidentiality and disclosure apply. The director may establish a list of health care providers who are approved to authorize HIV testing in emergency medical aid circumstances.

4.3. Mandated HIV Testing of Sexual Offenders and Management of Victims.

4.3.a. The testing of persons convicted of a sex-related crime as specified in W. Va. Code §16-3C-2(f) is under the direction of the court having jurisdiction of the criminal prosecution.

4.3.b. The director shall recommend guidelines for courts to follow in referring convicted sexual offenders for medical testing, sharing HIV test results of convicted sex offenders with victims, and advising victims or alleged victims of HIV counseling and testing services.
4.3.c. The director shall request access to all convicted sex offenders who test HIV positive for the purposes of contact notification consultation under the direction of the director. Contact notification information obtained from the convicted sex offender is protected information and shall be used by the director solely for referring individuals with a potential HIV exposure to HIV counseling and testing sources.

4.3.d. The director shall set the level of reimbursement the division shall pay for the mandated HIV testing and counseling and pre- and post-conviction HIV-related testing and counseling for which it is responsible pursuant to the provisions of W. Va. Code §16-3C-2(f).

§64-64-5. Cease and Desist Orders.

5.1. A cease and desist order issued under the authority of W. Va. Code §16-3C-2(f)(4) shall be in writing, and shall set forth the name of the person to be restricted, and the initial period of time during which the order remains effective, the terms of the restrictions and other conditions that are warranted to protect the public health.

5.2. If any person violates a cease and desist order issued pursuant to this rule and the person is a danger to others, the director shall apply to the circuit court of Kanawha County to enforce the cease and desist order by imposing any restrictions upon the person that are necessary to prevent the specific conduct which endangers the health of others.

§64-64-6. Review of Marriage License.

The division shall periodically review marriage licenses in order to determine compliance with the requirements of W. Va. Code §16-3C-2(g) regarding documentation of the provision of information concerning AIDS and HIV-related testing and counseling.

§64-64-7. Charting Information.

Health care providers may only enter the results of an HIV-related test in the chart of a patient if the statement in W. Va. Code §16-3C-3(c) is printed on the test report in the chart.

§64-64-8. Post-Exposure Care and Treatment.

8.1. A health facility shall have access to a knowledgeable trained health care provider to assess the HIV exposure risk of medical or emergency responders or others during all working hours, including nights and weekends. The assessment of HIV exposure risk and initiation of basic post-exposure care regimen requires knowledge or experience in clinical epidemiology, infection control, occupational health, or the clinical treatment of HIV. Consultation on the facility’s currently accepted practice, when prescribing post-exposure prophylaxis, is strongly encouraged.

8.2. A health facility shall have a written post-exposure HIV management plan patterned after current recommendations of the United States centers for disease control and prevention.

8.3. A laboratory shall not determine a test result to be positive, and a health care provider shall not reveal a positive test result to any person, without corroborating or confirmatory testing being conducted. However, a laboratory may release preliminary test results to the health care provider assessing the significant exposure for the purposes of determining post-exposure management of the medical or emergency responder or other person.

8.4. Health care providers shall report all confirmed positive test results to the division in compliance with Section 13 of this rule.

8.5. The employer of a medical or emergency responder who was exposed while performing a duty of his or her employment shall bear the costs of HIV tests of blood samples of the source patient and the responder, unless a workers’ compensation or other benefit program affords coverage for the testing. For a responder who tested negative for HIV antibodies immediately following the exposure, the employer shall also bear the costs of the United States centers for disease control and prevention’s recommended initial prophylactic treatment and additional HIV testing at three and six months after exposure, unless a workers’ compensation or other job-related employee benefit program affords coverage for the treatment and testing.

8.6. Relative to the management of source patient medical information, the medical or emergency responder reporting a significant exposure is subject to the requirements of the disclosure statement contained in W. Va. Code §16-3C-3(c) and to the remedies and penalties
specified in W. Va. Code §16-3C-5.


9.1. Any laboratory performing an HIV-related test in West Virginia shall have the statement of confidentiality in W. Va. Code §16-3C-3(c) appear on the report form or as an attachment to the report form returned to the health care provider or facility.

9.2. No person who obtains information protected by the provisions of W. Va. Code §16-3C-1 et seq. and this rule may convey the protected information to any other person except in strict compliance with W. Va. Code §16-3C-1 et seq. and this rule. Unauthorized disclosure will subject the person to all of the penalties available.

9.3. The victims or alleged victims of sexual crimes are eligible for HIV counseling and testing at public health HIV testing sites in West Virginia. The provisions of this rule and W. Va. Code W. Va. Code §16-3C-1 et seq. regarding voluntary testing and counseling apply to testing and counseling these individuals. All victim testing information is subject to the confidentiality requirements of this rule and W. Va. Code §16-3C-1 et seq. for voluntary testing.

9.4. An agent or employee of a health facility or health care provider has a need to know HIV test results under the provisions of W. Va. Code §16-3C-3(a)(4) when the information is medically necessary to protect the individual from a significant risk of transmission or will have an impact on the treatment modality.

9.5. HIV test results may be disclosed to medical or emergency responders who have been subject to a significant exposure during the course of medical practice or in the performance of professional duties. The medical or emergency responder is subject to the requirements of the disclosure statement contained in W. Va. Code §16-3C-3(c) and to the remedies and penalties provided in W. Va. Code §16-5C-5.

§64-64-10. Contact Notification.

10.1. Notification made by the director under W. Va. Code §16-3C-3(d) shall include an explanation of exposure to HIV, HIV prevention messages and information on accessibility to HIV counseling and testing services to the contact with a reported HIV exposure. The confidentiality rules that apply to the names of HIV-infected persons shall apply to the names of their contacts.

10.2. In contact notification situations, the division recommends that private health care providers refer contact notification activities to the division rather than attempt notification themselves. The division has an established program for notifying partners of persons with infectious conditions.

§64-64-11. Consent by Legal Representative.

11.1. Substituted consent for HIV-related testing or for the authorization of the release of test results shall be obtained in accordance with W. Va. Code §16-3C-4 and this rule.

11.2. Minors shall be treated as established under W. Va. Code §16-4-10.


School exclusions shall be in accordance with W. Va. Code §16-3C-6. If the student is under the jurisdiction of a protection or advocacy agency, a representative from that agency may be included in consultation. The provisions of this rule and of W. Va. Code §16-3C-1 et seq. regarding the confidentiality and the release of information are applicable in the school setting.


13.1. All health care providers in West Virginia who perform, or cause to have performed, serologic or other tests for HIV shall make a report of all HIV infection associated with laboratory tests that are positive or results that are indicative of the HIV infection to the director on forms provided by the director for that purpose as follows:

13.1.a. All positive (reactive) laboratory test results; and

13.1.b. All clinical status data.

13.2. These health care provider reports shall include:

13.2.a. The name and full address of the
laboratory;

13.2.b. The name of the tests performed, the date each test was performed and the results of the tests;

13.2.c. The legibly printed or typed name and location of the health care provider reporting the positive HIV laboratory results;

13.2.d. The name of the confidentially-tested or the identification code of the anonymously-tested individual;

13.2.e. Patient demographic information including the patient’s age, sex, race and address, unless the patient requests anonymous reporting;

13.2.f. Social and risk factor information of the patient relative to HIV infection; and

13.2.g. Other information concerning HIV infection judged necessary by the director.

13.3. Reports of HIV shall be submitted within thirty (30) days of the receipt of positive (reactive) test results.

13.4. Health care providers performing anonymous HIV testing on individuals shall use confidential reporting of HIV infection for patients revealing their identity in HIV infection consultation. If an individual who has been tested anonymously, either makes his or her identity known to the provider or rescinds the request for anonymity, the provider shall report the name to the director.

13.5. The director shall work with an individual's health care provider in any follow-up of reported positive laboratory tests or HIV infection.

13.6. Health care providers who provide HIV care to patients on the basis of a medical or a self referral shall submit an HIV infection report form to the division.

13.7. The reports of all HIV infection submitted in compliance with this rule are protected and are exempt from public disclosure under the exemption for medical records contained in W. Va. Code §29B-1-1 et seq., the Freedom of Information Act: Provided, That the reports are subject to the provisions of W. Va. Code §16-3C-1 et seq. This information shall not be used except as is necessary to enforce State public health laws and rules and to analyze the magnitude of HIV infection in the State for assisting in the development of adequate safeguards against its spread.


14.1. All laboratories conducting HIV testing in West Virginia or providing HIV testing results for use in this State shall make a report on the first and fifteenth days of each month of all laboratory tests that are positive or results that are indicative of the HIV infection to the director on forms provided by the director for that purpose as follows:

14.1.a. All positive (reactive) serologic antibody tests for HIV;

14.1.b. All positive (reactive) laboratory tests for the identification of HIV;

14.1.c. All CD4+ test results on peripheral blood with counts less than 200/mm$^3$ or less than fourteen percent (14%); and

14.1.d. All other positive laboratory test results which identify the presence of HIV or the progression of an HIV infection.

14.2. These reports shall include:

14.2.a. The name and full address of the laboratory;

14.2.b. The name of the test, the date performed, and the result;

14.2.c. The name and location of the health care provider who submitted the specimen;

14.2.d. The name of the patient, if known, or an identification code, if the name is not known, and the patient's sex, age and address, if available;

14.2.e. Other information concerning HIV infection management and control judged necessary by the director; and

14.2.f. The signature of the supervisor of the laboratory.
14.3. The laboratory shall submit the results of the laboratory reports related to Subdivisions 14.1.a through 14.1.d of this rule on the first and fifteenth days of each month.

14.4. If no reportable tests are performed during a reporting period, a statement to this effect shall be submitted by the supervisor of the laboratory.

14.5. The director shall work with an individual's health care provider in any follow-up of the reports of positive laboratory tests.

14.6. The reports of all positive tests submitted in compliance with this rule are protected and are exempt from public disclosure under the exemption for medical records contained in W. Va. Code §29B-1-1 et seq., the Freedom of Information Act: Provided, That the reports are subject to the provisions of W. Va. Code §16-3C-1 et seq. The information shall not be used except as is necessary to enforce State public health laws and rules and to analyze the magnitude of HIV infection in the State for assisting in the development of adequate safeguards against its spread.


15.1. Laboratories Required to be Approved.

15.1.a. All laboratories conducting HIV testing in this State or providing HIV testing results for use in this State shall be approved by the division.

15.1.b. A laboratory located in West Virginia and seeking approval shall:

15.1.b.1. Show that it complies with the applicable requirements of W. Va. Code §16-3C-1 et seq. and this rule;

15.1.b.2. Complete application forms when seeking initial approval or when there is a change of ownership, the laboratory administrator, or location; and

15.1.b.3. Be certified for moderate or high complexity tests under CLIA-88.

15.1.c. A laboratory located outside of West Virginia is eligible for approval only if it is approved for high complexity testing by the federal government regulations promulgated pursuant to CLIA-88 (42 CFR Part 493, Laboratory Requirements, as amended in the April 24, 1995, edition of the Federal Register (60 FR 20035).

15.2. Laboratory Director and Personnel Qualifications.

The laboratory director and personnel shall meet the qualifications set forth by the federal government pursuant to CLIA for certification of laboratories for participation in Medicare, and the relevant provisions of the October 1, 1994, edition of 42 CFR Part 493, Laboratory Requirements, as amended in the April 24, 1995, edition of the Federal Register (60 FR 20035), are hereby incorporated by reference.

15.3. Quality Control Standards.

A laboratory requesting approval shall demonstrate that a quality control program acceptable to the division is in effect for verification and assessment of accuracy, measurement of precision, and detection of error. The demonstration shall be evidenced, when applicable, in part by:

15.3.a. Selection of test methods appropriate to the needs of those served by the laboratory;

15.3.b. Use of controls and calibrating standards;

15.3.c. Recording of the acceptable limits and the results of controls and calibrating standards;

15.3.d. Recording of maintenance and calibration of equipment and instruments;

15.3.e. Labeling and dating of all reagents, solutions, standards, and control materials; and

15.3.f. Maintaining a manual containing all procedures and policies currently in use, which shall include action to be taken when control results are outside the acceptable limits and the procedure for reporting positive HIV test results to the division.

15.4. Proficiency Testing.

Laboratories shall participate in a proficiency testing program approved by the division. The testing shall be
conducted on a regular basis and satisfactory performance by the laboratory is mandatory. The laboratory is responsible for forwarding proficiency testing survey results to the division.

15.5. On-site Inspection.

The director may conduct an on-site inspection to determine compliance with this rule initially prior to approval, and thereafter as frequently as the director considers necessary to insure compliance with this subsection. The division has the right of entry upon proper identification at times judged necessary during operating hours in order to conduct the inspections.

15.6. Certificate of Approval; Revocation.

15.6.a. The director shall issue certificates of approval for a laboratory to perform HIV testing upon initial approval and on an annual basis thereafter pursuant to the conditions listed in this rule. Certificates issued shall contain the name and location of the laboratory, a laboratory code number, the name of the laboratory director and the date of expiration of the certificate.

15.6.b. Laboratories shall notify the division when there is a change in ownership, laboratory director, technical personnel or location of the laboratory.

15.6.e. The director may revoke or suspend a laboratory’s approval if the laboratory:

15.6.c.1. Performs unsatisfactorily in on-site inspections;

15.6.c.2. Fails to comply with this rule and all applicable provisions of W. Va. Code §16-3C-1 et seq.;

15.6.c.3. Fails to report positive test results to the division according to W. Va. Code §16-3C-8B and this rule; or

15.6.c.4. Closes.


Banking of blood is permitted in accordance with W. Va. Code §16-3C-9.

§64-64-17. Administrative Due Process.

Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.
ARTICLE 3C. AIDS-RELATED MEDICAL TESTING AND RECORDS CONFIDENTIALITY ACT.

§16-3C-1. Definitions.
When used in this article:
(a) "AIDS" means acquired immunodeficiency syndrome.
(b) "ARC" means AIDS-related complex.
(c) "Bureau" means the bureau of public health.
(d) "Commissioner" means the commissioner of the bureau of public health.
(e) "Department" means the state department of health and human resources.
(f) "Funeral director" shall have the same meaning ascribed to such term in section four, article six, chapter thirty of this code.
(g) "Convicted" includes pleas of guilty and pleas of nolo contendere accepted by the court having jurisdiction of the criminal prosecution, a finding of guilty following a jury trial or a trial to a court, and an adjudicated juvenile offender as defined in section three, article five-b, chapter forty-nine of this code.
(h) "Funeral establishment" shall have the same meaning ascribed to such term in section four, article six, chapter thirty of this code.
(i) "HIV" means the human immunodeficiency virus identified as the causative agent of AIDS.
(j) "HIV-related test" means a test for the HIV antibody or antigen or any future valid test approved by the bureau, the federal drug administration or the centers for disease control.
(k) "Health facility" means a hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory or other health care institution.
(l) "Health care provider" means any physician, dentist, nurse, paramedic, psychologist or other person providing medical, dental, nursing, psychological or other health care services of any kind.
(m) "Infant" means a person under six years of age.
(n) "Medical or emergency responders" means paid or volunteer firefighters, law-enforcement officers, emergency medical technicians, paramedics, or other emergency service personnel, providers or entities acting within the usual course of their duties; good samaritans and other nonmedical and nonemergency personnel providing assistance in emergencies; funeral directors; health care providers; commissioner of the bureau of public health; and all employees thereof and volunteers associated therewith.
(o) "Patient" or "test subject" or "subject of the test" means the person upon whom a HIV test is performed, or the person who has legal authority to make health care decisions for the test subject.
(p) "Person" includes any natural person, partnership, association, joint venture, trust, public or private corporation or health facility.
(q) "Release of test results" means a written authorization for disclosure of HIV-related test results that is signed, dated and specifies to whom disclosure is authorized and the time period the release is to be effective.
(r) "Significant exposure" means:
(1) Exposure to blood or body fluids through needlestick, instruments, sharps, surgery or traumatic events; or
(2) Exposure of mucous membranes to visible blood or body fluids, to which universal precautions apply according to the national centers for disease control, and laboratory specimens that contain HIV (e.g. suspensions of concentrated virus); or
(3) Exposure of skin to visible blood or body fluids, when the exposed skin is chapped, abraded or afflicted with dermatitis or the contact is prolonged or involving an extensive area.
(s) "Source patient" means any person whose body fluids have been the source of a significant exposure to a medical or emergency responder.
(t) "Victim" means the person or persons to whom transmission of bodily fluids from the perpetrator of
the crimes of sexual abuse, sexual assault, incest or sexual molestation occurred or was likely to have occurred in the commission of such crimes.

§16-3C-2. Testing.
(a) HIV-related testing may be requested by a physician, dentist or the commissioner for any of the following:
(1) When there is cause to believe that the test could be positive;
(2) When there is cause to believe that the test could provide information important in the care of the patient; or
(3) When there is cause to believe that the results of HIV-testing of samples of blood or body fluids from a source patient could provide information important in the care of medical or emergency responders or other persons identified in regulations proposed by the department for approval by the Legislature in accordance with the provisions of article three, chapter twenty-nine-a of this code: Provided, That the source patient whose blood or body fluids is being tested pursuant to this section must have come into contact with a medical or emergency responder or other person in such a way that a significant exposure has occurred;
(4) When any person voluntarily consents to the test.
(b) The requesting physician, dentist or the commissioner shall provide the patient with written information in the form of a booklet or pamphlet prepared or approved by the bureau or, in the case of persons who are unable to read, shall either show a video or film prepared or approved by the bureau to the patient, or read or cause to be read to the patient the information prepared or approved by the bureau which contains the following information:
(1) An explanation of the test, including its purpose, potential uses, limitations, the meaning of its results and any special relevance to pregnancy and prenatal care;
(2) An explanation of the procedures to be followed;
(3) An explanation that the test is voluntary and may be obtained anonymously;
(4) An explanation that the consent for the test may be withdrawn at any time prior to drawing the sample for the test and that such withdrawal of consent may be given orally if the consent was given orally, or shall be in writing if the consent was given in writing;
(5) An explanation of the nature and current knowledge of asymptomatic HIV infection, ARC and AIDS and the relationship between the test result and those diseases; and
(6) Information about behaviors known to pose risks for transmission of HIV infection.
(c) A person seeking an HIV-related test who wishes to remain anonymous has the right to do so, and to provide written, informed consent through use of a coded system with no linking or individual identity to the test requests or results. A health care provider who does not provide HIV-related tests on an anonymous basis shall refer such a person to a test site which does provide anonymous testing, or to any local or county health department which shall provide for performance of an HIV-related test and counseling. (d) At the time of learning of any test result, the patient shall be provided with counseling or referral for counseling for coping with the emotional consequences of learning any test result. This may be done by brochure or personally, or both.
(e) No consent for testing is required and the provisions of subsection (b) of this section do not apply for the following:
(1) A health care provider or health facility performing an HIV-related test on the donor or recipient when the health care provider or health facility procures, processes, distributes or uses a human body part (including tissue and blood or blood products) donated for a purpose specified under the uniform anatomical gift act, or for transplant recipients, or semen provided for the purpose of artificial insemination and such test is necessary to assure medical acceptability of a recipient or such gift or semen for the purposes intended;
(2) The performance of an HIV-related test in documented bona fide medical emergencies, as determined by a treating physician taking into account the nature and extent of the exposure to another person, when the subject of the test is unable or unwilling to grant or withhold consent, and the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment to a medical or emergency responder, or any other person who has come into contact with a source patient in such a way that a significant exposure necessitates HIV-testing or to a source patient who is unable to consent in accordance with regulations proposed by the department for approval by the Legislature in accordance with article three, chapter twenty-nine-a of this code: *Provided, That necessary treatment may not be withheld pending HIV test results: Provided, however, That all sampling and HIV-testing of samples of blood and body fluids, without the expressed written consent of the test subject, shall be through the use of a pseudonym and in accordance with regulations proposed by the department for approval by the Legislature in accordance with article three, chapter twenty-nine-a of this code: Provided further, That the department shall propose emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code on or before the first day of September, one thousand nine hundred ninety-eight, addressing such matters as, but not limited to:

(A) Sampling and testing of blood and body fluids for HIV-related infections including: (i) The taking of samples from source patients; (ii) testing samples; (iii) confidentiality; (iv) documentation; (v) post-test counseling; and (vi) notices to the department by health care providers of: (I) Test results found to be positive and situations where sampling; and (II) testing was performed without the written consent of the test subject; and

(B) Costs associated with sampling, testing, counseling, initial prophylactic treatment and compliance with this article: *Provided, That: (i) The ordering of samples of blood or body fluids for HIV-test or testing of available samples by: (I) A treating physician of a medical or emergency responder; or (II) a treating physician of the source patient; and (ii) the disclosure of the results of HIV-testing of the source patient, in accordance with regulations proposed by the department for approval by the Legislature pursuant to article three, chapter twenty-nine-a of this code, shall be deemed within acceptable standards of medical care in the state of West Virginia and shall not create a legal cause of action on the part of the source patient against: (i) The treating physician of the medical or emergency responder; or (ii) the treating physician of the source patient; or (iii) any health care provider or laboratory assisting such treating physicians.

(3) The performance of an HIV-related test for the purpose of research if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

(f) Mandated testing:

(1) The performance of any HIV-related testing that is or becomes mandatory shall not require consent of the subject but will include counseling.

(2) The court having jurisdiction of the criminal prosecution shall order that an HIV-related test be performed on any persons convicted of any of the following crimes or offenses:

(i) Prostitution; or

(ii) Sexual abuse, sexual assault, incest or sexual molestation.

(3) HIV-related tests performed on persons convicted of prostitution, sexual abuse, sexual assault, incest or sexual molestation shall be confidentially administered by a designee of the bureau or the local or county health department having proper jurisdiction. The commissioner may designate health care providers in regional jail facilities to administer HIV-related tests on such convicted persons if he or she deems it necessary and expedient.

(4) When the director of the department knows or has reason to believe, because of medical or epidemiological information, that a person, including, but not limited to, a person such as an IV drug abuser, or a person who may have a sexually transmitted disease, or a person who has sexually molested,
abused or assaulted another, has HIV infection and is or may be a danger to the public health, he may issue an order to:
(i) Require a person to be examined and tested to determine whether the person has HIV infection;
(ii) Require a person with HIV infection to report to a qualified physician or health worker for counseling; and
(iii) Direct a person with HIV infection to cease and desist from specified conduct which endangers the health of others.

(5) A person convicted of such offenses shall be required to undergo HIV-related testing and counseling immediately upon conviction and the court having jurisdiction of the criminal prosecution shall not release such convicted person from custody and shall revoke any order admitting the defendant to bail until HIV-related testing and counseling have been performed. The HIV-related test result obtained from the convicted person is to be transmitted to the court and, after the convicted person is sentenced, made part of the court record. If the convicted person is placed in the custody of the division of corrections, the court shall transmit a copy of the convicted person's HIV-related test results to the division of corrections. The HIV-related test results shall be closed and confidential and disclosed by the court and the bureau only in accordance with the provisions of section three of this article.

(6) A person charged with prostitution, sexual abuse, sexual assault, incest or sexual molestation shall be informed upon initial court appearance by the judge or magistrate responsible for setting the person's condition of release pending trial of the availability of voluntary HIV-related testing and counseling conducted by the bureau.

(7) The prosecuting attorney shall inform the victim, or parent or guardian of the victim, at the earliest stage of the proceedings of the availability of voluntary HIV-related testing and counseling conducted by the bureau and that his or her best health interest would be served by submitting to HIV-related testing and counseling. HIV-related testing for the victim shall be administered at his or her request on a confidential basis and shall be administered in accordance with the centers for disease control guidelines of the United States public health service in effect at the time of such request. The victim who obtains an HIV-related test shall be provided with pre- and post-test counseling regarding the nature, reliability and significance of the HIV-related test and the confidential nature of the test. HIV-related testing and counseling conducted pursuant to this subsection shall be performed by the designee of the commissioner of the bureau or by any local or county health department having proper jurisdiction.

(8) If a person receives counseling or is tested under this subsection and is found to be HIV infected, the person shall be referred by the health care provider performing the counseling or testing for appropriate medical care and support services. The local or county health departments or any other agency providing counseling or testing under this subsection shall not be financially responsible for medical care and support services received by a person as a result of a referral made under this subsection.

(9) The commissioner of the bureau or his or her designees may require an HIV test for the protection of a person who was possibly exposed to HIV infected blood or other body fluids as a result of receiving or rendering emergency medical aid or who possibly received such exposure as a funeral director. Results of such a test of the person causing exposure may be used by the requesting physician for the purpose of determining appropriate therapy, counseling and psychological support for the person rendering emergency medical aid including good Samaritans, as well as for the patient, or individual receiving the emergency medical aid.

(10) If an HIV-related test required on persons convicted of prostitution, sexual abuse, sexual assault, incest or sexual molestation results in a negative reaction, upon motion of the state, the court having jurisdiction over the criminal prosecution may require the subject of the test to submit to further HIV-related tests performed under the direction of the bureau in accordance with the centers for disease control guidelines of the United States public health service in effect at the time of the motion of the state.
(11) The costs of mandated testing and counseling provided under this subsection and pre- and postconviction HIV-related testing and counseling provided the victim under the direction of the bureau pursuant to this subsection shall be paid by the bureau.
(12) The court having jurisdiction of the criminal prosecution shall order a person convicted of prostitution, sexual abuse, sexual assault, incest or sexual molestation to pay restitution to the state for the costs of any HIV-related testing and counseling provided the convicted person and the victim, unless the court has determined such convicted person to be indigent.
(13) Any funds recovered by the state as a result of an award of restitution under this subsection shall be paid into the state treasury to the credit of a special revenue fund to be known as the "HIV-testing fund" which is hereby created. The moneys so credited to such fund may be used solely by the bureau for the purposes of facilitating the performance of HIV-related testing and counseling under the provisions of this article.

(g) Premarital screening:
(1) Every person who is empowered to issue a marriage license shall, at the time of issuance thereof, distribute to the applicants for the license, information concerning acquired immunodeficiency syndrome (AIDS) and inform them of the availability of HIV-related testing and counseling. The informational brochures shall be furnished by the bureau.
(2) A notation that each applicant has received the AIDS informational brochure shall be placed on file with the marriage license on forms provided by the bureau.

(h) The commissioner of the bureau may obtain and test specimens for AIDS or HIV infection for research or epidemiological purposes without consent of the person from whom the specimen is obtained if all personal identifying information is removed from the specimen prior to testing.

(i) Nothing in this section is applicable to any insurer regulated under chapter thirty-three of this code: Provided, That the commissioner of insurance shall develop standards regarding consent for use by insurers which test for the presence of the HIV antibody.

(j) Whenever consent of the subject to the performance of HIV-related testing is required under this article, any such consent obtained, whether orally or in writing, shall be deemed to be a valid and informed consent if it is given after compliance with the provisions of subsection (b) of this section.

§16-3C-3. Confidentiality of records; permitted disclosure; no duty to notify.
(a) No person may disclose or be compelled to disclose the identity of any person upon whom an HIV-related test is performed, or the results of such a test in a manner which permits identification of the subject of the test, except to the following persons:
(1) The subject of the test;
(2) The victim of the crimes of sexual abuse, sexual assault, incest or sexual molestation at the request of the victim or the victim's legal guardian, or of the parent or legal guardian of the victim if the victim is an infant where disclosure of the HIV-related test results of the convicted sex offender are requested;
(3) Any person who secures a specific release of test results executed by the subject of the test;
(4) A funeral director or an authorized agent or employee of a health facility or health care provider if the funeral establishment, health facility or health care provider itself is authorized to obtain the test results, the agent or employee provides patient care or handles or processes specimens of body fluids or tissues and the agent or employee has a need to know such information: Provided, That such funeral director, agent or employee shall maintain the confidentiality of such information;
(5) Licensed medical personnel or appropriate health care personnel providing care to the subject of the test, when knowledge of the test results is necessary or useful to provide appropriate care or treatment, in an appropriate manner: Provided, That such personnel shall maintain the confidentiality of such test
results. The entry on a patient's chart of an HIV-related illness by the attending or other treating physician or other health care provider shall not constitute a breach of confidentiality requirements imposed by this article;
(6) The bureau or the centers for disease control of the United States public health service in accordance with reporting requirements for a diagnosed case of AIDS, or a related condition;
(7) A health facility or health care provider which procures, processes, distributes or uses: (A) A human body part from a deceased person with respect to medical information regarding that person; (B) semen provided prior to the effective date of this article for the purpose of artificial insemination; (C) blood or blood products for transfusion or injection; or (D) human body parts for transplant with respect to medical information regarding the donor or recipient;
(8) Health facility staff committees or accreditation or oversight review organizations which are conducting program monitoring, program evaluation or service reviews so long as any identity remains anonymous; and
(9) A person allowed access to said record by a court order which is issued in compliance with the following provisions:
(i) No court of this state may issue such order unless the court finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for disclosure against the privacy interest of the test subject and the public interest;
(ii) Pleadings pertaining to disclosure of test results shall substitute a pseudonym for the true name of the test subject of the test. The disclosure to the parties of the test subject's true name shall be communicated confidentially in documents not filed with the court;
(iii) Before granting any such order, the court shall, if possible, provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party;
(iv) Court proceedings as to disclosure of test results shall be conducted in camera unless the subject of the test agrees to a hearing in open court or unless the court determines that the public hearing is necessary to the public interest and the proper administration of justice; and
(v) Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure, which shall specify the person who may have access to the information, the purposes for which the information may be used and appropriate prohibitions on future disclosure.
(b) No person to whom the results of an HIV-related test have been disclosed pursuant to subsection (a) of this section may disclose the test results to another person except as authorized by said subsection.
(c) Whenever disclosure is made pursuant to this section, except when such disclosure is made to persons in accordance with subdivisions (1) and (6), subsection (a) of this section, it shall be accompanied by a statement in writing which includes the following or substantially similar language: "This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of the information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. A general authorization for the release of medical or other information is NOT sufficient for this purpose."
(d) Notwithstanding the provisions set forth in subsections (a) through (c) of this section, the use of HIV test results to inform individuals named or identified as spouses, sex partners or contacts, or persons who have shared needles that they may be at risk of having acquired the HIV infection as a result of possible exchange of body fluids, is permitted: Provided, That the bureau shall make a good faith effort to inform spouses, sex partners, contacts or persons who have shared needles that they may be at risk of having acquired the HIV infection as a result of possible exchange of body fluids: Provided, however, That the bureau shall have no notification obligations when the bureau determines that there has been no likely
exposure of such persons to HIV from the infected test subject within the ten-year period immediately prior to the diagnosis of the infection. The name or identity of the person whose HIV test result was positive is to remain confidential. Spouses, contacts, or sex partners or persons who have shared needles may be tested anonymously at the state bureau of public health's designated test sites, or at their own expense by a health care provider or an approved laboratory of their choice. A cause of action will not arise against the bureau, a physician or other health care provider from any such notification.

(e) There is no duty on the part of the physician or health care provider to notify the spouse or other sexual partner of, or persons who have shared needles with, an infected individual of their HIV infection and a cause of action will not arise from any failure to make such notification. However, if contact is not made, the bureau will be so notified.

§16-3C-4. Substituted consent.
(a) If the person whose consent is necessary under this article for HIV-related testing or the authorization of the release of test results is unable to give such consent or authorization because of mental incapacity or incompetency, the consent or authorization shall be obtained from another person in the following order of preference:
(1) A person holding a durable power of attorney for health care decisions;
(2) The person's duly appointed legal guardian;
(3) The person's next-of-kin in the following order of preference: spouse, parent, adult child, sibling, uncle or aunt, and grandparent.
(b) The person's inability to consent shall not be permitted to result in prolonged delay or denial of necessary medical treatment.
(c) The information required to be provided to the patient pursuant to subsections (b) and (d), section two of this article, shall be provided to the person giving substituted consent hereunder.

§16-3C-5. Remedies and penalties.
(a) Any person aggrieved by a violation of this article has right of action in the circuit court and may recover for the violation:
(1) Against any person who recklessly violates a provision of this article, liquidated damages of one thousand dollars or actual damages, whichever is greater; or
(2) Against any person who intentionally or maliciously violated a provision of this article, liquidated damages of ten thousand dollars or actual damages, whichever is greater; and
(3) Reasonable attorney fees; and
(4) Such other relief, including an injunction, as the court may consider appropriate.
(b) Any action under this article is barred unless the action is commenced within five years after the violation occurs.
(c) Nothing in this article limits the rights of the subject of an HIV-related test to recover damages or other relief under any other applicable law.
(d) Nothing in this article may be construed to impose civil liability for disclosure of an HIV-related test result in accordance with any reporting guidelines or requirements of the department or the centers for disease control of the United States public health service.

§16-3C-6. Prohibiting certain acts; HIV tests results.
(a) A positive HIV test report, or the diagnosis of AIDS related complex (ARC), or the diagnosis of the AIDS syndrome or disease, may not constitute a basis upon which to deny the individual so diagnosed,
access to quality health care: Provided, That this subsection does not apply to insurance.

(b) No student of any school or institution of higher learning, public or private, may be excluded from attending the school or institution of higher learning, or from participating in school sponsored activities, on the basis of a positive HIV test, or a diagnosis of ARC, or AIDS syndrome or disease. Exclusion from attendance or participation, as described above, shall be determined on a case by case basis, in consultation with the individual's parents, medical care provider, health authorities, school or institution administrators or medical advisors, in accordance with policies and guidelines which may have been established by the entities. Exclusion may only be based on the student representing an unacceptable risk as agreed to by the department for the transmission of the HIV to others because of the stage or nature of the illness.

§16-3C-7. Department of corrections to conduct AIDS related study.
The commissioner of the department of corrections is authorized and directed to conduct a study at penal institutions (including jails administered by counties and municipalities) to determine whether it would be prudent and reasonable to offer or require of each inmate at such institutions testing, educational classes or counseling related to AIDS and HIV infections. This shall be done in consultation with the department of health. The commissioner shall complete the study and present the findings and recommendations in a report to be filed with the director of the department of health, the President of the Senate and the Speaker of the House of Delegates within six months of the effective date of this article.

§16-3C-8. Administrative implementation.
(a) The commissioner of the bureau shall immediately implement and enforce the provisions of this article, and shall adopt rules to the extent necessary for further implementation of the article. The rules proposed by the bureau pursuant to this article may include procedures for taking appropriate action with regard to health care facilities or health care providers which violate this article or the rules promulgated hereunder. The provisions of the state administrative procedures act apply to all administrative rules and procedures of the bureau pursuant to this article, except that in case of conflict between the state administrative procedures act and this article, the provisions of this article shall control.

(b) The bureau shall promulgate rules to assure adequate quality control for all laboratories conducting HIV tests and to provide for a reporting and monitoring system for reporting to the bureau all positive HIV tests results.

§16-3C-9. Individual banking of blood by health care providers for elective surgery or medical procedures.
Any person may, in contemplation of elective surgery or other elective medical procedures for which a blood transfusion may be required, request the health care provider conducting such surgery or medical procedure, or any private, public or nonprofit blood bank, to make or cause to be made appropriate provisions to store and bank that individual's blood for use during such surgery or medical procedure. The health care provider or the private, public or nonprofit blood bank shall, upon such request, store and bank a person's blood and the health care provider shall use such blood in the elective surgery or medical procedure to the extent such blood is available.