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## ROSTER

Program Title: HIV/AIDS RULE & LAW INITIAL 4 HOUR

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# Florida HIV/AIDS Law And The Rule-4 Hour Self-Directed Study Course

## Contents:

- Description of HIV/AIDS
- Transmission of HIV
- Prevention/Infection Control
- Policy development
- Clinical management
- » Immunology
- Current Florida Law and its impact on testing, confidentiality of test results and treatment of patients.
- Recent research

## Learning Objectives:

- Gain an understanding of HIV/AIDS and the modes of transmission.
- Learn the basic steps that should be taken to prevent the spread of HIV/AIDS.
- Gain an understanding of Florida Law and legal requirements related to HIV/AIDS testing and the confidentiality of test results.

381.003	Communicable disease and AIDS prevention and control.
381.0031	Report of diseases of public health significance to department.
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**381.003 Communicable disease and AIDS prevention and control.—**

(1) The department shall conduct communicable disease prevention and control program as part of fulfilling its public health mission. A communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indirectly; the communicable disease program must include, but need not be limited to:

(a) Programs for the prevention and control of tuberculosis in accordance with chapter 392.

(b) Programs for the prevention and control of human immunodeficiency virus infection and acquired immune deficiency syndrome in accordance with chapter 384 and this chapter.

(c) Programs for the prevention and control of sexually transmissible diseases in accordance with chapter 384.

(d) Programs for the prevention, control, and reporting of diseases of public health significance as provided for in this chapter.

(e) Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children as required by s. 232.032 and the development of an automated, electronic, and centralized database or registry of immunizations. The department shall ensure that all children in this state are immunized against vaccine-preventable diseases. The immunization registry shall allow the department to enhance current immunization activities for the purpose of improving the immunization of all children in this state.

1. Except as provided in subparagraph 2., the department shall include all children born in this state in the immunization registry by using the birth records from the Office of Vital Statistics. The department shall add other children to the registry as immunization services are provided.

2. The parent or guardian of a child may refuse to have the child included in the immunization registry by signing a form obtained from the department, or from the health care practitioner or entity that provides the immunization, which indicates that the parent or guardian does not wish to have the child included in the immunization registry. The decision to not participate in the immunization registry must be noted in the registry.

3. The immunization registry shall allow for immunization records to be electronically transferred to entities that are required by law to have such records, including schools, licensed child care facilities, and any other entity that is required by law to obtain proof of a child's immunizations.

4. Any health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who complies with rules adopted by the department to access the immunization registry may, through the immunization registry, directly access immunization records and update a child's immunization history or exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care. The information included in the immunization registry must include the child's name, date of birth, address, and any other unique identifier necessary to correctly identify the child; the immunization record, including the date, type of administered vaccine, and vaccine lot number; and the presence or

absence of any adverse reaction or contraindication related to the immunization. Information received by the department for the immunization registry retains its status as confidential medical information and the department must maintain the confidentiality of that information as otherwise required by law. A health care practitioner or other agency that obtains information from the immunization registry must maintain the confidentiality of any medical records in accordance with s. 456.057 or as otherwise required by law. (2) The department may adopt, repeal, and amend rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for investigating disease, timeframes for reporting disease, definitions, procedures for managing specific diseases, requirements for follow-up reports of known or suspected exposure to disease, and procedures for providing access to confidential information necessary for disease investigations. For purposes of the immunization registry, the rules may include procedures for a health care practitioner to obtain authorization to use the immunization registry, methods for a parent or guardian to elect not to participate in the immunization registry, and procedures for a health care practitioner licensed under chapter 458, chapter 459, or chapter 464 to access and share electronic immunization records with other entities allowed by law to have access to the records.

**History.**—s. 14, ch. 91-297; s. 3, ch. 98-151; s. 3, ch. 2000-242; s. 7, ch. 2000-367; s. 16, ch. 2001-62.

### **381.0031 Report of diseases of public health significance to department.—**

(1) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; any hospital licensed under part I of chapter 395; or any laboratory licensed under chapter 483 that diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

(2) Periodically the department shall issue a list of infectious or noninfectious diseases determined by it to be a threat to public health and therefore of significance to public health and shall furnish a copy of the list to the practitioners listed in subsection (1).

(3) Reports required by this section must be in accordance with methods specified by rule of the department.

(4) Information submitted in reports required by this section is confidential, exempt from the provisions of s. 119.07(1), and is to be made public only when necessary to public health. A report so submitted is not a violation of the confidential relationship between practitioner and patient.

(5) The department may obtain and inspect copies of medical records, records of laboratory tests, and other medical-related information for reported cases of diseases of public health significance described in subsection (2). The department shall examine the records of a person who has a disease of public health significance only for purposes of preventing and eliminating outbreaks of disease and making epidemiological investigations of reported cases of diseases of public health significance, notwithstanding any other law to the contrary. Health care practitioners, licensed health care facilities, and laboratories shall allow the department to inspect and obtain copies of such medical records and medical-related information, notwithstanding any other law to the contrary. Release of medical records and medical-related information to the department by a health care practitioner, licensed health care facility, or laboratory, or by an authorized employee or agent thereof, does not constitute a violation of the confidentiality of patient records. A health care practitioner, health care facility, or laboratory, or any employee or agent thereof, may not be held liable in any manner for damages and is not subject to criminal penalties for providing patient records to the department as authorized by this section.

(6) The department may adopt rules related to reporting diseases of significance to public health, which must specify the information to be included in the report, who is required to report, the method and time period for reporting, requirements for enforcement, and required follow-up activities by the department which are necessary to protect public health.

This section does not affect s. 384.25.

**History.**—s. 2, ch. 29834, 1955; ss. 19, 35, ch. 69-106; s. 67, ch. 77-147; s. 4, ch. 89-311; s. 2, ch. 90-347; s. 15, ch. 91-297; s. 2, ch. 95-188; s. 184, ch. 96-406; s. 175, ch. 97-101; s. 4, ch. 98-151; s. 252, ch. 98-166; s. 8, ch. 2000-367.

**Note.**—Fourier s. 381.231.

381.00315 Public health advisories.—The State Health Officer is responsible for declaring public health emergencies and issuing public health advisories. Prior to issuing any health advisory, the State Health Officer must consult with any state or local agency regarding areas of responsibility which may be affected by such advisory- Upon determining that issuing a health advisory is necessary to protect the public health and safety, and prior to issuing the advisory, the State Health Officer must notify each county health department within the area which is affected by the advisory of the State Health Officer's intent to JSSU6 the advisory. The State Health Officer is authorized to take any action appropriate to enforce any health advisory.

History.—s. 16, ch. 96-403; s. 63, ch. 97-100.

#### **381.0032 Epidemiological research.—**

(1) The department may conduct studies concerning the epidemiology of diseases of public health significance, such as acquired immune deficiency syndrome and other diseases in Florida. These studies may not duplicate national studies but shall be designed to provide special insight and understanding into Florida-specific problems given this state's unique climate and geography, demographic mix, and high rate of immigration.

(2) Epidemiological studies designed by the department shall emphasize practical applications and utility in the control of diseases of public health significance, such as acute or chronic diseases caused by infectious agents, host factors, or toxic substances. These studies shall, to the maximum extent possible, use state and local public health workers as field teams, study design team members, reviewers, and co authors. Epidemiological studies conducted pursuant to this section shall be directed by the State Health Officer or his or her designee.

(3) The department shall work with the various universities and colleges in this state, including, but not limited to, the College of Public Health at the University of South Florida, when it deems it appropriate and necessary in carrying out such studies.

History.—s. 23, oh. 88-360; s. 16, ch. 91-297; s. 648, ch. 95-148.

Note.—Formers. 381.614.

381.00325 Hepatitis A awareness program.—The Department of Health shall develop a Hepatitis A awareness program. This program shall include information regarding the appropriate education of the public and information regarding the availability of Hepatitis A vaccine. The department shall work with private businesses and associations in developing the program and in disseminating the information.

History.—s. 36, ch. 2000-367.

#### **381.0034 Requirement for instruction on human immunodeficiency virus and acquired immune deficiency syndrome.—**

(1) As of July 1, 1991, the Department of Health shall require each person licensed or certified under chapter 401, chapter 467, part IV of chapter 468, or chapter 483, as a condition of biennial relicensure, to complete an educational course approved by the department on the modes of transmission, infection control procedures, clinical management, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome. Such course shall include information on current Florida law on acquired immune deficiency syndrome and its impact on testing, confidentiality of test results, and treatment of patients. Each such licensee or certificate holder shall submit confirmation of having completed said course, on a form provided by the department, when submitting fees or application for each biennial renewal.

(2) Failure to complete the requirements of this section shall be grounds for disciplinary action contained in the chapters specified in subsection (1). In addition to discipline by the department, the licensee or certificate holder shall be required to complete said course.

(3) The department shall require, as a condition of granting a license under the chapters specified in subsection (1), that an applicant making initial application for licensure complete an educational course acceptable to the department on human immunodeficiency virus and acquired immune deficiency syndrome. An applicant who has not taken a course at the time of licensure shall, upon an affidavit showing good cause, be allowed 6 months to complete this requirement.

(4) The department shall have the authority to adopt rules to carry out the provisions of this section.

(5) Any professional holding two or more licenses or certificates subject to the provisions of this section shall be permitted to show proof of having taken one department-approved course on human immunodeficiency virus and acquired immune deficiency syndrome, for purposes of relicensure or

recertification for the additional licenses.

History.—s. 66, ch. 91-297; s. 40, ch. 95-196; s. 31, ch. 97-101.

**381.0035 Educational course on human immunodeficiency virus and acquired immune deficiency syndrome; employees and clients of certain health care facilities.—**

(1) The Department of Health shall require all employees and clients of facilities licensed under chapters 393, 394, and 397 and employees of facilities licensed under chapter 395 and parts II, III, IV, and VI of chapter 400 to complete, biennially, a continuing educational course on the modes of transmission, infection control procedures, clinical management, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome with an emphasis on appropriate behavior and attitude change. Such instruction shall include information on current Florida law and its impact on testing, confidentiality of test results, and treatment of patients and any protocols and procedures applicable to human immunodeficiency counseling and testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to ss. 381.004 and 384.25.

(2) New employees shall be required to complete a course on human immunodeficiency virus and acquired immune deficiency syndrome, with instruction to include information on current Florida law and its impact on testing, confidentiality of test results, and treatment of patients.

(3) Facilities licensed under chapters 393, 394, 395, 397, and parts II, III, IV, and VI of chapter 400 shall maintain a record of employees and dates of attendance at human immunodeficiency virus and acquired immune deficiency syndrome educational courses.

(4) The department shall have the authority to review the records of each facility to determine compliance with the requirements of this section. The department may adopt rules to carry out the provisions of this section.

**History.—**s. 8, ch. BB-380; ss. 17, 69, ch. 91-297; s. 63, ch. 92-289; s. 32, ch. 97-101; s. 1, ch. 98-171; s. 190, ch. 99-13.

**Note.—**Former s. 381.043.

**381.0036 Planning for implementation of educational requirements concerning human immunodeficiency virus and acquired immune deficiency syndrome for specified applicants for professional licensure.—**The Department of Business and Professional Regulation and the Department of Health are hereby directed to begin planning for the implementation of the sections of this act which require, as a part of initial licensure, applicants for certain specified professions to complete an educational course on the transmission, control, treatment, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome. Such planning shall include collecting information from the facilities and programs which educate and train the licensed professionals affected by the licensure requirements of this act and shall also include developing rules for the implementation of the licensure requirements.

**History.—**s. 6, ch. 8B-3B0; s. 17, ch. 91-297; s. 37, ch. 94-218; s. 33, ch. 97-101.

**Note.—**Former s. 381.044.

**381.0037 Findings; intent.—**The Legislature finds that acquired immune deficiency syndrome, otherwise known as AIDS, constitutes a serious and unique danger to the public health and welfare. The Legislature finds that acquired immune deficiency syndrome is transmitted by sexual activity, by intravenous drug use, or from an infected mother to a fetus and that public fear of contagion from casual contact is not supported by any scientific evidence. The Legislature finds that acquired immune deficiency syndrome is transmitted by a retrovirus which makes the possibility of development of an immunization or cure highly unlikely in the near future. The Legislature finds that, once infected, there is a high probability that an individual will develop acquired immune deficiency syndrome or a related syndrome and die a premature death as a result but may live productively for years in a communicable state without showing any signs or symptoms of illness. The Legislature finds the unique methods of transmission of this disease and its inevitably fatal course have raised public fears; changed the attitudes of employers, insurers, educators, law enforcement personnel, and health and medical providers about dealing with the disease; and unexpectedly raised the medical costs of this state. The Legislature intends to establish programs and requirements related to acquired immune deficiency syndrome which carefully balance medical necessity, the right to privacy, and protection of the public from harm and which establish public programs for the care and treatment of persons with acquired immune deficiency syndrome and related conditions.

History.—s. 1, ch. 88-380; s. 17, ch. 91-297.

Note.—Former s. 381.607.

381.0038 Education.—The Department of Health shall establish a program to educate the public about the threat of acquired immune deficiency syndrome.

(1) The acquired immune deficiency syndrome education program shall:

- (a) Be designed to reach all segments of Florida's population;
  - (b) Contain special components designed to reach non-English-speaking and other minority groups within the state;
  - (c) Impart knowledge to the public about methods of transmission of acquired immune deficiency syndrome and methods of prevention;
  - (d) Educate the public about transmission risks in social, employment, and educational situations;
  - (e) Educate health care workers and health facility employees about methods of transmission and prevention in their unique workplace environments;
  - (f) Contain special components designed to reach persons who may frequently engage in behaviors placing them at a high risk for acquiring acquired immune deficiency syndrome;
  - (g) Provide information and consultation to state agencies to educate all state employees; and
  - (h) Provide information and consultation to state and local agencies to educate law enforcement and correctional personnel and inmates.
  - (i) Provide information and consultation to local governments to educate local government employees.
  - (j) Make information available to private employers and encourage them to distribute this information to their employees.
  - (k) Contain special components which emphasize appropriate behavior and attitude change.
  - (l) Contain components that include information about domestic violence and the risk factors associated with domestic violence and AIDS.
- (2) The program designed by the Department of Health shall utilize all forms of the media and shall place emphasis on the design of educational materials that can be used by businesses, schools, and health care providers in the regular course of their business.

(3) The department may contract with other persons in the design, development, and distribution of the components of the education program.

**History.**—s. 2, ch. 88-380; s. 17, ch. 91-297; s. 1, ch. 95-187; s. 34, ch. 97-101.

**Note.**—Former s. 381.608.

381.0039 Oversight of AIDS education programs.—The Department of Education, the Department of Health, and the Department of Business and Professional Regulation are directed to establish an interagency agreement to oversee the quality and cost efficiency of acquired immune deficiency syndrome education programs being administered in the state pursuant to chapters 381, 456, 943, and 945. The interagency agreement shall also include development, where appropriate, of methods for coordinating educational programs for various professional groups.

**History.**—s. 16, ch. 89-350; s. 17, ch. 91-297; s. 38, ch. 94-218; s. 35, ch. 97-101; s. 19, ch. 98-166; s. 9, ch. 2000-160.

**Note.**—Former s. 381.6081.

### **381.004 HIV testing.—**

(1) **LEGISLATIVE INTENT.**—The Legislature finds that the use of tests designed to reveal a condition indicative of human immunodeficiency virus infection can be a valuable tool in protecting the public health. The Legislature finds that despite existing laws, regulations, and professional standards which require or promote the informed, voluntary, and confidential use of tests designed to reveal human immunodeficiency virus infection, many members of the public are deterred from seeking such testing because they misunderstand the nature of the test or fear that test results will be disclosed without their consent. The Legislature finds that the public health will be served by facilitating informed, voluntary, and confidential use of tests designed to detect human immunodeficiency virus infection.

(2) **DEFINITIONS.**—As used in this section:

(a) "HIV test" means a test ordered after July 6, 1988, to determine the presence of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency virus infection.

(b) "HIV test result" means a laboratory report of a human immunodeficiency virus test result entered into a medical record on or after July 6, 1988, or any report or notation in a medical record of a laboratory report of a human immunodeficiency virus test. As used in this section, the term "HIV test result" does not include test results reported to a health care provider by a patient.

(c) "Significant exposure" means:

1. Exposure to blood or body fluids through needle stick, instruments, or sharps;

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 Prevention, including, without limitations, the following body fluids:

- a. Blood.
- b. Semen.
- c. Vaginal secretions.
- d. Cerebro-spinal fluid (CSF).
- e. Synovial fluid.
- f. Pleural fluid.
- g. Peritoneal fluid,
- h. Pericardial fluid,
- i. Amniotic fluid.
- j. Laboratory specimens that contain HIV (e.g., suspensions of concentrated virus); or

3. Exposure of skin to visible blood or body fluids, especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area.

(d) "Preliminary HIV test" means an antibody screening test, such as the enzyme-linked immunosorbent assays (ELISAs) or the Single-Use Diagnostic System (SUDS).

(e) "Test subject" or "subject of the test" means the person upon whom an HIV test is performed, or the person who has legal authority to make health care decisions for the test subject.

**(3) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED CONSENT; RESULTS; COUNSELING; CONFIDENTIALITY.—**

(a) No person in this state shall order a test designed to identify the human immunodeficiency virus, or its antigen or antibody, without first obtaining the informed consent of the person upon whom the test is being performed, except as specified in paragraph (h). Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test to the extent provided by law. Information shall also be provided on the fact that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (4)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, phone numbers, and hours of operation of the sites. Consent need not be in writing provided there is documentation in the medical record that the test has been explained and the consent has been obtained.

(b) Except as provided in paragraph (h), informed consent must be obtained from a legal guardian or other person authorized by law when the person:

1. Is not competent, is incapacitated, or is otherwise unable to make an informed judgment; or
2. Has not reached the age of majority, except as provided in s. 384.30.

(c) The person ordering the test or that person's designee shall ensure that all reasonable efforts are made to notify the test subject of his or her test result. Notification of a person with a positive test result shall include information on the availability of appropriate medical and support services, on the importance of notifying partners who may have been exposed, and on preventing transmission of HIV. Notification of a person with a negative test result shall include, as appropriate, information on preventing the transmission of HIV. When testing occurs in a hospital emergency department, detention facility, or other facility and the test subject has been released before being notified of positive test results, informing the county health department for that department to notify the test subject fulfills this responsibility.

(d) No test result shall be determined as positive, and no positive test result shall be revealed to any person, without corroborating or confirmatory tests being conducted except in the following situations:

1. Preliminary test results may be released to licensed physicians or the medical or nonmedical personnel subject to the significant exposure for purposes of subparagraphs (h)10., 11., and 12.
2. Preliminary test results may be released to health care providers and to the person tested when decisions about medical care or treatment of, or recommendation to, the person tested and, in the case of an intrapartum or postpartum woman, when care, treatment, or recommendations regarding her newborn, cannot await the results of confirmatory testing. Positive preliminary HIV test results shall not be characterized to the patient as a diagnosis of HIV infection. Justification for the use of preliminary test results must be documented in the medical record by the health care provider who ordered the test. This subparagraph does not authorize the release of preliminary test results for the purpose of routine identification of HIV-infected individuals or when HIV testing is incidental to the preliminary diagnosis or care of a patient. Corroborating or confirmatory testing must be conducted as follow-up to a positive preliminary test. Results shall be communicated to the patient according to statute regardless of the outcome. Except as



provided in this section, test results are confidential and exempt from the provisions of s. 119.07(1).

(e) Except as provided in this section, the identity of any person upon whom a test has been performed and test results are confidential and exempt from the provisions of s. 119.07(1). No person who has obtained or has knowledge of a test result pursuant to this section may disclose or be compelled to disclose the identity of any person upon whom a 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 or the subject's legally authorized representative.
2. Any person, including third-party payors, designated in a legally effective release of the test results

executed prior to or after the test by the subject of the test or the subject's legally authorized representative. The test subject may in writing authorize the disclosure of the test subject's HIV test results to third party payors, who need not be specifically identified, and to other persons to whom the test subject subsequently issues a general release of medical information. A general release without such prior written authorization is not sufficient to release HIV test results.

3. An authorized agent or employee of a health facility or health care provider if the health facility or health care provider itself is authorized to obtain the test results, the agent or employee participates in the administration or provision of patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a need to know such information. The department shall adopt a rule defining which persons have a need to know pursuant to this subparagraph.

4. Health care providers consulting between themselves or with health care facilities to determine diagnosis and treatment. For purposes of this subparagraph, health care providers shall include licensed health care professionals employed by or associated with state, county, or municipal detention facilities when such health care professionals are acting exclusively for the purpose of providing diagnoses or treatment of persons in the custody of such facilities.

5. The department, in accordance with rules for reporting and controlling the spread of disease, as otherwise provided by state law.

6. 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; or
- b. Semen provided prior to July 6, 1988, for the purpose of artificial insemination.

7. Health facility staff committees, for the purposes of conducting program monitoring, program evaluation, or service reviews pursuant to chapters 395 and 766.

8. Authorized medical or epidemiological researchers who may not further disclose any identifying characteristics or information.

9. A person allowed access by a court order which is issued in compliance with the following provisions:

a. No court of this state shall 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 which may be disserved by disclosure which deters blood, organ, and semen donation and future human immunodeficiency virus-related testing or which may lead to discrimination. This paragraph shall not apply to blood bank donor records.

b. Pleadings pertaining to disclosure of test results shall substitute a pseudonym for the true name of the subject of the test. The disclosure to the parties of the subject's true name shall be communicated confidentially in documents not filed with the court.

c. Before granting any such order, the court shall 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.

d. 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 a public hearing is necessary to the public interest and the proper administration of justice.

e. Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure which shall specify the persons who may have access to the information, the purposes for which the information shall be used, and appropriate prohibitions on future disclosure.

10. A person allowed access by order of a judge of compensation claims of the Division of Administrative Hearings. A judge of compensation claims shall not issue such order unless he or she finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means.

11. Those employees of the department or of child-placing or child-caring agencies or of family foster homes, licensed pursuant to s. 409.175, who are directly involved in the placement, care, control, or custody of such test subject and who have a need to know such information; adoptive parents of such test subject; or

any adult custodian, any adult relative, or any person responsible for the child's welfare, if the test subject was not tested under subparagraph (b)2. and if a reasonable attempt has been made to locate and inform the legal guardian of a test result. The department shall adopt a rule to implement this subparagraph.

12. Those employees of residential facilities or of community-based care programs that care for developmentally disabled persons, pursuant to chapter 393, who are directly involved in the care, control, or custody of such test subject and who have a need to know such information.

13. A health care provider involved in the delivery of a child can note the mother's HIV test results in the child's medical record.

14. Medical personnel or nonmedical personnel who have been subject to a significant exposure during the course of medical practice or in the performance of professional duties, or individuals who are the subject of the significant exposure as provided in subparagraphs (h)10.-12.

15. The medical examiner shall disclose positive HIV test results to the department in accordance with rules for reporting and controlling the spread of disease.

(f) Except as provided in this section, the identity of a person upon whom a test has been performed is confidential and exempt from the provisions of s. 119.07(1). No person to whom the results of a test have been disclosed may disclose the test results to another person except as authorized by this subsection and by ss. 951.27 and 960.003. Whenever disclosure is made pursuant to this subsection, 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 such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is NOT sufficient for this purpose." An oral disclosure shall be accompanied by oral notice and followed by a written notice within 10 days, except that this notice shall not be required for disclosures made pursuant to subparagraphs (e)3. and 4.

(g) Human immunodeficiency virus test results contained in the medical records of a hospital licensed under chapter 395 may be released in accordance with s. 395.3025 without being subject to the requirements of subparagraph (e)2., subparagraph (e)9., or paragraph (f); provided the hospital has obtained written informed consent for the HIV test in accordance with provisions of this section.

(h) Notwithstanding the provisions of paragraph (a), informed consent is not required:

1. When testing for sexually transmissible diseases is required by state or federal law, or by rule including the following situations:

a. HIV testing pursuant to s. 796.08 of persons convicted of prostitution or of procuring another to commit prostitution.

b. Testing for HIV by a medical examiner in accordance with s. 406.11.

2. Those exceptions provided for blood, plasma, organs, skin, semen, or other human tissue pursuant to s. 381.0041.

3. For the performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies when the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment to the person being tested and the patient is unable to consent, as supported by documentation in the medical record. Notification of test results in accordance with paragraph (c) is required.

4. For the performance of an HIV-related test by licensed medical personnel for medical diagnosis of acute illness where, in the opinion of the attending physician, obtaining informed consent would be detrimental to the patient, as supported by documentation in the medical record, and the test results are necessary for medical diagnostic purposes to provide appropriate care or treatment to the person being tested. Notification of test results in accordance with paragraph (c) is required if it would not be detrimental to the patient. This subparagraph does not authorize the routine testing of patients for HIV infection without informed consent.

5. When HIV testing is performed as part of an autopsy for which consent was obtained pursuant to s. 872.04.

6. For the performance of an HIV test upon a defendant pursuant to the victim's request in a prosecution for any type of sexual battery where a blood sample is taken from the defendant voluntarily, pursuant to court order for any purpose, or pursuant to the provisions of s. 775.0877, s. 951.27, or s. 960.003; however, the results of any HIV test performed shall be disclosed solely to the victim and the defendant, except as provided in ss. 775.0877, 951.27, and 960.003.

7. When an HIV test is mandated by court order.

8. For epidemiological research pursuant to s. 381.0032, for research consistent with institutional review boards created by 45 C.F.R. part 46, or for 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.

9. When human tissue is collected lawfully without the consent of the donor for corneal removal as authorized by s. 765.5185 or enucleation of the eyes as authorized by s. 765.519.

10. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice and where a blood sample is available that was taken from that individual voluntarily by medical personnel for other purposes. The term "medical personnel" includes a licensed or certified health care professional; an employee of a health care professional or health care facility; employees of a laboratory licensed under chapter 483; personnel of a blood bank or plasma center; a medical student or other student who is receiving training as a health care professional at a health care facility; and a paramedic or emergency medical technician certified by the department to perform life-support procedures under s. 401.23.

a. Prior to performance of an HIV test on a voluntarily obtained blood sample, the individual from whom the blood was obtained shall be requested to consent to the performance of the test and to the release of the results. The individual's refusal to consent and all information concerning the performance of an HIV test and any HIV test result shall be documented only in the medical personnel's record unless the individual gives written consent to entering this information on the individual's medical record.

b. Reasonable attempts to locate the individual and to obtain consent shall be made, and all attempts must be documented. If the individual cannot be found, an HIV test may be conducted on the available blood sample. If the individual does not voluntarily consent to the performance of an HIV test, the individual shall be informed that an HIV test will be performed, and counseling shall be furnished as provided in this section. However, HIV testing shall be conducted only after a licensed physician documents, in the medical record of the medical personnel, that there has been a significant exposure and that, in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel.

c. Costs of any HIV test of a blood sample performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment shall not be borne by the medical personnel or the employer of the medical personnel.

d. In order to utilize the provisions of this subparagraph, the medical personnel must either be tested for HIV pursuant to this section or provide the results of an HIV test taken within 6 months prior to the significant exposure if such test results are negative.

e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).

f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample is not available, the medical personnel or the employer of such person acting on behalf of the employee may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

11. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice of the medical personnel while the medical personnel provides emergency medical treatment to the individual; or who comes into contact with nonmedical personnel in such a way that a significant exposure has occurred while the nonmedical personnel provides emergency medical assistance during a medical emergency. For the purposes of this subparagraph, a medical emergency means an emergency medical condition outside of a hospital or health care facility that provides physician care. The test may be performed only during the course of treatment for the medical emergency.

a. An individual who is capable of providing consent shall be requested to consent to an HIV test prior to the testing. The individual's refusal to consent, and all information concerning the performance of an HIV test and its result, shall be documented only in the medical personnel's record unless the individual gives written consent to entering this information on the individual's medical record.

b. HIV testing shall be conducted only after a licensed physician documents, in the medical record of the medical personnel or nonmedical personnel, that there has been a significant exposure and that, in the

physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.

c. Costs of any HIV test performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment shall not be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel.

d. In order to utilize the provisions of this subparagraph, the medical personnel or nonmedical personnel shall be tested for HIV pursuant to this section or shall provide the results of an HIV test taken within 6 months prior to the significant exposure if such test results are negative.

e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s.119.07(1).

f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample was not obtained during treatment for the medical emergency, the medical personnel, the employer of the medical personnel acting on behalf of the employee, or the nonmedical personnel may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

12. For the performance of an HIV test by the medical examiner or attending physician upon an individual who expired or could not be resuscitated while receiving emergency medical assistance or care and who was the source of a significant exposure to medical or nonmedical personnel providing such assistance or care.

a. HIV testing may be conducted only after a licensed physician documents in the medical record of the medical personnel or nonmedical personnel that there has been a significant exposure and that, in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.

b. Costs of any HIV test performed under this subparagraph may not be charged to the deceased or to the family of the deceased person.

c. For the provisions of this subparagraph to be applicable, the medical personnel or nonmedical personnel must be tested for HIV under this section or must provide the results of an HIV test taken within 6 months before the significant exposure if such test results are negative.

d. A person who receives the results of an HIV test pursuant to this subparagraph shall comply with paragraph (e).

13. For the performance of an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant as necessary to provide appropriate care and treatment of the infant when, after a reasonable attempt, a parent cannot be contacted to provide consent. The medical records of the infant shall reflect the reason consent of the parent was not initially obtained. Test results shall be provided to the parent when the parent is located.

14. For the performance of HIV testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive.

15. For the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.

#### (4) COUNTY HEALTH DEPARTMENT NETWORK OF VOLUNTARY HUMAN IMMUNODEFICIENCY VIRUS TESTING PROGRAMS.—

(a) The Department of Health shall establish a network of voluntary human immunodeficiency virus testing programs in every county in the state. These programs shall be conducted in each health department established under the provisions of part I of chapter 154. Additional programs may be contracted to other private providers to the extent that finances permit and local circumstances dictate.

(b) Each county health department shall have the ability to provide counseling and testing for human immunodeficiency virus to each patient who receives services and shall offer such testing on a voluntary basis to each patient who presents himself or herself for services in a public health program designated by the State Health Officer by rule.

(c) Each county health department shall provide a program of counseling and testing for human immunodeficiency virus infection, on both an anonymous and confidential basis. Counseling provided to a patient tested on both an anonymous and confidential basis shall include informing the patient of the

availability of partner-notification services, the benefits of such services, and the confidentiality protections available as part of such services. The Department of Health or its designated agent shall continue to provide for anonymous testing through an alternative testing site program with sites throughout all areas of the state. Each county health department shall maintain a list of anonymous testing sites. The list shall include the locations, phone numbers, and hours of operation of the sites and shall be disseminated to all persons and programs offering human immunodeficiency virus testing within the service area of the county health department, including physicians licensed under chapter 458 or chapter 459. Except as provided in this section, the identity of a person upon whom a test has been performed and test results are confidential and exempt from the provisions of s. 119.07(1).

(d) The result of a serologic test conducted under the auspices of the Department of Health shall not be used to determine if a person may be insured for disability, health, or life insurance or to screen or determine suitability for, or to discharge a person from, employment. Any person who violates the provisions of this subsection is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(5) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS; REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM REGISTRATION.—No county health department and no other person in this state shall conduct or hold themselves out to the public as conducting a testing program for acquired immune deficiency syndrome or human immunodeficiency virus status without first registering with the Department of Health, reregistering each year, complying with all other applicable provisions of state law, and meeting the following requirements:

(a) The program must be directed by a person with a minimum number of contact hours of experience in the counseling of persons with acquired immune deficiency syndrome or human immunodeficiency virus infection, as established by the Department of Health by rule.

(b) The program must have all medical care supervised by a physician licensed under the provisions of chapter 458 or chapter 459.

(c) The program shall have all laboratory procedures performed in a laboratory licensed under the provisions of chapter 483.

(d) The program must meet all the informed consent criteria contained in subsection (3).

(e) The program must provide the opportunity for pretest counseling on the meaning of a test for human immunodeficiency virus, including medical indications for the test; the possibility of false positive or false negative results; the potential need for confirmatory testing; the potential social, medical, and economic consequences of a positive test result; and the need to eliminate high-risk behavior.

(f) The program must provide supplemental corroborative testing on all positive test results before the results of any positive test are provided to the patient. Except as provided in this section, the identity of any person upon whom a test has been performed and test results are confidential and exempt from the provisions of s. 119.07(1).

(g) The program must provide the opportunity for face-to-face posttest counseling on the meaning of the test results; the possible need for additional testing; the social, medical, and economic consequences of a positive test result; and the need to eliminate behavior which might spread the disease to others.

(h) Each person providing posttest counseling to a patient with a positive test result shall receive specialized training, to be specified by rule of the department, about the special needs of persons with positive results, including recognition of possible suicidal behavior, and shall refer the patient for further health and social services as appropriate.

(i) When services are provided for a charge during pretest counseling, testing, supplemental testing, and posttest counseling, the program must provide a complete list of all such charges to the patient and the Department of Health.

(j) Nothing in this subsection shall be construed to require a facility licensed under chapter 483 or a person licensed under the provisions of chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 466, or chapter 467 to register with the Department of Health if he or she does not advertise or hold himself or herself out to the public as conducting testing programs for human immunodeficiency virus infection or specializing in such testing.

(k) The department shall deny, suspend, or revoke the registration of any person or agency that violates this section, or any rule adopted under this section, constituting an emergency affecting the immediate health, safety, and welfare of a person receiving service.

(6) PENALTIES.—

(a) Any violation of this section by a facility or licensed health care provider shall be a ground for disciplinary action contained in the facility's or professional's respective licensing chapter.

(b) Any person who violates the confidentiality provisions of this section and s. 951.27 commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c) Any person who obtains information that identifies an individual who has a sexually transmissible disease including human immunodeficiency virus or acquired immunodeficiency syndrome, who knew or should have known the nature of the information and maliciously, or for monetary gain, disseminates this information or otherwise makes this information known to any other person, except by providing it either to a physician or nurse employed by the department or to a law enforcement agency, commits a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083.

(7) EXEMPTIONS.—Except as provided in paragraph (4)(d) and ss. 627.429 and 641.3007, insurers and others participating in activities related to the insurance application and underwriting process shall be exempt from this section.

(8) MODEL PROTOCOL FOR COUNSELING AND TESTING FOR HUMAN IMMUNODEFICIENCY VIRUS.—The Department of Health shall develop, by rule, a model protocol consistent with the provisions of this section for counseling and testing persons for the human immunodeficiency virus. The protocol shall include criteria for evaluating a patient's risk for human immunodeficiency virus infection and for offering human immunodeficiency virus testing, on a voluntary basis, as a routine part of primary health care or admission to a health care facility. The Department of Health shall ensure that the protocols developed under this section are made available to health care providers.

(9) FEES.—

(a) Each person or private organization registered as an AIDS or HIV testing site shall pay the department a fee which shall be set by rule of the department.

(b) Fees established pursuant to paragraph (a) shall be an amount sufficient to meet all costs incurred by the department in carrying out its registration, data collection, complaint monitoring, and administrative responsibilities under this section, for all private AIDS or HIV testing sites, but shall not exceed \$100.

(c) No other fees shall be charged by other governmental agencies for these purposes.

(10) RULES.—The Department of Health may adopt rules to implement this section, including definitions of terms, procedures for accessing confidential information, requirements for testing, and requirements for registered testing sites.

(11) TESTING AS A CONDITION OF TREATMENT OR ADMISSION.—

(a) It is unlawful for any facility the operation of which, or for any person engaged in an occupation the practice of which, requires a license by the Agency for Health Care Administration, the Department of Health, or the Department of Business and Professional Regulation, to require any person to take or submit to a human immunodeficiency virus-related test as a condition of admission to any such facility or as a condition of purchasing or obtaining any service or product for which the license is required. This subsection shall not be construed to prohibit any physician in good faith from declining to provide a particular treatment requested by a patient if the appropriateness of that treatment can only be determined through a human immunodeficiency virus-related test

(b) The Agency for Health Care Administration, the Department of Health, and the Department of Business and Professional Regulation shall adopt rules implementing this subsection.

(c) Any violation of this subsection or the rules implementing it shall be punishable as provided in subsection (6).

History.—s. 21, ch. 88-380; s. 2, ch. 89-289; s. 6, ch. 89-350; s. 3, ch. 90-210; s. 3, ch. 90-292; s. 3, ch. 90-344; ss. 17, 67, ch. 91-297- s 12. ch. 92-33; s. 2, ch. 92-171; s. 64, ch. 92-289; s. 10, ch. 93-227; s. 3, ch. 93-230; s. 4, ch. 93-264; s. 39, ch. 94-218; s. 94, ch. 95-143- s 1032. ch. 95-148; s. 1, ch. 95-308; s. 1, ch. 95-387; s. 1, ch. 96-179; s. 185, ch. 96-406; s. 64, ch. 97-100; s. 176, ch. 97-101; s. 2, ch. 98-171; s. 20, ch. 98-191; s. 191, ch. 99-13; s. B, ch. 99-397; s. 4, ch. 2000-242; s. 9, ch. 2000-367; s. 17, ch. 2001-S2; s. 6, ch. 2001-91; s. 76, ch. 2001-226.

Note.—Former s. 381.609.

#### 381.0041 Donation and transfer of human tissue; testing requirements.—

(1) Every donation of blood, plasma, organs, skin, or other human tissue for transfusion or transplantation to another shall be tested prior to transfusion or other use for human immunodeficiency virus infection and other communicable diseases specified by rule of the Department of Health. Tests for the human immunodeficiency virus infection shall be performed only after obtaining written, informed consent from the potential donor or the donor's legal representative. Such consent may be given by a minor pursuant to s. 743.06. Obtaining consent shall include a fair explanation of the procedures to be followed and the meaning and use of the test results. Such explanation shall include a description of the confidential nature of the test as described in s. 381.004(3). If consent for testing is not given, then the person shall not be accepted as a donor except as otherwise provided in subsection (3).

(2) Notwithstanding the provisions of subsection (1), written, informed consent to perform testing shall not be required:

(a) When the blood, plasma, organ, skin, or other human tissue is received for processing or testing from an out-of-state blood bank;

(b) When blood or tissue is received from a health care facility or health care provider for reference testing or processing and the results of such test are reported back to the facility or provider; or

(c) When an unrevoked anatomical gift has been made pursuant to s. 765.514, by will or other written instrument, and the donor is deceased or incompetent.

(3) No person shall collect any blood, organ, skin, or other human tissue from one human being and hold it for, or actually perform, any implantation, transplantation, transfusion, grafting, or any other method of transfer to another human being without first testing such tissue for the human immunodeficiency virus and other communicable diseases specified by rule of the Department of Health, or without performing another process approved by rule of the Department of Health capable of killing the causative agent of those diseases specified by rule. Such testing shall not be required:

(a) When there is insufficient time to perform testing because of a life-threatening emergency circumstance and the blood is transferred with the recipient's informed consent.

(b) For a donation of semen made by the spouse of a recipient for the purposes of artificial Insemination or other reproductive procedure.

(c) When there is insufficient time to obtain the results of a confirmatory test for any tissue or organ which is to be transplanted, notwithstanding the provisions of s. 381.004(3)(d). In such circumstances, the results of preliminary screening tests may be released to the potential recipient's treating physician for use in determining organ or tissue suitability.

(4) All human blood, organs, skin, or other human tissue which is to be transfused or transplanted to another and is found positive for human immunodeficiency virus or other communicable disease specified by rule of the Department of Health shall be rendered noncommunicable by the person holding the tissue or shall be destroyed, unless the human tissue is specifically labeled to identify the human immunodeficiency virus and:

(a) Is used for research purposes; or

(b) Is used to save the life of another and is transferred with the recipient's informed consent.

(5) Each person who collects human blood, organs, skin, or other human tissue who finds evidence after confirmatory testing of human immunodeficiency virus in the donor shall notify the donor of the presence of the virus. When notifying the donor pursuant to this requirement, the donor shall be provided the following information:

(a) The meaning of the test results;

(b) Measures for the prevention of the transmission of the human immunodeficiency virus;

(c) The availability in the geographic area of any appropriate health care services, including mental health care, and appropriate social and support services;

(d) The benefits of locating and counseling any individual by whom the infected individual may have been exposed to human immunodeficiency virus and any individual whom the infected individual may have exposed to the virus; and

(e) The availability, if any, of the services of public health authorities with respect to locating and counseling any individual described in paragraph (d).

(6) Human immunodeficiency virus tests performed pursuant to autologous blood donations which have not been confirmed as positive by confirmatory testing may be revealed to the donor's treating physician when such test results may be necessary for the diagnosis, treatment, or care of the donor.

(7) Any blood donor who tests positive for human immunodeficiency virus based upon confirmatory testing shall be notified in the following manner:

(a) The donor shall be sent written notification by certified mail that abnormal test results exist with respect to his or her blood donation, and the blood bank shall offer the opportunity to discuss the nature and significance of the findings by telephone or in person.

(b) If the blood bank does not receive a response from the donor within 30 days, it shall send the actual test results and the information required by subsection (5) to the donor by certified mail.

(8) The Department of Health shall develop, in conjunction with persons who collect human tissue, a model protocol for providing the information required in subsection (5).

(9) All blood banks shall be governed by the confidentiality provisions of s. 381.004(3).

(10) The Department of Health is authorized to adopt rules to implement this section. In adopting rules pertaining to this section, the department shall consider the rules of the United States Food and Drug Administration and shall conform to those rules to the extent feasible without jeopardizing the public health.

(11)(a) Any person who fails to test blood, plasma, organs, skin, or other human tissue which is to be transfused or transplanted, or violates the confidentiality provisions required by this section, is guilty of a



misdemeanor of the first degree, punishable as provided in s. 775.082 ors. 775.083.

(b) Any person who has human immunodeficiency virus infection, who knows he or she is infected with human immunodeficiency virus, and who has been informed that he or she may communicate this disease by donating blood, plasma, organs, skin, or other human tissue who donates blood, plasma, organs, skin, or other human tissue is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, ors. 775.084.

(12) Prior to the transplant of an organ or artificial insemination, the institution or physician responsible for overseeing the procedure must provide the prospective recipient a warning as to the risks of contracting human immunodeficiency virus.

History.—s. 22, ch. 88-380; s. 7, ch. 89-350; s. 4, ch. 90-292; s. 4, ch! 90-344; s. 17, ch. 91-297; s. 67, ch. 95-143; s. 650. ch. 95-148; s. 186, ch. 96-406; s. 177, ch. 97-101; s. 77, ch. 2001-226. Note.—Formers. 381.6105.

**381.0042 Patient care for persons with human immunodeficiency virus infection.**—The department may establish acquired immune deficiency syndrome patient care networks in each region of the state where the numbers of cases of acquired immune deficiency syndrome and other human immunodeficiency virus infections justifies the establishment of cost-effective regional patient care networks. Such networks shall be delineated by rule of the department which shall take into account natural trade areas and centers of medical excellence that specialize in the treatment of acquired immune deficiency syndrome, as well as available federal, state, and other funds. Each patient care network shall include representation of persons with human immunodeficiency virus infection; health care providers; business interests; the department, including, but not limited to, county health departments; and local units of government. Each network shall plan for the care and treatment of persons with acquired immune deficiency syndrome and acquired immune deficiency syndrome related complex in a cost-effective, dignified manner which emphasizes outpatient and home care. Once each year, beginning April 1989, each network shall make its recommendations concerning the needs for patient care to the department.

History.—s. 39, ch. 88-380; s. 17, ch. 91-297; s. 36, ch. 97-101.

Note.—Formers. 381.612.

#### **381.0045 Targeted outreach for pregnant women.—**

(1) This section may be cited as the "Targeted Outreach for Pregnant Women Act of 1998."

(2) It is the purpose of this section to establish a targeted outreach program for high-risk pregnant women who may not seek proper prenatal care, who suffer from substance abuse problems, or who are infected with human immunodeficiency virus (HIV), and to provide these women with links to much needed services and information.

(3) The department shall:

(a) Conduct outreach programs through contracts with, grants to, or other working relationships with persons or entities where the target population is likely to be found.

(b) Provide outreach that is peer-based, culturally sensitive, and performed in a nonjudgmental manner.

(c) Encourage high-risk pregnant women of unknown status to be tested for HIV.

(d) Educate women not receiving prenatal care as to the benefits of such care.

(e) Provide HIV-infected pregnant women with information so they can make an informed decision about the use of Zidovudine (AZT).

(f) Link women with substance abuse treatment, when available, and act as a liaison with Healthy Start coalitions, children's medical services, Ryan White-funded providers, and other services of the Department of Health.

(g) Provide continued over site to HIV-exposed newborns.

(4) The types of entities the department is encouraged to contract with, provide grants to, or enter into other working relationships with may include, but are not limited to, faith-based organizations, academic institutions, religious organizations, nonprofit community centers, and other social-services-related entities.

History.—s. 1, ch. 98-307; s. 18, ch. 2001-62.

#### **381.0046 Statewide HIV and AIDS prevention campaign.—**

(1) The Department of Health shall develop and implement a statewide HIV and AIDS prevention campaign that is directed towards minorities who are at risk of HIV infection. The campaign shall include

television, radio, and outdoor advertising; public service announcements; and peer-to-peer outreach. Each campaign message and concept shall be evaluated with members of the target group to ensure its effectiveness. The campaign shall provide information on the risk of HIV and AIDS infection and strategies to follow for prevention, early detection, and treatment. The campaign shall use culturally sensitive literature and educational materials and promote the development of individual skills for behavior modification.

(2) The Department of Health shall establish four positions within the department for HIV and AIDS regional minority coordinators and one position for a statewide HIV and AIDS minority coordinator. The coordinators shall facilitate statewide efforts to implement and coordinate HIV and AIDS prevention and treatment programs. The statewide coordinator shall report directly to the chief of the Bureau of HIV and AIDS within the Department of Health.

(3) The Department of Health shall, with assistance from the Minority HIV and AIDS Task Force and the statewide coordinator, plan and conduct a statewide Black Leadership Conference on HIV and AIDS by January 2000. The conference shall provide workshops for minority organizations in building skills and improving an organization's capacity to conduct HIV and AIDS prevention and treatment programs.

History.—s. 201. ch. 99-397.

## HUMAN IMMUNODEFICIENCY VIRUS (HIV)

- 64D-2.001 Patient Care Networks.
- 64D-2.002 Definitions.
- 64D-2.003 Confidentiality.
- 64D-2.004 Testing Requirements.
- 64D-2.0G5 Blood and Human Tissue Donations.
- 64D-2.006 Registration of HIV Testing Programs.

## 64D-2.001 Patient Care Networks.

(1) Pursuant to Section 381.0042, Florida Statutes (F.S.), a patient care network shall be established in each of the following geographical areas:

- (a) South Florida which consists of Dade and Monroe Counties.
- (b) Palm Beach County.
- (c) East Central Florida which consists of Orange, Osceola, Seminole and Brevard Counties.
- (d) West Central Florida which consists of Hillsborough, Polk, Pinellas and Pasco Counties.
- (e) Northeast Florida which consists of Duval, St. Johns, Volusia, Nassau, Baker, Clay and Flagler Counties.

(2) Each patient care network established above shall include representation as described in Section 381.0042, F.S., and shall provide services as required by that section through contract with the department.

(3) The department shall contract with patient care networks for the provision of services pursuant to Section 381.0042, F.S.

*Specific Authority* 3810042 FS. *Law Implemented* 381.0042 FS. *History-New* 12-24-95, *Formerly* 10D-93.0087.

## 64D-2.002 Definitions.

As used in this chapter, "HIV test," "HIV test result," "preliminary test," "Significant exposure,\* and "Test subject" have the same meaning as in Section 381.004(2), F.S., and the following words and phrases shall have the following meanings:

- (1) "Blood" - Whole human blood or components of human blood, including plasma.
- (2) "Blood Bank" - Any facility licensed under Chapter 483, Part I, F.S., including plasma centers, where blood or plasma is procured, donated, processed, stored or distributed.
- (3) "Confirmatory test" - A corroborative or supplemental HIV test, such as a Western Blot, licensed by the United States Food and Drug Administration (FDA) to validate a positive preliminary HIV test; or other supplemental or corroborative tests authorized by the State AIDS Program in consultation with the Centers for Disease Control and Prevention (CDC), the Association of State and Territorial Public Health Laboratory Directors, or the FDA, e.g., the immunofluorescent assay (IFA).
- (4) "Health care facility" - A hospital, nursing home, clinic, blood bank, plasma center, sperm bank, clinical laboratory, intermediate care facility, ambulatory surgical center, public health facility licensed under Chapter 154, mental health facility licensed under Chapter 394 or drug treatment or rehabilitation facility licensed under Chapter 397, F.S., emergency center, walk-in emergency clinic, birthing center, or health maintenance organization.
- (5) "Health care provider" - Any licensed physician, dentist, podiatrist, naturopath, nurse, advanced registered nurse practitioner (ARNP), physician assistant, dental assistant, dental hygienist, paramedic, emergency medical technician, psychologist, mental health professional, lay midwife, any person licensed under the Division of Medical Quality Assurance at the DOH, an administrator, employee or agent of a health care facility or other person providing medical, nursing, psychological, or other health care services or medical or other students receiving training as health care professionals at a health care facility.
- (6) "Laboratory" - Any facility licensed under Chapter 483, F.S., where HIV tests are performed. This definition does not include blood banks or plasma centers.
- (7) "Medical personnel" - An authorized agent or employee of a health care facility, health care provider, health care professional, blood bank or plasma center, a licensed or certified health care professional; a medical or other student receiving training as a health care professional at a health care facility; a paramedic or emergency medical technician certified by the Department to perform life support procedures pursuant to the provisions of Section 401.23, F.S.
- (8) "Reasonable attempt" - A documented effort to locate an individual, for example: contact by last known phone number, relative's phone number, agency contacts, or certified mail.

*Specific Authority* 381.0011(13), 381.003(2), 381.004(10), 381.0041(10) FS. *Law Implemented* 381.0011, 381.003, 381.004 FS. *History-New* 11-6-85, *Formerly* 10D-93.62, *Amended* 7-12-89, 5-30-90, 7-20-92, 5-1-96, *Formerly* 10D-93.062, *Amended* 8-24-99.



#### 64D-2.003 Confidentiality.

(1) Any person, including the department, and any county health department, contract provider, testing program authorized by the department, health care provider or health care facility shall comply with the confidentiality provisions of Section 381.004(3)(e), (f), F.S., and this rule in administering the HIV test, protecting the identity of the test subject, *and* managing records which contain laboratory reports of HIV test results or any report or notation of a laboratory report of an HIV test.

(2) No person, including health care facilities and health care providers, as defined in subsections 64D-2.002(4) and (5), F.A.C., shall disclose or be compelled to disclose the identity of a test subject or his or her HIV test results, except to the following persons:

(a) The subject of the test.

(b) Any person designated in a legally effective release executed by the test subject prior to or after the performance of the HIV test. The following releases are legally effective:

1. A specific release that states the test subject's HIV test results can be disclosed to a named third party, except that third party payers need not be specifically identified.

2. A general release that states the test subject's medical record can be disclosed to a named third party, except that third party payers need not be specifically identified, provided the general release is preceded by the test subject's express written authorization.

a. The prior written authorization shall state that the test subject's HIV test results can be disclosed to third party payers, who need not be specifically identified, and to other persons to whom the test subject subsequently issues a general release of medical information.

b. Health care providers and health care facilities shall not honor a general release without this express prior written authorization if the material to be released would disclose the identity of a test subject or his or her HIV test result.

3. A hospital can honor a general release without prior written authorization, provided the hospital first obtains the test subject's written informed consent in accordance with Rule 64D-2.004, F.A.C., and releases the information in accordance with Section 335.3025, F.S. The informed consent shall include a statement to the effect that the test subject's HIV test results can be released to anyone to whom the test subject gives written permission to see or to copy his or her medical record.

(c) Any medical personnel who experience a significant exposure during the course of employment or in the performance of professional duties, or non-medical personnel who experience a significant exposure while providing emergency assistance.

(d) An authorized agent or employee of a health care facility or health care provider if:

1. The health care facility or health care provider itself is authorized to know or obtain the identity of a test subject or his or her HIV test result; and

2. The agent or employee has a "need to know" as defined in subparagraph 64D-2.003(2)(d)3., F.A.C., and performs one of the following functions:

a. Participates in or administers the business operations of a health care provider or health care facility;

b. Provides or participates in providing patient care; or

c. Handles or processes specimens of body fluids or tissues.

3. An agent or employee has a need to know the identity of a test subject or his or her HIV test result if:

a. The agent or employee has a need to know the identity of a test subject or his or her HIV test result to discharge properly his or her duties in the ordinary course of participating in or administering the business operations of a health care facility or health care provider. Examples of these agents or employees are:

(I) Financial staff who compile or review patient records as part of routine billing activities.

(II) Transcribers who enter medical information into computers or records.

(III) Personnel involved in utilization review, risk management or peer review activities in which patient records are normally shared among reviewers.

(IV) Supervisors responsible for the activities described in sub-subparagraph 64D-2.003(2)(d)3.b., F.A.C.

b. The agent or employee has a need to know the identity of a test subject or his or her HIV test results to discharge properly his or her duties in the ordinary course of providing patient care. Examples of these agents or employees include, but are not limited to:

(I) Licensed professionals, such as physicians, nurses or social workers, who normally are permitted to review the medical record of a test subject.

(II) Licensed professionals who regularly participate as part of a multi-disciplinary medical team responsible for the care of patients located on a particular ward or floor, but who can not themselves provide or determine diagnosis or treatment of a test subject.

c. The agent or employee has a need to know the identity of a test subject or his or her HIV test results to learn or to teach properly in the ordinary course of an approved educational program in a medical teaching facility or a research program under Chapter 405, F.S. Examples of these agents or employees include, but are not limited to:

- (l) Students, interns, and residents involved in making rounds at a teaching hospital.
  - (ll) Researchers and their assistants engaged in research authorized under Chapter 405, F.S.
  - (e) Health care providers involved in the care or treatment of a test subject and consulting between or among themselves or with health care facilities to determine diagnosis or treatment of a test subject This is not an exception to Section 395.3025, F.S., which requires hospitals to obtain written authorization before furnishing patient records to anyone other than the patient.
    1. A health care provider involved in the delivery of a child can note the mother's HIV test results on the child's medical record.
    2. For the purpose of paragraph 64D-2.0Q3(2)(e), F.A.C., health care providers shall include licensed health care professionals employed by or associated with state, county or municipal detention facilities when such health care professionals are acting exclusively for the purpose of providing diagnosis or treatment of persons in the care, custody, or control of such facilities.
  - (f) The department, in accordance with rules for reporting and controlling the spread of disease, as otherwise provided by state law.
  - (g) A health facility or health care provider which procures, processes, distributes, or uses:
    1. A human body part from a deceased person, with respect to medical information regarding the person; or
    2. Semen provided prior to July 6, 1988, for the purpose of artificial insemination.
  - (h) Health facility staff committees for the purposes of conducting program monitoring, program evaluation or service reviews. Health facility staff committees include medical review committees as defined in Section 766.101, F.S.
  - (i) Authorized medical or epidemiological researchers who can not further disclose any identifying characteristics or information.
  - (j) Those persons authorized under Section 796.08(3), F.S., to receive HIV test results of convicted prostitutes tested pursuant to Section 796.08(3), F.S. Authorized persons include:
    1. Medical personnel which includes those involved in the diagnosis or treatment of the person tested.
    2. Appropriate state agencies which include those diagnosing, treating or making payment or administrative determinations related to HIV testing.
    3. Courts of appropriate jurisdiction in the case, including appellate courts, and any persons so ordered by the court, including probation officers if treatment and counseling are conditions of release from probation, community control, or incarceration.
  - (k) Pursuant to Section 960.003(2)-(5), F.S., and Section 775.0877(2), F.S., the victim of a criminal offense involving the transmission of body fluids from one person to another shall, upon request, obtain the HIV test results of the person charged with or convicted of the criminal offense. The test results shall be disclosed in accordance with Section 381.004(3)(c), F.S. The test results shall not be disclosed to any other person except as expressly authorized by law or court order.
  - (l) In accordance with specific circumstances established in Section 455.674, F.S., a practitioner regulated through the Division of Medical Quality Assurance within the Department of Health can disclose the identity of an HIV positive patient to the patient's sex or needle-sharing partner. Any notification of a sex or needle-sharing partner pursuant to this section shall be done in accordance with the "Partner Notification Protocol for Practitioners", dated March 1999, incorporated by reference in this rule. This protocol can be obtained from the Department of Health, Bureau of HIV/AIDS, 4052 Bald Cypress Way, Bin A09, Tallahassee, Florida 32399-1715.
  - (m) Employees of the department, child placing or child-caring agencies, or of family foster homes licensed pursuant to Section 409.175, F.S., who are directly involved in the placement care, control, or custody of a test subject and have a need to know such information pursuant to Rule 10M-6.120, F.A.C.; the adoptive parents of the test subject; or the adult custodian, adult relative or other person who is responsible for the child's welfare, if the test subject was not tested pursuant to Section 384.30, F.S., and if, after a reasonable attempt, the parent or legal guardian cannot be located and informed of the test result. The details of the reasonable attempt must be documented in the medical record of the child.
  - (n) Employees of residential facilities or community-based care programs licensed under Chapter 393, F.S., for developmentally disabled persons if the employees are directly involved in the care, control, or custody of such test subject and have a need to know such information.
  - (o) A person allowed access by a court order which is issued in compliance with Section 381.004(3)(e)9., F.S.
  - (p) A person allowed access by order of a judge of compensation claims of the Division of Workers' Compensation of the Department of Labor and Employment Security. Such order shall not be issued by a judge of compensation claims unless the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means.
- (3) All patient records, client records or medical records containing HIV test results are recommended to be kept in the following manner:

(a) The written informed consent form or documentation of informed consent and HIV test results shall be kept in a patient's medical record. The confidentiality requirements of this rule shall not prohibit the computerization of medical records including HIV test results when such records are kept in accordance with sound practices of record keeping.

(b) When an HIV test is performed without informed consent, the test results shall be disclosed only as provided in this rule and shall be kept according to the confidentiality requirements of this rule.

(c) No patient records shall be marked, coded or distinguished on the outside so as to identify HIV test results or that an HIV test was or was not performed.

(d) The health care facility or residential facility shall establish a uniform procedure to maintain confidential medical records which ensures access only to persons authorized to review or receive the contents.

(e) A subpoena for medical records containing HIV test results is not sufficient to release such records, except for HIV testing performed in hospitals as provided in Section 381.004(3)(g), F.S.

(4) Pursuant to Section 381.004(3)(f), F.S., oral disclosure of HIV test results shall be accompanied by oral notice and followed by a written notice within 10 days. This written notice shall include the following statement: "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 such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is NOT sufficient for this purpose." This written statement shall not be required for disclosures made in accordance with Section 381.004(3)(e)3., and 4., F.S.

(5) The anonymity of individuals tested for HIV in county health department anonymous test sites or other testing programs approved through the department registration process to conduct anonymous testing, shall be ensured as follows:

(a) Names or other specified identifying information about test subjects shall not be collected.

(b) A unique identification number shall be assigned to the test subject, and identically numbered labels shall be used to identify all records and blood specimens;

(c) The identification number shall be given to the individual for the individual to secure test results and receive ancillary services at a later time; and

(d) Fees shall not be charged for HIV anonymous testing if the test subject verbally declares an inability to pay in accordance with Section 402.33, F.S.

*Specific Authority 381.0011, 381.004(10), 381.0041(10), 384.33 FS. Law Implemented 381.0011, 381.0031(4), 381.004, 381.0041, 455.674 FS. History-New 11-6-85, Formerly 10D-93.64, Amended 7-12-89, 5-30-90, 1-20-92, Formerly 10D-93.064, Amended 8-24-99.*

#### 64D-2.004 Testing Requirements.

(1) Pursuant to Section 381.004(3)(a), F.S., informed consent shall be obtained prior to testing for HIV except in the limited situations outlined in Section 381.004(3)(h), F.S. Informed consent shall include an explanation that the information identifying the test subject and the results-of the test are confidential and protected against further disclosure to the extent provided by law. Information shall also be included on the fact that persons who test positive will be reported to the local county health department, that anonymous testing is available and the locations of anonymous testing sites.

(2) In addition to the information on confidentiality, reporting and anonymous testing listed above, an explanation of the following information constitutes sound and reasonable practice in providing information sufficient to secure informed consent:

(a) An HIV test is a test to determine if an individual is infected with the virus which causes AIDS;

(b) The potential uses and limitations of the test;

(c) The procedures to be followed; and

(d) HIV testing is voluntary and consent: to be tested can be withdrawn at any time prior to testing.

(3) Informed consent to perform a test for HIV need not be in writing, except in the situations listed below in subsection 640-2.004(4), F.A.C., if there is documentation in the medical record that the test has been explained and consent has been obtained.

(4) Informed consent to perform a test for HIV shall be in writing for the following:

(a) From the potential donor or from the donor's legal representative prior to the first donation of blood, plasma, organs, skin, semen, or other human tissue. The consent form must specify that the donor is consenting to repeated HIV testing of each of his donations for the subsequent year. The consent form must be signed annually prior to transfusion or other use;

(b) Prior to testing for HIV for insurance purposes, in accordance with Section 627.429, F.S.; or

(c) Prior to testing for HIV for contract purposes in a health maintenance organization, in accordance with Section 641.3007, F.S.

(5) The following minors can be tested for HIV without parental consent provided the minor gives informed consent:

(a) Any minor who requests examination, testing, consultation or treatment for a sexually transmissible disease, including HIV, in accordance with Section 384.30, F.S., and who demonstrates sufficient knowledge and maturity to make an informed judgment.

(b) Any minor who has reached the age of 17 years who gave consent to the donation of his or her blood, in compliance with Section 743.06, F.S.

(c) Any married minor or unwed pregnant minor, in accordance with Section 743.065, F.S.

(6) Any health care provider attending a pregnant woman for conditions related to her pregnancy shall counsel the woman on the potential benefits, potential risks and limitations of treatment to reduce the risk of transmission from infected women to their babies and offer HIV testing in accordance with Section 384.31, F.S.

(7) Pursuant to Section 381.004(8), F.S., the Department of Health developed the Model Protocol for HIV Counseling and Testing for County Health Departments and Registered Testing Programs, dated March 29, 1999, and the Model Protocol for HIV Counseling and Testing Conducted Outside County Health Departments and Registered Testing Programs, dated March 29, 1999, consistent with the provisions of this section and incorporates these documents by reference in this rule. The model protocols can be obtained from the Department of Health, Bureau of HIV/AIDS, 2020 Capital Circle, S. E., Bin A09, Tallahassee, Florida 32399-1715.

(8) Persons ordering an HIV test must ensure that all reasonable efforts are made to notify the test subject of the test result and relate certain information to the test subject in accordance with Section 381.004(3)(c), F.S., and the applicable Model Protocol for HIV Counseling and Testing specified in subsection 640-2.004(7), F.A.C. If the test subject was tested in a facility, such as a jail or hospital emergency department, and was released before being notified of a positive HIV test result, the facility may inform the county health department to notify the test subject. Blood banks and persons who collect blood, organs, skin, semen, or other tissue shall comply with Rule 64D-2.005, F.A.C., and Section 381.0041(5), (6), F.S.

*Specific Authority 381.0011, 381.004(10). 381.0041(10). 384.33 FS. Law Implemented 381.0011. 381.0031(4), 381.004, 381.0041, 384.31 FS. History-New 11-6-85, Formerly 10D-93.67, Amended 7-12-89, 1-20-92, 5-1-96. Formerly 10D-93.067, Amended 8-24-99.*

#### **64D-2.005 Blood and Human Tissue Donations.**

(1) The HIV test shall be performed by a laboratory licensed under Chapter 483, F.S., in compliance with the standards of the Clinical Laboratory Improvement Act of 1967 (CLIA) [42 U.S.C. 263a (1988)], or be licensed under standards equivalent to the minimum requirements of Chapter 483, F.S., in the state in which it is located, and must successfully participate in an HIV proficiency testing program, provided the clinical laboratory is qualified to perform the test. (2) No blood, plasma, organ, skin, semen, or other human tissue from donors whose blood is reactive to HIV shall be released for transfusion or transplantation to another. Such blood shall be retested using a confirmatory test prior to release of test results outside the facility. Test results may be released immediately to the physician of an organ donation recipient, prior to confirmatory testing.

(3) The recipient's physician shall be notified of HIV confirmatory test results within 24 hours by the medical director of the facility in the event that blood, plasma, organ, skin, semen, or other tissue is transferred and is subsequently reported positive on confirmatory test. The donor or his legal representative shall also be notified in accordance with the Model Protocol for Counseling Donors.

(4) The Model Protocol for Counseling Donors, developed pursuant to Section 381.0041(8), F.S., provides a list of the information that shall be included in the letter of notification to donors who test positive to HIV based on confirmatory testing. The Model Protocol for Counseling Donors, effective 7-12-89, is available through the - Department of Health, Bureau of HIV/AIDS, 4052 Bald Cypress Way, Bin A09, Tallahassee, Florida 32399-1715.

(5) Any blood, plasma, organ, skin, semen, or other human tissue from a donor whose blood test for HIV or hepatitis is repeatedly reactive, or originating from an individual diagnosed with AIDS or ARC, shall not be shipped or used for transfer to another, except as provided by Title 42 Part 72, Title 49 Part 173, and Title 39 Part III Code of Federal Regulations. Such human tissue shall be destroyed, treated, or disposed, in accordance with Section 381.6105(4), F.S., and with the rules promulgated to implement Chapter 88-130, Laws of Florida, relating to biohazardous waste.

(6) The blood of any human tissue donor testing negative for HIV or hepatitis at the time of donation shall not require retesting by the collecting facility when such tissue is collected for transplantation, implantation, transfusion, grafting, or any other method of transfer to another human.

*Specific Authority 381.0041(10) FS. Law Implemented 381.0041 FS. History-New 7-12-89, Amended 5-1-96. Formerly 10D-93.073.*

#### **64D-2.006 Registration of HIV Testing Programs.**

(1)(a) All county health departments and persons who conduct or make any personal, telephone or mail contact or other communication to a person, or make any announcement, solicitation, display, or advertisement to inform the general public that they are conducting a testing program as defined in (b) below, must first register with the Department of Health, Bureau of HIV/AIDS and must reregister annually. Initial registration and subsequent reregistration shall be approved by the department based upon compliance with Section 381.004(5), F.S.

(b) For the purpose of this rule, an HIV testing program is a program which provides HIV testing services with the sole purpose of identifying HIV infection. This definition does not apply to any health care provider who performs or provides HIV testing services which are incidental to the primary diagnosis or care of a patient if the health care provider does not announce, solicit, display or advertise that they are conducting a testing program.

(c) When the testing program satisfactorily completes the registration or reregistration requirements, the department shall mail a certificate of registration to the program.

(2) An application for initial registration to conduct an HIV testing program shall be made to the department on DH Form 1781, 11/98, Application for Registration and Reregistration of HIV Testing Programs, incorporated by reference in this rule. The application can be obtained from the Department of Health, Bureau of HIV/AIDS, 4052 Bald Cypress Way, S. E., Bin A09, Tallahassee, Florida 32399-1715. A completed application shall be mailed to the Department of Health, Bureau of HIV/AIDS, Attention: Counseling and Testing Program Registration at the same address and shall be accompanied by the \$100.00 initial registration fee. No fee is required for reregistration.

(3) The initial registration fee shall be made payable to the department and will be deposited in the Department of Health Deputy Secretary for Health Grants and Donations Trust Fund.

(4) Persons or facilities receiving funding pursuant to Section 381.004(4), F.S., shall be exempt from payment of the initial registration fee.

(5) Effective October 1, 1998, HIV testing programs must reregister with the department annually. The application form for reregistration, DH Form 1781, 11/98, will be mailed by the Department of Health, Bureau of HIV/AIDS to the registered testing program 60 days prior to the program's reregistration date. Reregistration dates have been established as follows:

(a) Testing programs registered with the department prior to October 1, 1998, will be notified in writing of their reregistration date by January 31, 1999.

(b) Testing programs who register with the department on or after October 1, 1998, will be sent a certificate of registration with a designated reregistration date.

(6) Pursuant to this section, if the application for reregistration is not received by the reregistration date, the certification is expired and the program is not authorized to continue operating.

(7) Each certificate of registration shall be valid only for the person or facility to which it was issued.

(8) The certificate of registration shall not be subject to sale, assignment or other transfer.

(9) The department shall be notified in writing no later than 15 days upon change of ownership or classification, suspension, revocation, or voluntary cessation of operation and the certificate of registration shall be returned immediately to the department.

(10) The department shall deny, suspend, or revoke the registration of a person or agency which:

(a) fails to comply with Section 381.004(5), F.S., or the rules in implementation thereof; or

(b) causes to happen an intentional or negligent act which physically or materially affects the health, safety, or welfare of the person receiving services.

(11) Pursuant to Section 381.004(5)(a), F.S., the program shall be directed by a person with a minimum of 15 contact hours of experience in counseling persons with human immunodeficiency virus. Examples of counseling include: informing a test subject of an HIV positive test result; providing case management services to HIV-infected persons; facilitating a support group for HIV-infected persons; and providing medical care.

(12) Each person providing post-test counseling to a patient with a positive test result shall have received specialized training which shall be equivalent to the Department of Health specialized training in providing post-test counseling to HIV-positive clients. Specialized training must include information on the following:

(a) Confidentiality, the meaning of a positive test result and the importance of not donating blood, blood products, tissues, or sperm;

(b) Early intervention, referrals and linkages to care/services;

(c) Prevention of secondary HIV transmission;

(d) Partner counseling and referral services;

(e) HIV infection reporting; and

(f) Documentation of test results.

*Specific Authority 381.004 FS. Law Implemented 381.004 FS. History-New 11-29-89, Amended 5-1-96. Formerly 10D-93.076, Amc.i^\_\_ -24PS.*

## **Model Protocol for HIV Counseling and Testing Conducted Outside County Health Departments and Registered Testing Programs**

This model protocol provides guidelines on performing confidential HIV counseling and testing in accordance with statutory requirements and established public health policy. Florida law carefully structures the manner in which health care providers may perform HTV tests. The law requires those who perform HTV tests to obtain the informed consent of the test subject, confirm positive preliminary results with a supplemental test before informing the test subject of the result, except as provided for in s. 381.004(3)(d)2., F.S., and make a reasonable attempt to notify the test subject of his or her test result.

Evaluating an individual's risk for HIV infection and offering HIV testing on a voluntary basis should be a routine part of primary health care. Risk assessment should take place without regard to age, religion, sexual orientation, gender, race/ethnicity, marital status, economic status, social or other cultural factors.

### ***L Risk Assessment***

Risk assessment involves asking the individual a series of open-ended questions to determine behaviors that may put them at risk for HTV infection. When conducting the risk assessment, it is important to assure the client that all information is confidential under Florida law. Questions should be asked in a professional, culturally sensitive, non-judgmental manner.

The following criteria should be used to help the test subject determine his or her level of risk:

- Sexual behavior
- Substance use/abuse
- Needle sharing
- Occupational exposure
- <sup>1</sup> Blood/blood products/transplants
- <sup>1</sup> Partners at risk for HTV
- <sup>1</sup> History of sexually transmitted disease(s)  
Child of woman with HIV/AIDS  
History of sexual assault/domestic violence  
Sex for drugs/money

Appropriate referrals should be made based on information obtained in the risk assessment. The Florida Domestic Violence Hotline (1-800-500-1119) provides information and referrals in English, Spanish and Creole.

## Z *Pre-Test Counseling*

Florida law no longer requires pre-test counseling, except in the case of a provider who attends a pregnant woman for conditions related to her pregnancy (see item 6); however, it is recommended that HIV testing be preceded by a pre-test counseling session consisting of the following elements:

- Purpose of the HIV test;
- Indications for testing (medical indication and/or information obtained from the risk assessment);
- The possible need for retesting;
- Information on how to avoid contracting and transmitting HIV infection;
- Potential social, medical, and economic effects of a positive test result;
- » Options for eliminating and/or reducing risk behavior;
- The availability of support services for those awaiting test results (e.g., hotlines, health care professional's name and telephone number, county health department number); and,
- Scheduling a specific date for receiving test results. (It is recommended that positive results always be disclosed during a face-to-face post-test counseling session.)

If the health care provider chooses to release negative HFV test results without face-to-face post-test counseling, a system should be in place to ensure the confidentiality of this information. This system might include giving the results over the telephone after test subjects identify themselves with a previously agreed upon code word or number. This process should be explained to clients prior to administering the HIV test. Florida law imposes strict penalties for breaches of confidentiality.

### 3. *Informed Consent*

- No person shall perform an HIV test without first obtaining the informed consent of the test subject or his or her legal representative. The limited exceptions to obtaining informed consent can be found in s. 381.004 (3)(h), F.S.
- When obtaining informed consent, explain the right to confidential treatment of information identifying the subject of the test and the results of the test to the extent provided by law. Persons with knowledge of an individual's HIV test result have legal obligations to protect this information from unauthorized disclosure. Special provisions for hospitals are listed in s. 381.004(3)(g), F.S.
- Consent need not be in writing provided that documentation is included in the medical record indicating that the test was explained and informed consent was obtained. (A few limited exceptions are included in Rule 64D-2.004(4), F.A.C.).

- In accordance with Administrative Rule 64D-2.004, Testing Requirements, an explanation of the following information represents a sound and reasonable standard for obtaining informed consent:
  - a. An HIV test is a test to determine if an individual is infected with the virus which causes AIDS;
  - b. The potential uses and limitations of the test (the reliability of the results and what positive, negative or indeterminate results do and do not mean);
  - c. The procedures to be followed; and,
  - d. HIV testing is voluntary and consent to be tested can be withdrawn at any time prior to testing.
- Persons who volunteer to be tested confidentially for HTV should be informed that positive test results will be reported to the local county health department so that health department staff may contact persons who test positive to offer follow-up activities. Examples of voluntary follow-up activities are post-test counseling for persons who do not return for test results, referrals for medical evaluation, case management services and voluntary partner notification. (Exemptions from HIV reporting include persons tested anonymously at a registered anonymous test site, testing in the event of a significant exposure or university-based medical research protocols approved by the Department of Health.)
- The test subject must also be given information on the availability and location of anonymous test sites. Each county health department maintains a list of available anonymous test sites to be disseminated to all persons and programs offering HTV testing within their service area.

#### **4. *Post-Test Counseling***

The person ordering the test or that person's designee shall ensure that all reasonable efforts are made to notify the test subject of his or her test result, in the case of a hospital emergency department, detention facility, or other facility where the test subject has been released before being notified of positive test results, informing the county health department for the department to notify the test subject fulfills this responsibility. When test subjects are given their test results, Florida law requires that, at a minimum, the following information be provided:

- For positives, information on preventing transmission of HIV, the availability of appropriate medical and support services and on the importance of notifying sex and/or needle-sharing partners who may have been exposed. Providers must make a good faith effort to ensure that spouses and former spouses (from the past ten years) of HIV-infected persons are notified that they may have been exposed to HIV infection.
  - For negatives, information on preventing the transmission of HTV, if appropriate.
- <sup>1</sup> Although Florida law no longer requires a face-to-face post-test counseling session, it is recommended that providers conduct such a session when the individual tests positive or is a high-risk negative. A post-test counseling session should consist of the following elements:
- <sup>1</sup> The meaning of the test results;

- The potential social, medical and economic effects of a positive test result;
- The possible need for retesting;
- A reassessment of risk;
- Availability of health care, mental health, social and support services for those testing negative;
- Options for eliminating and/or reducing the transmission of HTV infection to the individual and/or partners;
- A discussion of the increased risk for TB and appropriate referrals for TB testing and treatment; and,
- Other appropriate referrals (e.g., STD, primary care, psychosocial).

5. *Release of Preliminary HIV Test Results*

Pursuant to s. 381.004(3)(d), F.S., preliminary test results may be released to health care providers and to the person tested when decisions about medical care or treatment cannot await the results of confirmatory testing. Positive preliminary HIV test results shall not be characterized to the patient as a diagnosis of HTV infection. Justification for the use of preliminary test results must be documented in the medical record by the health care provider who ordered the test. This does not authorize the release of preliminary test results for the purpose of routine identification of HIV-infected individuals or when HFV testing is incidental to the preliminary diagnosis or care of a patient. Corroborating or confirmatory testing must be conducted as follow up to a positive preliminary test. Results shall be communicated to the patient according to statute regardless of outcome.

6. *Pregnant Women/Special Provisions (This requirement was effective October 1, 1996)*

Florida law (s. 384.31, F.S.) requires a health care provider who attends a pregnant woman for conditions relating to her pregnancy to offer testing for HIV and counsel her on the availability of treatment if she tests positive.

If the pregnant woman objects to HIV testing, a reasonable attempt must be made to obtain a written statement of objection, signed by the patient, which shall be placed in her medical record. (If a pregnant woman tests HIV negative, consideration should be given to offering the test again at a later date during her pregnancy because of the window period of up to 6 months between exposure to HIV and testing positive for antibodies and the risk of exposure during pregnancy through sex or needle sharing.)

When a pregnant woman tests HIV positive, in addition to the medical and support services listed above, she should also be referred to the Healthy Start Care Coordination System. For more information on the availability of services, contact the Family Health Line at 1-800-451-BABY or the Florida AIDS Hotline at 1-800-FLA-AIDS.

SECTION OF CHAPTER 456, 2001 STATUTES HEALTH  
PROFESSIONS AND OCCUPATIONS: GENERAL PROVISIONS

456.33 Requirement for instruction for certain licensees on HIV and AIDS.—

(1) The appropriate board shall require each person licensed or certified under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; part I of chapter 464; chapter 465; chapter 466; part II, part III, part V, or part X of chapter 468; or chapter 486 to complete a continuing educational course, approved by the board, on human immunodeficiency virus and acquired immune deficiency syndrome as part of biennial relicensure or recertification. The course shall consist of education on the modes of transmission, infection control procedures, clinical management, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome. Such course shall include information on current Florida law on acquired immune deficiency syndrome and its impact on testing, confidentiality of test results, treatment of patients, and any protocols and procedures applicable to human immunodeficiency virus counseling and testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to ss. 381.004 and 384.25.

(2) Each such licensee or certificateholder shall submit confirmation of having completed said course, on a form as provided by the board, when submitting fees for each biennial renewal.

(3) The board shall have the authority to approve additional equivalent courses that may be used to satisfy the requirements in subsection (1). Each licensing board that requires a licensee to complete an educational course pursuant to this section may count the hours required for completion of the course included in the total continuing educational requirements as required by law.

(4) Any person holding two or more licenses subject to the provisions of this section shall be permitted to show proof of having taken one board-approved course on human immunodeficiency virus and acquired immune deficiency syndrome, for purposes of relicensure or recertification for additional licenses.

(5) Failure to comply with the above requirements shall constitute grounds for disciplinary action under each respective licensing chapter and s. 456.072(1)(e). In addition to discipline by the board, the licensee shall be required to complete the course.

(6) The board shall require as a condition of granting a license under the chapters and parts specified in subsection (1) that an applicant making initial application for licensure complete an educational course acceptable to the board on human immunodeficiency virus and acquired immune deficiency syndrome. An applicant who has not taken a course at the time of licensure shall, upon an affidavit showing good cause, be allowed 6 months to complete this requirement.

(7) The board shall have the authority to adopt rules to carry out the provisions of this section.

(8) The board shall report to the Legislature by March 1 of each year as to the implementation and compliance with the requirements of this section.

(9)(a) In lieu of completing a course as required in subsection (1), the licensee may complete a course in end-of-life care and palliative health care, so long as the licensee completed an approved AIDS/HIV course in the immediately preceding biennium.

(b) In lieu of completing a course as required by subsection (1), a person licensed under chapter 466 who has completed an approved AIDS/HIV course in the immediately preceding 2 years may complete a course [ij]approved by the Board of Dentistry.

History—s 63, ch. 97-261; s. 4, ch. 98-171; s. 9, ch. 99-331; s. 82, ch. 99-397; s. 60, ch. 2000-160; s. 113, ch. 2000-318; s. 2, ch. 2001-176; s. 2, ch. 2001-250; S. 106, ch. 2001-277.

[1]Note.—As amended by s. 2, ch. 2001-176, and s. 106, ch. 2001-277. The amendment by s. 2, ch. 2001-250. contains the same material, ordered differently, and substitutes the word "designated" for the word "approved."

.—Former s. 455.604.

## **HIV/AIDS TRAINING**

### **I. CAUSE**

Acquired Immune Deficiency Syndrome (AIDS) is caused by a virus called human immunodeficiency virus (HIV). It can be transmitted in the following ways:

- Unprotected sex between men that results in exposure to semen or blood,
- Unprotected sex between a man and a woman that results in exposure to semen or blood,
- Exposure to blood through the use of shared needles and syringes by intravenous drug users,
- Transmission to a baby by an infected mother before birth, during delivery or when breast feeding,
- In very rare cases, through transfusion of infected blood or blood products,
- Through an occupational exposure, most commonly involving a needle stick or puncture of the skin in a health care setting.

Common sense precautions should be taken in all settings to prevent contact with blood and other body fluids. Universal precautions should be followed, including the use of latex gloves when handling blood and other body fluids - even when you think the risk is minimal.

### **STATISTICS**

- A. The first AIDS case was reported in the United States in June 1981.
- B. The number of cumulative reported AIDS cases in the world as of May 31, 2000 was 2,201,468.
- C. The number of cumulative reported AIDS cases in the U.S. as of December 31, 2000 was 774,467, approximately 11 % (83,239) of which occurred in Florida.
- D. A disproportionately large percentage of the AIDS cases reported worldwide are from the U.S. This is due in part to our superior reporting system, earlier initiation of reporting requirements, and a strong public health surveillance system in the U.S.
- E. Florida ranks third in the nation in the number of total AIDS cases and second in the nation in the number of pediatric AIDS cases.
- F. AIDS related illnesses are the twelfth leading cause of death in Florida.
- G. AIDS related illnesses are the seventh leading cause of death among Floridians between the ages of 15 to 24; and the leading cause of death among African American male and female Floridians between the ages of 25 and 44.

- H. In Florida, a state that is a haven for retirees, the percentage of people older than 50 with AIDS is above the national average. According to the Center for Disease Control, sexually active older people are much less likely than the young to use condoms.
- I. Although it has only 14 percent of the state population, Dade County (Miami) alone, reports about 30 percent of all Florida AIDS cases. The four southeastern counties (Dade, Broward, Palm Beach, and Monroe) report about 57 percent of all Florida AIDS cases. In contrast, Gilchrist County reported the fewest number of cases.
- J. Nearly all transmissions of HIV through transfusion of blood or blood products occurred before screening of the blood supply for HTV antibody was initiated in 1985. The number of persons reported with AIDS who were exposed through blood transfusions in the United States was 284 in 2000, down from a peak of 1,098 in 1993.
- K. The Center for Disease Control has reported 56 health care workers in the U.S. with documented HIV seroconversion following an occupational exposure. The CDC is also aware of another 138 cases of HIV infection or AIDS among health care workers who are not involved in high risk behavior and who reported an occupational exposure to blood, body fluids or HIV-infected laboratory material, but for whom seroconversion after exposure was not documented.
- L. Most HIV cases occur from high- risk behavior rather than from an occupational exposure such as a needle stick or wound puncture.
- M. Only 2.1 % of the HIV tests performed by county public health departments in Florida in 2000 were positive.

### **III. RISK GROUPS VS. RISKY BEHAVIOR**

- A. Of the cumulative total number of cases reported in the Florida., those with the highest risk of AIDS as June 30, 2001 were:
- Homosexual/bisexual men (41 %)
  - Injecting drug users (17 %)
  - Heterosexual contacts with others at risk (18%)
  - Homosexual/bisexual men who are injecting drug users (5 %)
  - Hemophiliac (0%)
  - Transfusion related (1 %)
  - None of the above (19 %)
- B. In 2000, more than two-thirds of the HIV infections reported in Florida were among young men (age 13 to 24) who had sex with men.
- C. According to a report in the Summer 2001 issue of the Journal of the American Medical Women's Association, teenage girls' rate of HIV infection from heterosexual sex rose by almost 117 percent between 1994 and 1998. This points out the need for

culturally appropriate HIV education and prevention efforts among adolescent women before they become sexually active and engage in high-risk behavior

- D. A disproportionate number of cumulative AIDS cases through June 30, 2001 in Florida occurred in minority groups - 46 % were African Americans; 15 % were Hispanic; and 38 % were white.
- E. Women are becoming increasingly more affected by HIV. In Florida, women accounted for 18 percent of reported AIDS cases in 1991 compared to 29 percent in 2000.
- F. The incidence of reported AIDS cases among women in Florida was highest for exposure through heterosexual behavior (45 %) followed by intravenous drug users (25%).
- G. Just because someone is in a high-risk group, does not mean that he/she practices high-risk behaviors. It is what you do, not who you are, that puts you at risk for HTV.
  - 1. Uninfected homosexual men can practice mutual monogamy and not be at risk of contracting HIV.
  - 2. Injecting drug users can avoid risk of infection by not sharing needles.
  - 3. A heterosexual man or woman can have only one sexual contact with an infected person and contract HIV if proper precautions are not taken.
  - 4. The best protection against HTV is sexual abstinence or a mutually monogamous relationship with someone who is not infected with the virus.
- H. The chances of becoming infected with HIV from a transfusion are very low, with studies putting the risk as low as 1 in 350,000. In contrast, the chances of becoming infected from having unprotected, penetrative sexual contact with an HIV-infected individual are between 1 in 3 and about 1 in 100. The chances of becoming infected from shooting drugs and sharing needles may be as high as a 1 in 2 in some areas of the country. The chances of infection for health care workers from a needle stick with HIV-infected blood are about 1 in 350.

#### IV. DISEASE SPECTRUM (PATHOGENICITY AND IMMUNOLOGY)

- A. The human immune system is made up of several lines of defense against bacteria, viruses, fungi, and other parasites. These defenses include: the skin, the mucous lining of the mouth and vagina, the hairs and cilia of the nose and respiratory system, antibodies and enzymes in tears and sweat and stomach acids. These are the primary and secondary lines of defense in the human body. Within the body, there is a further line of defense known as the immune system.
- B. When bacteria, viruses, fungi or other parasites get into the bloodstream, the body reacts by producing antibodies that help to prevent disease or infection. T-4 helper lymphocytes are an integral part of the immune system. HIV attacks and destroys these T-4 cells. HIV also attacks white blood cells.

- C. When HIV enters the bloodstream, the immune system produces antibodies to destroy HIV. These antibodies can destroy free-floating virus in the bloodstream, but cannot destroy HIV once it enters the T-4 cells. In effect, HIV hides inside the very cell that normally would direct its destruction.
- D. There is a high concentration of T-4 cells and macrophages *in* blood, semen, breast milk and, to a lesser extent, in vaginal secretions. These body fluids, especially blood, are the primary targets of HIV. Other body fluids, such as tears, saliva, and urine, have an extremely low concentration of T-4 cells and macrophages. These body fluids are not likely to contain HIV in concentrations capable of transmitting infection. There are no documented cases of HFV infection through contact with tears, saliva, or urine.
- E. A normal count in a healthy human adult is between 800 and 1,000 T cells per cubic millimeter (milliliter) of blood. By the time an infected individual begins to experience opportunistic diseases and infections as a result of the destructive process of HIV, the T-cell count of close to zero per milliliter. Persons with full-blown AIDS can have a T-cell count of close to zero per milliliter. At that point, their immune, systems can no longer protect them from opportunistic infections and conditions.
- F. HIV does not kill the individual who becomes infected, it simply sets the body up for opportunistic diseases and conditions to attack and do the damage. Once the body can no longer defend itself, even a common cold or influenza can be devastating. There are more than 20 opportunistic diseases and conditions associated with AIDS. The most common is tuberculosis. TB remains the principal cause of death in persons with HIV infection worldwide.
- G. For adults in developed countries, the average time to developing full blown AIDS after initial HIV infection is about 10 to 11 years in the absence of antiretroviral therapy or with older treatment regimens.

## V. DIAGNOSIS, TESTING AND NOTIFICATION

- A. Nearly all HIV tests currently performed in the U.S. are antibody tests. The most widely used antibody test is the ELISA (Enzyme-linked Immunosorbant Assay). In 1995, the Florida Legislature authorized the used of FDA-approved home access HIV test kits.
- B. A positive HIV test indicates that the tested individual is infected and is capable of infecting others. A negative test means that the tested individual either is not infected or was recently infected and has not yet developed antibodies to the virus.
- C. If the first test is positive, at least one additional ELISA test is done on the same specimen of blood. In private laboratories, if both tests are positive, a supplemental test is performed to confirm the initial results. Only if the supplemental test is positive, a positive result is reported. In Florida's public labs, up to four ELISAs may be done using two different brand test kits before the supplemental test. The two most often used supplemental tests are the IFA (immunofluorescent assay) and the

Western Blot. Florida law requires that a supplemental test be positive before the tested individual can be told (s)he is infected.

- D. It usually takes two to 12 weeks from the point a person becomes infected with HIV to the point that his/her antibody blood test is positive. It can take up to six months for the blood to seroconvert after infection with HTV, but most people (95 percent) will test positive within three months. Within six months, 98 percent of infected persons have a positive antibody test.
- E. In 1998, pre-test counseling requirements were eliminated and specific post-test counseling procedures are left to the individual medical practice, hi most cases, the test cannot be performed without the informed consent of the person being tested. Regardless of the test result, it may only be given in person and the tested individual must be offered post-test counseling on the meaning of the results. In the case of home access testing, notification and post-test counseling may be by telephone.
- F. The Centers for Disease Control and Prevention (CDC) defines AIDS as a positive HIV antibody or antigen test and either a T-cell (CD\$) count of less than 200 cells per milliliter (or T-cells that are less than 14 percent of total lymphocytes) or diagnosis of one or more opportunistic diseases or conditions associated with AIDS.

## VI. PREVENTION

### A. Sexual transmission—Remember ABC (Abstinence, Be with one partner, wear a Condom)

- 1. Abstinence from sexual activity is the only sure way not to become infected through sex.
- 2. Mutual monogamy, sex with only one partner, by two persons who are not already infected is the next best thing to abstinence for avoiding contracting HTV/AIDS through sex.
- 3. If abstinence and mutual monogamy are not options, latex condoms are the next best protection. Condoms with Nonoxynol-9, a spermicide, are me best type. Nonoxynol-9 actually kills HTV in the laboratory. Read the label carefully. Check the expiration date. Use only one time. Use from start to finish. Use only water-based lubricants.

### B. Drug use

- 1. injecting drug users should not share needles. If needles must be shared, they should be rinsed in bleach two times, then in water two times before each use.
- 2. Crack cocaine and other drugs may lead to trading sex for drugs. The more sexual partners an individual has had, the greater the likelihood of contracting HIV.
- 3. Admission to a drug rehabilitation program should be considered.

### C. In the health care setting

1. Health care workers should take universal precautions, which means that they should assume that all patients are infected with HIV or Hepatitis-B virus. Needle sticks rarely result in HIV infection, however, health care workers never should recap needles, intentionally bend or break needles or remove needles from syringes.
2. Health care workers always should wear gloves when touching blood, body fluids, mucous membranes, non-intact skin and items soiled with blood or body fluids. Gloves should be changed after contact with each patient or resident and hands should be washed properly and frequently.
3. Health care workers who have open lesions or weeping sores should discontinue direct patient care.
4. While HTV usually dies immediately when it is outside the body, a 1:10 solution of bleach water will quickly kill HIV on surfaces and may be used as an extra precaution for health care workers who deal directly with the body fluids of others.

## VII. CORRECTING COMMON MISCONCEPTIONS ABOUT TRANSMISSION OF AIDS

- A. AIDS is not transmitted through casual contact. It is okay to hug, kiss, and shake hands with a person who has AIDS. The CDC recommends against "French" or open-mouthed kissing with an infected person because of the possibility of contact with blood. However, no case of AIDS reported to the CDC can be attributed to transmission through any kind of kissing.
- B. You cannot get AIDS by giving blood. Hospitals and blood banks need blood desperately. It is perfectly safe to give.
- C. You cannot get AIDS from eating utensils, hot tubs, restaurants or mosquitoes. CDC and other scientific studies have shown no biological evidence to indicate that HTV is able to infect insect cells or to reproduce in insects. Insect transmission of hepatitis B virus or HBV, another blood borne virus, has never been reported.

## VIII. TREATMENT

- A. There is no cure for HIV/AIDS. Currently, the best that infected persons can hope for is that available drugs will prolong their lives and keep them healthier while infected.
- B. It originally was believed that very few cells in infected persons harbor or produce HIV and that virus replication was restricted during the period of clinical latency. However, early virus detection methods were insensitive and newer, more sensitive tools have shown that virus replication is active throughout the course of the infection and proceeds at levels far higher than previously imagined. HIV replication has been directly linked to the process of T-cell destruction and depletion. In addition, ongoing HIV replication in the face of an active but incompletely effective host antiviral immune response is believed to be responsible for the secondary manifestations of the HIV, including wasting and dementia.

- C. The most effective intervention therapy for persons with HTV is a combination of antiretroviral prescription drugs. Antiretroviral drugs have improved the length and quality of life for HIV-infected persons,
- D. Some HTV infected people on antiretroviral treatment inaccurately assume that they are not infectious and continue to engage in behavior that can infect other people.
- E. Studies indicate that the use of zidovudine (ZDV) and other antiviral drugs immediately (within 1 to 2 hours) after an occupational exposure may prevent infection with HIV. 3TC should be added to ZDV for increased effectiveness and for use against ZDV-resistant viruses. IDV should be added for the highest risk exposures involving large amounts of HIV infected blood. Even if HTV infection is not prevented, early treatment may lessen the severity of symptoms and delay the onset of AIDS. Guidelines for post occupational exposure treatment can be found on the CDC web site.
- F. Antiviral drugs commonly used to treat HTV are expensive and may cause side effects, including upset stomach, tiredness, or headaches and, in rare instances, may cause pancreatitis, jaundice or kidney stones.
- G. The only drug that has been shown to reduce the risk of HIV transmission from a pregnant woman to her baby is ZDV.

## **IX. NEW ADULT AND ADOLESCENT TREATMENT GUIDELINES**

- A. The Panel on Clinical Practices for the Treatment of HTV infection published an updated version of the Guidelines for the Use of Antiretroviral Agents hi HTV-Infected Adults and Adolescents on February 5,2001.. The revised treatment guidelines provide more conservative recommendations for initiating antiretroviral therapy than earlier editions. Some of the recommendations include:
  - Offering anti-retroviral treatment to asymptomatic patients with fewer than 350 CD4+ T cells, HTV RNA levels exceeding 30,000 copies/mL (bDNA assay), or 55,000 copies/mL (RT-PCR assay).
  - Offering antiretroviral treatment to all patients with a CD4+ T cell count of less than 200 or clinically defined AIDS.
  - Strategies for assessing and assisting adherence to a complex drug regimen before initiation of therapy.
  - The addition of a new protease inhibitor Kaletra® (lopinavir = ritonavir) and the combination of ritonavir = indinavir to the Strongly Recommended category of antiretroviral agents.
  - Expanded discussion of adverse clinical events including lactic acidosis/hepatic steatosis.

- B. Copies of the current and archived guidelines are available from the HIV/AIDS Treatment Information Service (ATIS) by calling 1-800-448-0440, or online at the ATIS web site <http://hivatic.org/trtgdlns.html>.

## **X. NEW STRATEGIES FOR TREATMENT INTERRUPTIONS**

Findings from a study presented at the 8<sup>th</sup> Conference on Retroviruses and Opportunistic Infections suggests that it may be possible for some HIV-positive patients to cycle their drug therapies on and off" with few negative effects. Dr. Anthony Fauci Initiated the study in a small population with the hopes that HIV patients could be weaned off the drug therapies for extended periods of time. One study of 24 patients who had a 2 months on, 1 month-off treatment cycle found that in most patients, the virus rebounded during the non-treatment month. More promising results were seen in a companion experiment with 10 subjects who had treatment cycles of seven days on and seven days off. The virus remained fully suppressed during the off weeks, although HIV was soon detected in the bloodstreams of two patients who failed to restart their weekly treatments as scheduled. In describing the study results, Dr. Fauci stated, "This is a big deal to people. These people are positively inclined to being off-drug 50% of the time."

## **XII. DRUG RESISTENT STRAINS UPDATE**

A new study of nine U.S. and Canadian cities from Dr. Susan Little of the University of California indicates that drug-resistant strains of HIV have increased to 14% among newly infected individuals. The report, presented at the Eighth Annual Conference on Retroviruses and Opportunistic Infections in Chicago, revealed increased resistance in a group of 394 individuals who, because they had flu-like symptoms, were diagnosed as having HIV and treated within three months of infection. According to Dr. Little, resistance to one or more drugs was identified in 14% of the participants between 1999 to 2000, up from 3.5 % between 1995 and 1998. Furthermore, resistance to two or more of the three classes of AIDS drugs rose to 5.8% during the 1999 to 2000 period, up from 0.4% between 1995 and 1998. Dr. Little suggested that all newly infected people be tested for drug resistance, even if they do not plan to start drug treatment for a while, because the testing could help track the prevalence of resistant strains geographically for public health purposes.

## **XIII. REPORTING/CONFIDENTIALITY**

- A. Florida physicians *are required by* law to report all cases of diagnosed HIV infection and AIDS to the state Department of Health.
- B. Physicians *must* release HIV status information to county public health units for the purpose of partner notification. Physicians *may* notify an infected patient's sex or needle-sharing partner without the patient's consent, provided the patient has disclosed the identity of the partner and refuses to voluntarily notify the partner. Physicians must inform the patient of their intention to inform the partner.
- C. Hospitals *may* treat patients' medical records containing HIV results just as they would any other hospital medical record, except that disclosure of test results among its staff and employee, is restricted to those who have a clear need to know.

However, hospital staff first must explain to patients (before HTV tests are administered) that HIV test results included in hospital records have a limited right to confidentiality. The Department of Health has by definition permitted disclosure of a patient's HIV status if an employee in the normal proper performance of duties would need access to a patient's record or if the employee has experienced a significant exposure to a patient's body fluids or tissue.

D. There are two types of releases that may be given by an HTV-infected person:

1. A specific release authorizing the release of HIV test results to a third party or named person such as a doctor and a general release directing disclosure of an entire medical record to a third party.
2. The general release allows disclosure of a medical record containing an HTV test result only if it is preceded by the infected person's prior written authorization permitting the provider to release HTV test results along with the rest of the medical record.

E. Legislation passed in 1998 now allows for the release of preliminary HTV test results when decisions about medical care or treatment cannot await the results of confirmatory testing. With new testing technology (i.e. rapid HTV screening tests), this change will allow health care providers to make important decisions about medical care treatment without waiting two weeks for confirmatory testing.

Additionally, health care workers involved in the delivery of a child can note the mother's HIV test results in the child's medical record. The legislation also authorizes HIV testing without informed consent when the source of the significant exposure expires during the treatment for the medical emergency.

F. When HIV test information is disclosed by a provider, it must be accompanied by a warning of the existence by the super-confidentiality requirements in Florida law through the following statement 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 further disclosure of such information without the written consent of the person to whom such information pertains, or as otherwise permitted by law. A general authorization for the release of medical or other information is not sufficient for this purpose."

## INFORMATION SECURITY & CONFIDENTIALITY POLICIES

According to the Department of Health these are considered "best practices" policies for information security and confidentiality. This covers all patient information. With the new HIPAA requirements in these areas, the policies listed below are excellent guidelines for handling medical records and medical information relevant to the residents in the facility. Although these policies are specifically addressed as the policies of the Department of Health, they feel these are ones that can be adopted by any organization.

### Policy: Security 1

- Security one requires the establishment of information security policies, protocols and procedures by the Department of Health.
- Second, it requires the policies, protocols and procedures to be in compliance with federal and state laws and rules and other Department of Health policies and to be updated as necessary.
- Third, the policy requires annual monitoring for compliance.

### Policy: Security 2

- Security two states that the director of each Department of Health division, office, county health department, Children's Medical Service clinic and the A.G. Holley Hospital is responsible for information security in their designated entity.,
- This policy also requires each director to designate an information security coordinator and place these job responsibilities in the designee's position description.

### Policy: Security 3

- Security three instructs all directors to designate information custodians for each information set. Examples of information sets are: computerized databases, hard-copy medical records, clinic logs, case report files.
- Information custodians are responsible for protecting confidentiality and data integrity as well as ensuring appropriate access.

### Policy: Security 4

- Security four mandates that the Department of Health follow the Records Retention Schedule, Department of State, Division of Library and Information Services, Bureau of Archives and Records Management. The Department of State recently delegated the records retention authority to the individual state agencies.

### Policy: Security 5

- Security five orders the Department of Health to archive and destroy records according to the established records retention guidelines for each type of document.
- The confidentiality and security of records must be maintained whenever archiving or destroying them.

### Policy: Security 6

- Security six requires that all Department of Health facilities designate "secure areas" to maintain confidential information.

- This policy lists the physical requirements for a designated "secure area," as well as procedures for monitoring access and removing information as necessary.

Policy: Security 7

- Security seven details requirements for maintaining security and confidentiality of information in a clinic or office setting, when taken out of the facility and when mailed or faxed to an individual authorized to receive the information.
- Clinic setting procedures include: telephone answering, clinic labeling, client billing, appointment scheduling, medical record labeling. .
- Administrative procedures include when to release confidential information, how to correctly fax and mail this information to another destination.
- Field security procedures include how to maintain information when carried out of an office or clinic setting.

Policy: Security 8

- Security eight requires that the designated security coordinator conduct an annual risk assessment and document corrective actions that need to be taken, along with anticipated dates of completion.
- The risk assessment and corrective action plan are filed with the Department of Health information security coordinator. These documents are considered confidential and should be maintained in accordance with Security 7.

Policy: Security 9

- » Security nine outlines the correct procedure for confidentiality and security incident reporting.

Policy: Security 10

- Security 10 requires each Department of Health employee and volunteer to sign the "Confidentiality and Security Statement of Understanding" form.

Policy: Security 11

- Security 11 references the "Department of Health Employee Handbook" as the standards for criminal background checks/fingerprinting, loyalty oath, code of ethics, maintaining confidential information, protection of property, equipment or materials, computer records and systems, review, and performance planning system, and standards of conduct and discipline.

Policy: Security 12

- Security 12 addresses information security and confidentiality with contracted providers. All providers are required to follow the Department of Health Information Security Policies, Protocols and Procedures.

Policy: Security 13

- Security 13 requires all Department of Health employees and volunteers to have initial information security training within 30 days of employment and prior to accessing any confidential information.
- This policy also requires annual update training for all employees and volunteers.

Policy: Security 14

- Security 14 details the conditions under which confidential may be released and the requirements that must be met prior to release.
- Included in this section are client release and access, third-party payers, worker's compensation, legal requests, the Department of Children and Families, immunization information, medical records with federal and state statutory protections, and exceptions to the written release requirement.

Policy: Security 15

- Security 15 addresses the procedure for maintaining and disclosing HTV test results.
- A general medical release is not sufficient for the release of HTV test information. Clients must sign a specific release using the Authorization for Release of Medical Information (Form DH 3111).
- A subpoena is not sufficient to release HTV test results. A court order is required.
- HTV test results are given to the client directly, and clients are posttest counseled face-to-face. County health department and contract provider staff do not provide test results over the phone.

Policy: Security 16

- Security 16 defines the correct procedures for maintaining HTV/AIDS, STD and TB case reports.
- Included in this section are requirements for maintaining computers and laptop computers, secured areas, data encryption, shredding information, line lists containing names or identifiers, as well as procedures for telephoning, faxing, mailing or transmitting this information.

Policy: Security 17

- Security 17 details the correct procedures for releasing HIV/AIDS case registry information. Patient-specific data is only released by HIV/AIDS surveillance staff to other department staff with a need-to-know.
- When released outside of the Department of Health, aggregated, cross-tabulated data for geographical areas with a less than 500,000 population will be edited so that cell sizes less than three will not be shown.

Policy: Security 18

- Security 18 lists the Information Resource Management security policy. Included are requirements for network server areas, virus protection, data encryption, password protection, data back-up and disaster recovery.

As you can see, there are many requirements related to information security and confidentiality. You can find more information on the HIPAA requirements at [www.hcfa.gov/hipaa](http://www.hcfa.gov/hipaa). The timeframe to keep medical records in Florida is five (5) years.

## **Summary of Public Health Service Guidelines for the Management of Health Care Worker Exposures to HTV and Recommendations for Post-Occupational Prophylaxis (PEP)**

The CDC updated the guidelines for the management of HIV exposures, and post occupational prophylaxis on May 15, 1998. This report updates and consolidates all previous PHS recommendations for the management of health-care workers (HCWs) who have occupational exposure to blood and other body fluids that may contain human immunodeficiency virus (HTV); it includes recommendations for HTV postexposure prophylaxis (PEP) and discusses the scientific rationale for PEP. The decision to recommend HTV postexposure prophylaxis must take into account the nature of the exposure (e.g., needlestick or potentially infectious fluid that comes in contact with a mucous membrane) and the amount of blood or body fluid involved in the exposure. Other considerations include pregnancy in the HCW and exposure to virus known or suspected to be resistant to antiretroviral drugs. Assessments of the risk for infection resulting from the exposure and of the infectivity of the exposure source are key determinants of offering PEP. Systems should be in place for the timely evaluation and management of exposed HCWs and for consultation with experts in the treatment of HTV when using PEP.

Recommendations for PEP have been modified to include a basic 4-week regimen of two drugs (zidovudine and lamivudine) for most HIV exposures and an expanded regimen that includes the addition of a protease inhibitor (indinavir or nelfinavir) for HTV exposures that pose an increased risk for transmission or where resistance to one or more of the antiretroviral agents recommended for PEP is known or suspected. An algorithm is provided to guide clinicians and exposed health-care workers in deciding when to consider PEP.

Occupational exposures should be considered urgent medical concerns to ensure timely administration of PEP. Health-care organizations should have protocols that promote prompt reporting and facilitate access to postexposure care. Enrollment of health care workers (HCWs) in registries designed to assess side effects in HCWs who take PEP is encouraged.

Although preventing blood exposures is the primary means of preventing occupationally acquired human immunodeficiency virus (HIV) infection, appropriate postexposure management is an important element of workplace safety. Post exposure management is commonly referred to by the acronym **PEP**.

Health-care organizations should make available to their workers a system that includes written protocols for prompt reporting, evaluation, counseling, treatment, and follow-up of occupational exposures that may place HCWs at risk for acquiring any bloodborne infection, including HTV. Employers also are required to establish exposure-control plans, including postexposure follow-up for their employees, and to comply with incident reporting requirements mandated by the Occupational Safety and Health Administration (15). Access to clinicians who can provide postexposure care should be available during all working hours, including nights and weekends. Antiretroviral agents for PEP should be available for timely administration (i.e., either by providing access to PEP drugs on site or creating links with other facilities or providers to make them available offsite). Persons responsible for providing postexposure counseling should be familiar with evaluation and treatment protocols and the facility's procedures for obtaining drugs for PEP.

HCWs should be educated to report occupational exposures immediately after they occur, particularly because PEP is most likely to be effective if implemented as soon after the exposure as possible (41,55,56). HCWs who are at risk for occupational exposure to HIV should be taught the principles of postexposure management, including options for PEP, as part of job orientation and ongoing job training.

## **EXPOSURE REPORTING**

*If an occupational exposure occurs, the circumstances and postexposure management should be recorded in the HCWs confidential medical record (usually on a form the facility designates for this purpose). Relevant information includes*

- . date and time of exposure;
  - details of the procedure being performed, including where and how the exposure occurred, and if the exposure was related to a sharp device, the type of device and how and when in the course of handling the device the exposure occurred;
- details of the exposure, including the type and amount of fluid or material and the severity of the exposure (e.g., for a percutaneous exposure, depth of injury and whether fluid was injected; or for a skin or mucous-membrane exposure, the estimated volume of material and duration of contact and the condition of the skin {e.g., chapped, abraded, or intact});
- . details about the exposure source (i.e., whether the source material contained HTV or other bloodborne pathogen {s}), and if the source is an HTV-infected person, the stage of disease, history of antiretroviral therapy, and viral load, if known; and
- . details about counseling, postexposure management, and follow-up.

## **EXPOSURE MANAGEMENT**

### **Treatment of an Exposure Site**

- «. Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. There is no evidence that the use of antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk for HIV transmission. However, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.

### **Assessment of Infection Risk**

- After an occupational exposure, the source-person and the exposed HCW should be evaluated to determine the need for HIV PEP. Follow-up for hepatitis B virus and hepatitis C virus infections also should be conducted in accordance with previously published CDC recommendations.
- . Evaluation of exposure. The exposure should be evaluated for potential to transmit HTV based on the type of body substance involved and the route and severity of the exposure. Exposures to blood, fluid containing visible blood, or other potentially infectious fluid (including semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids) or tissue through a percutaneous injury (i.e., needlestick or other penetrating sharps-related event) or through contact with a mucous membrane are

situations that pose a risk for bloodborne transmission and require further evaluation. In addition, any direct contact (i.e., personal protective equipment either was not used or was ineffective in protecting skin or mucous membranes) with concentrated HTV in a research laboratory or production facility is considered an exposure that requires clinical evaluation to assess the need for PEP.

- For skin exposures, follow-up is indicated if it involves direct contact with a body fluid listed above and there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound). However, if the contact is prolonged or involves a large area of intact skin, postexposure follow-up may be considered on a case-by-case basis or if requested by the HCW.
- For human bites, the clinical evaluation must consider possible exposure of both the bite recipient and the person who inflicted the bite. HTV transmission only rarely has been reported by this route (100,101; CDC, unpublished data, 1998). If a bite results in blood exposure to either person involved, postexposure follow-up, including consideration of PEP, should be provided.
- Evaluation and testing of an exposure source. The person whose blood or body fluids are the source of an occupational exposure should be evaluated for HIV infection. Information available in the medical record at the time of exposure (e.g., laboratory test results, admitting diagnosis, or past medical history) or from the source person may suggest or rule out possible HIV infection. Examples of information to consider when evaluating an exposure source for possible HIV infection include laboratory information (e.g., prior HTV testing results or results of immunologic testing {e.g., CD4+ count}), clinical symptoms (e.g., acute syndrome suggestive of primary HIV infection or undiagnosed immunodeficiency disease), and history of possible HIV exposures (e.g., injecting-drug use, sexual contact with a known HIV-positive partner, unprotected sexual contact with multiple partners {heterosexual and/or homosexual}, or receipt of blood or blood products before 1983).

If the source is known to have HIV infection, available information about this person's stage of infection (i.e., asymptomatic or AIDS), CD4+ T-cell count, results of viral load testing, and current and previous antiretroviral therapy, should be gathered for consideration in choosing an appropriate PEP regimen. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the PEP regimen can be made after PEP has been started, as appropriate.

If the HIV serostatus of the source person is unknown, the source person should be informed of the incident and, if consent is obtained, tested for serologic evidence of HIV infection. If consent cannot be obtained (e.g., patient is unconscious), procedures should be followed for testing source persons according to applicable state and local laws. Confidentiality of the source person should be maintained at all times.

HIV-antibody testing of an exposure source should be performed as soon as possible. Hospitals, clinics, and other sites that manage exposed HCWs should consult their laboratories regarding the most appropriate test to use to expedite these results. An FDA-approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if testing by enzyme immunoassay (EIA) cannot be completed within 24-48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunofluorescent antibody is not necessary for making initial decisions about postexposure management but should be done to complete the testing process.

- If the source is HIV seronegative and has no clinical evidence of acquired immunodeficiency syndrome (AIDS) or symptoms of HIV infection, no further testing of the source is indicated. It is unclear whether follow-up testing of a source who is HIV negative at the time of exposure, but recently (i.e., within the last 3-6 months) engaged in behaviors that pose a risk for HIV transmission, is useful in postexposure management of HCWs; HCWs who become infected generally seroconvert before repeat testing of a source would normally be performed.
- » If the exposure source is unknown, information about where and under what circumstances the exposure occurred should be assessed epidemiologically for risk for transmission of HTV. Certain situations, as well as the, type of exposure, may suggest an increased or decreased risk; an important consideration is the prevalence of HIV in the population group (i.e., institution or community) from which the contaminated source material is derived. For example, an exposure that occurs in a geographic area where injecting-drug use is prevalent or on an AIDS unit in a health-care facility would be considered epidemiologically to have a higher risk for transmission than one that occurs in a nursing home for the elderly where no known HIV-infected residents are present. In addition, exposure to a blood-filled hollow needle or visibly bloody device suggests a higher-risk exposure than exposure to a needle that was most likely used for giving an injection. Decisions regarding appropriate management should be individualized based on the risk assessment.
- HTV testing of needles or other sharp instruments associated with an exposure, regardless of whether the source is known or unknown, is not recommended. The reliability and interpretation of findings in such circumstances are unknown.

### **Clinical Evaluation and Baseline Testing of Exposed Health Care Workers**

Exposed health care workers (HCWs) should be evaluated for susceptibility to bloodborne pathogen infections. Baseline testing (i.e., testing to establish serostatus at the time of exposure) for HIV antibody should be performed. If the source person is seronegative for HTV, baseline testing or further follow-up of the HCW normally is not necessary. If the source person has recently engaged in behaviors that are associated with a risk for HTV transmission, baseline and follow-up HTV-antibody testing (e.g., 3 and/or 6 months postexposure) of the HCW should be considered. Serologic testing should be made available to all HCWs who are concerned that they may have been exposed to HIV.

For purposes of considering HIV PEP, the evaluation also should include information about medications the HCW may be taking and any current or underlying medical conditions or circumstances (i.e., pregnancy, breast feeding, or renal or hepatic disease) that may influence drug selection. Pregnancy testing should be offered to all nonpregnant women of childbearing age whose pregnancy status is unknown.

### **HIV PEP**

The following recommendations apply to situations where an HCW has had an exposure to a source person with HTV or where information suggests that there is a likelihood that the source person is HIV-infected. These recommendations are based on the risk for HTV infection after different types of exposure and limited data regarding efficacy and toxicity of PEP. Because most occupational HIV exposures do not result in the transmission of HTV, potential toxicity must be carefully considered when prescribing PEP. When possible, these recommendations

should be implemented in consultation with persons having expertise in antiretroviral therapy and HIV transmission.

### **Explaining PEP to Health Care Workers**

Recommendations for chemoprophylaxis should be explained to HCWs who have sustained occupational HIV exposures. For exposures for which PEP is considered appropriate, HCWs should be informed that a) knowledge about the efficacy and toxicity of drugs used for PEP are limited; b) only ZDV has been shown to prevent HIV transmission in humans; c) there are no data to address whether adding other antiretroviral drugs provides any additional benefit for PEP, but experts recommend combination drug regimens because of increased potency and concerns about drug-resistant virus; d) data regarding toxicity of antiretroviral drugs in persons without HIV infection or in pregnant women are limited for ZDV and not known regarding other antiretroviral drugs; and e) any or all drugs for PEP may be declined by the HCW. HCWs who have HIV occupational exposures for which PEP is not recommended should be informed that the potential side effects and toxicity of taking PEP outweigh the negligible risk of transmission posed by the type of exposure.

### **Timing of PEP Initiation**

PEP should be initiated as soon as possible. The interval within which PEP should be started for optimal efficacy is not known. Animal studies have demonstrated the importance of starting PEP within hours after an exposure. To assure timely access to PEP, an occupational exposure should be regarded as an urgent medical concern and PEP started as soon as possible after the exposure (i.e., within a few hours rather than days). If there is a question about which antiretroviral drugs to use, or whether to use two or three drugs, it is probably better to start ZDV and 3TC immediately than to delay PEP administration. Although animal studies suggest that PEP probably is not effective when started later than 24-36 hours postexposure, the interval after which there is no benefit from PEP for humans is undefined. Therefore, if appropriate for the exposure, PEP should be started even when the interval since exposure exceeds 36 hours. Initiating therapy after a longer interval (e.g., 1-2 weeks) may be considered for exposures that represent an increased risk for transmission; even if infection is not prevented, early treatment of acute HTV infection may be beneficial. The optimal duration of PEP is unknown. Because 4 weeks of ZDV appeared protective in HCWs (2), PEP probably should be administered for 4 weeks, if tolerated.

### **Monitoring and Management of PEP Toxicity**

If PEP is used, drug-toxicity monitoring should be performed at baseline and again 2 weeks after starting PEP. Clinical judgement, based on medical conditions that may exist in the HCW and any toxicity associated with drugs included in the PEP regimen, should determine the scope of testing. Minimally these should include a complete blood count and renal and hepatic chemical function tests. Monitoring for evidence of hyperglycemia should be included for HCWs whose regimen includes any PI; if the HCW is receiving IDV, monitoring for crystalluria, hematuria, hemolytic anemia, and hepatitis also should be included. If toxicity is noted, modification of the regimen should be considered after expert consultation; further diagnostic studies may be indicated.

HCWs who fail to complete the recommended regimen often do so because of the side effects they experience (e.g., nausea and diarrhea). These symptoms often can be managed without changing the regimen by prescribing antimotility and antiemetic agents or other medications that target the specific symptoms. In other situations, modifying the dose interval (i.e., administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer), may help promote adherence to the regimen.

### **Counseling and Education**

- Although HTV infection following an occupational exposure occurs infrequently, the emotional impact of the exposure often is substantial. In addition, HCWs are given seemingly conflicting information. Although HCWs are told that there is a low risk for HTV transmission, a 4-week regimen of PEP is recommended and they are asked to commit to behavioral measures (i.e., sexual abstinence or condom use) to prevent secondary transmission, all of which influence their lives for several weeks to months. Therefore, access to persons who are knowledgeable about occupational HIV transmission and who can deal with the many concerns an HIV exposure may raise for the HCW is an important element of postexposure management.
- HFV-exposed HCWs should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially during the first 6-12 weeks after the exposure when most HIV-infected persons are expected to seroconvert: use sexual abstinence or condoms to prevent sexual transmission and to avoid pregnancy; and refrain from donating blood, plasma, organs, tissue, or semen. If the exposed HCW is breastfeeding, she should be counseled about the risk for HTV transmission through breast milk, and discontinuation of breastfeeding should be considered, especially following high-risk exposures. If the HCW chooses to receive PEP, temporary discontinuation of breastfeeding while she is taking PEP should be considered to avoid exposing the infant to these agents. NRTIs are known to pass into breast milk; it is not known whether this also is true for PIs.

There is no need to modify an HCW's patient-care responsibilities to prevent transmission to patients based solely on an HTV exposure. If HIV seroconversion is detected, the HCW should be evaluated according to published recommendations for HIV-infected HCWs.

Exposed HCWs should be advised to seek medical evaluation for any acute illness that occurs during the follow-up period. Such an illness, particularly if characterized by fever, rash, myalgia, fatigue, malaise, or lymphadenopathy, may be indicative of acute HIV infection but also may be due to a drug reaction or another medical condition.

Exposed HCWs who choose to take PEP should be advised of the importance of completing the prescribed regimen. Information should be provided about potential drug interactions and the drugs that should not be taken with PEP, the side effects of the drugs that have been prescribed (See Appendix), measures to minimize these effects, and the methods of clinical monitoring for toxicity during the follow-up period. They should be advised that the evaluation of certain symptoms should not be delayed (e.g., back or abdominal pain, pain on urination or blood in the urine, or symptoms of hyperglycemia {i.e., increased thirst and/or frequent urination}).

## **SURVEILLANCE OF HEALTH CARE WORKERS WITH HIV/AIDS CDC, 2/21/01**

Of the adults reported with AIDS in the United States through June 30, 2000, 22,618 had been employed in health care. These cases represented 5.1% of the 445,380 AIDS cases reported to CDC for whom occupational information was known. The specific occupations are as follows: 1,714 physicians, 114 surgeons, 4,928 nurses, 474 dental workers, 431 paramedics, 2,965 technicians, 1019 therapists, and 4,985 health aides. The remainder are maintenance workers, administrative staff, etc. Overall, 74% of the health care workers with AIDS, including 1,345 physicians, 85 surgeons, 3,660 nurses, 374 dental workers, and 304 paramedics are reported to have died. CDC has reported 56 health care workers in the U.S. with documented HTV seroconversion following occupational exposure. These individuals include 19 laboratory workers (16 of whom were clinical laboratory workers), 23 nurses, 6 physicians, 2 surgical technicians, 1 dialysis technician, 1 respiratory therapist, 1 health aide, 1 morgue technician, and 2 housekeepers. There exposures were as follows: 48 had percutaneous (puncture/cut injury) exposure, 5 had mucocutaneous (mucous membrane and/or skin) exposure, 2 had dual exposure (percutaneous and mucocutaneous), and 1 had an unknown route of exposure. CDC is also aware of 138 other cases of HIV infection or AIDS among health care workers who have not reported other risk factors for HTV infection and who report a history of occupational exposure to blood, body fluids, or HIY-infected laboratory material, but for whom seroconversion after exposure was not documented. The number of these workers who acquired their infection through occupational exposures is unknown. The complete report is online at: <http://www.cdc.gov/hiv/pubs/facts/hcwsurv.htm>.

### **NEEDLESTICK SAFETY AND PREVENTION ACT**

On November 6, 2000, President Clinton signed the Needlestick Safety and Prevention Act into law (Public Law 106-430). The Act requires hospitals and health care facilities to use newer safety devices to reduce the number of needle stick injuries suffered by health care workers and patients. These safety devices automatically cover needle tips after they have been used to prevent transmission of disease. The Act requires the Secretary of the federal Department of Labor to create new standards to protect workers exposed to blood-borne pathogens and requires employers to establish an injury log to record the kind of devices and location of all needle stick accidents. The Act sets minimum standards for private sector employees and states that have their own OSHA plans may exceed the minimum federal standards. The revised blood-borne-pathogens standard was published in the Federal Register on January 18, 2001. The Needlestick Safety and Prevention Act provided an effective date of 90 days after its publication in the Federal Register. The updated rules became effective April 18, 2001.

The revisions to OSHA's blood-borne-pathogens standard are in four main areas: (1) modification of definitions relating to engineering controls; (2) revision and updating of the Exposure Control Plan to account for innovations in procedure and technological developments that reduce the risk of exposure incidents and make clear that employers must implement the safer medical devices that are appropriate, commercially available, and effective; (3) solicitation of employee input from non-managerial employees responsible for direct patient care as part of the Exposure and Control Plan in the identification, evaluation, and selection of effective

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engineering and work practice controls; and (4) record keeping requirements for employers to maintain a sharps injury log to serve as a tool for identifying high risk areas and evaluating devices.

## **Background**

The Occupational Safety and Health Administration published the Occupational Exposure to Bloodborne Pathogens standard in 1991 because of a significant health risk associated with exposure to viruses and other microorganisms that cause bloodborne diseases. Of primary concern are the human immunodeficiency virus (HIV) and the hepatitis B and hepatitis C viruses.

The standard sets forth requirements for employers with workers exposed to blood or other potentially infectious materials. In order to reduce or eliminate the hazards of occupational exposure, an employer must implement an exposure control plan for the worksite with details on employee protection measures. The plan must also describe how an employer will use a combination of engineering and work practice controls, ensure the use of personal protective clothing and equipment, provide training, medical surveillance, hepatitis B vaccinations, and signs and labels, among other provisions. Engineering controls are the primary means of eliminating or minimizing employee exposure and include the use of safer medical devices, such as needleless devices, shielded needle devices, and plastic capillary tubes.

Nearly 10 years have passed since the bloodborne pathogens standard was published. Since then, many different medical devices have been developed to reduce the risk of needlesticks and other sharps injuries. These devices replace sharps with non-needle devices or incorporate safety features designed to reduce injury. Despite these advances in technology, needlesticks and other sharps injuries continue to be of concern due to the high frequency of their occurrence and the severity of the health effects.

The Centers for Disease Control and Prevention estimate that healthcare workers sustain nearly 600,000 percutaneous injuries annually involving contaminated sharps, his response to both the continued concern over such exposures and the technological developments which can increase employee protection, Congress passed the **Needlestick Safety and Prevention Act** directing OSHA to revise the bloodborne pathogens standard to establish in greater detail requirements that employers identify and make use of effective and safer medical devices. That revision was published on Jan. 18, 2001, and became effective April 18, 2001.

## **Summary**

The revision to OSHA's bloodborne pathogens standard added new requirements for employers, including additions to the exposure control plan and keeping a sharps injury log. It does not impose new requirements for employers to protect workers from sharps injuries; the original standard already required employers to adopt engineering and work practice controls that would eliminate or minimize employee exposure from hazards associated with bloodborne pathogens. The revision does, however, specify in greater detail the engineering controls, such as safer medical devices, which must be used to reduce or eliminate worker exposure.

## **Exposure Control Plan**

The revision includes new requirements regarding the employer's Exposure Control Plan, including an annual review and update to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens. The employer must:

- take into account innovations in medical procedure and technological developments that reduce the risk of exposure (e.g., newly available medical devices designed to reduce needlesticks); and
- document consideration and use of appropriate, commercially-available, and effective safer devices (e.g., describe the devices identified as candidates for use, the method(s) used to evaluate those devices, and justification for the eventual selection).

No one medical device is considered appropriate or effective for all circumstances. Employers must select devices that, based on reasonable judgment:

- will not jeopardize patient or employee safety or be medically inadvisable; and
- will make an exposure incident involving a contaminated sharp less likely to occur.

## **Employee Input**

Employers must solicit input from non-managerial employees responsible for direct patient care regarding the identification, evaluation, and selection of effective engineering controls, including safer medical devices. Employees selected should represent the range of exposure situations encountered in the workplace, such as those in geriatric, pediatric, or nuclear medicine, and others involved in direct care of patients.

OSHA will check for compliance with this provision during inspections by questioning a representative number of employees to determine if and how their input was requested.

## **Documentation of employee input**

Employers are required to document, in the Exposure Control Plan, how they received input from employees. This obligation can be met by:

- Listing the employees involved and describing the process by which input was requested; or
- Presenting other documentation, including references to the minutes of meetings, copies of documents used to request employee participation, or records of responses received from employees.

## **Recordkeeping**

Employers who have employees who are occupationally exposed to blood or other potentially infectious materials, and who are required to maintain a log of occupational injuries and illnesses under existing recordkeeping rules, must also maintain a sharps injury log. That log will be maintained in a manner that protects the privacy of employees. At a minimum, the log will contain the following:

- the type and brand of device involved in the incident;

- \* location of the incident (e.g., department or work area); and
- description of the incident

The sharps injury log may include additional information as long as an employee's privacy is protected. The format of the log can be determined by the employer.

### **Modification of Definitions**

The revision to the bloodborne pathogens standard includes modification of definitions relating to engineering controls. Two terms have been added to the standard, while the description of an existing term has been amended.

### **Engineering Controls**

Engineering Controls include all control measures that isolate or remove a hazard from the workplace, such as sharps disposal containers and self-sheathing needles. The original bloodborne pathogens standard was not specific regarding the applicability of various engineering controls (other than the above examples) in the healthcare setting. The revision now specifies that "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems" constitute an effective engineering control, and must be used where feasible.

### **Sharps with Engineered Sharps Injury Protections**

This is a new term which includes nonneedle sharps or needle devices containing built-in safety features that are used for collecting fluids or administering medications or other fluids, or other procedures involving the risk of sharps injury. This description covers a broad array of devices, including:

- syringes with a sliding sheath that shields the attached needle after use;
- needles that retract into a syringe after use;
- shielded or retracting catheters
- intravenous medication (IV) delivery systems that use a catheter port with a needle housed in a protective covering.

### **Needleless Systems**

This is a new term defined as devices which provide an alternative to needles for various procedures to reduce the risk of injury involving contaminated sharps. Examples include:

- IV medication systems which administer medication or fluids through a catheter port using non-needle connections; and
- jet injection systems which deliver liquid medication beneath the skin or through a muscle.

## POSTEXPOSURE REGISTRIES

Health-care providers in the United States are encouraged to enroll HCWs who receive PEP in a confidential registry developed by CDC, Glaxo Wellcome Inc., and Merck & Co., Inc., to assess toxicity; telephone (888) 737-4448 ({888} PEP-4HIV), or write the HIV PEP Registry, 1410 Commonwealth Drive, Suite 215, Wilmington, NC 28405. Unusual or serious and unexpected toxicity from antiretroviral drugs should be reported to the manufacturer and/or FDA, telephone (800)332-1088.

Health-care providers also should report instances of prenatal exposure to antiretroviral agents to the Antiretroviral Pregnancy Registry. The registry is an epidemiologic project to collect observational, nonexperimental data on antiretroviral drug exposure during pregnancy to assess potential teratogenicity. Referrals should be directed to the Antiretroviral Pregnancy Registry, 1410 Commonwealth Drive, Suite 215, Wilmington, NC 28405; telephone (800) 258-4263 or (800) 722-9292, ext. 39437; fax (800) 800-1052.

A protocol has been developed to evaluate HIV seroconversion in an HCW who received PEP. These events can be reported to CDC, telephone (404) 639-6425.

## RESOURCES FOR CONSULTATION

Clinicians who seek consultation on HTV PEP for assistance in managing an occupational exposure should access local experts in HTV treatment as much as possible. In addition, the "National Clinicians' Post-Exposure Prophylaxis Hotline (PEP-Line)" has been created to assist clinicians with these issues; telephone (888) 448-4911. Other resources and registries include the HIV Postexposure Prophylaxis Registry, the Antiretroviral Pregnancy Registry, FDA, and CDC.

**For more information about HIV/AIDS education programs, HTV testing sites or general questions about HIV or AIDS, call the AIDS hotline (1-800-FLA-AIDS, 1-800-352-2437) or a Department of Health Area HTV/AIDS Coordinator.**

## SOURCES:

Florida Department of Health, Bureau of HIV/AIDS  
National Center for Injury Prevention and Control  
Centers for Disease Control and Prevention

# STATE & NATIONAL HIV/AIDS RESOURCE LIST

- > **THE STATE OF FLORIDA HIV/AIDS HOTLINE: 1 (800) FLA-AIDS (352-2437)**  
(Operational Hours: 9 AM -11 PM)  
  
*Spanish:* 1(800)545-7432      *Creole:* 1 (800) AIDS-101
- > **STATE OF FLORIDA DEPT. OF HEALTH HIV/AIDS PROGRAM OFFICE, TAMPA**  
  
(813)871-7561 or (813)871-7996
- > **NATIONAL HIV/AIDS HOTLINE: 1 (800) 342-2437**  
(Operational Hours: 24 Hours)  
  
*Spanish:* 1 (800) 344-7432      TTY/7TD; 1 (800) 243-7889
- > **NATIONAL AIDS INFORMATION CLEARINGHOUSE: 1 (800) 458-5231**  
(Operational Hours: 9 AM - 7 PM)

## DEPARTMENT OF HEALTH AREA HIV/AIDS COORDINATORS

For information about AIDS Educational programs, HIV testing, or HIV/AIDS in general, contact your Area AIDS Coordinator or the AIDS Hotline 1 (800) 352-2437.

### Area 1 Office

Heather Renfroe  
1295 W. Fairfield Drive, #143  
Pensacola, FL 32501  
(850)595-6762  
FAX (850) 595-6761

### Area 2A Office

Julie Vandermeer  
Bay County Health Department  
597 W. 11 Street  
Panama City, FL 32401  
(850) 872-4455  
FAX (850) 747-5487

### Area 2B Office

David Gavin  
Leon County Health Department  
1515 Old Bainbridge Road  
Tallahassee, FL 32303  
(850) 487-2223, ext. 153  
FAX (850) 488-1384

### Area 3 & 13 Offices

Robert (Bobby) Davis  
Alachua County Health Department  
224 SE 24<sup>th</sup> Street  
Gainesville, FL 32641  
(352) 334-7964  
FAX (352) 334-7934

### Area 4 Office

David Andress  
Duval County Health Department  
1833 Boulevard, Suite 502  
Jacksonville, FL 32206  
(904) 798-2790, ext. 5602  
FAX (904) 798-2787

### Area 5 Office

Lisa Cohen  
Pinellas County Health Department  
500 7th Avenue South  
St. Petersburg, FL 33701  
(727) 824-6902  
FAX (727) 893-1681

**Area 6 Office**

Lisle House  
Hillsborough County Health Department  
4951A E. Adamo Drive, Suite 120  
Tampa, FL 33619  
(813)307-8026  
FAX (813) 307-4465

**Area 7 Office**

Jeannine Gurley  
Orange County Health Department  
604 Courtland Street, Suite 200  
Orlando, FL 32804  
(407) 623-1180, ext. 199  
FAX (407) 741-4689

**Area 8 Office**

Gail Counts  
Health Program Office  
P.O. Box 9309  
Ft. Myers, FL 33902  
Physical: 2295 Victoria Ave, STE 209C  
(941)338-2737  
FAX (941) 338-2746

**Area 9 Office**

Paul A. Moore ..  
Palm Beach County Health Department  
P.O. Box 29  
West Palm Beach, FL 33402  
Physical: 301 Broadway, Riviera Bch 33404  
(561)882-3102  
FAX (561) 845-4435

**Area 10 Office**

Lisa Agate  
Broward County Health Department  
2421 S.W. 6th Avenue (Annex)  
Ft. Lauderdale, FL 33315  
(954) 467-4774  
FAX (954) 762-3999

**Area 11A Office**

Evelyn Ullah  
Dade County Health Department  
1444 Biscayne Boulevard, Suite 350  
Miami, FL 33132  
(305)377-5022  
FAX (305) 377-5108

**Area 11B**

Cindy Francisco  
Monroe County Health Dept.  
P.O. Box 6193  
Key West, FL 33041-6193  
Physical: 5100 College Rd., 33040  
(305) 293-7520  
FAX (305) 292-6871

**Area 12 Office**

Thomas Pare  
Volusia County Health Department  
509 South Clyde Morris Boulevard  
Daytona Beach, FL 32114-3929  
(386) 947-4076  
FAX (3 86) 947-3206

**Area 13 Office (refer to Area 3)****Area 14 Office**

William W. Wilbanks, Jr. Polk  
County Health Department 1290  
GolfView Avenue - 4th Floor  
Bartow, FL 33830-6740 (863)519-  
7900 FAX (863) 534-7046

**Area 15 Office**

Owen Mobley  
St. Lucie County Health Department  
P.O. Box 580  
Port St. Lucie, FL 34954  
Physical: 719 Avenue C, Ft. Pierce 34954  
(56i) 462-3848  
FAX (561)462-3 897

**Headquarters**

Bureau of HIV/AIDS  
4052 Bald Cypress Way - Bin # A09  
Tallahassee, FL 32399-1715  
(850) 245-4334  
FAX (850) 414-0038

Physical Address: Bureau of  
HIV/AIDS 2585 Merchants  
Row Blvd Tallahassee, FL  
32311

## WEBSITE LINKS

*Below are some links that you may find useful.*

Florida Department of Health, HTV/AIDS Program	<a href="http://www9.myflorida.com/disease%20ctrl/aids/">http://www9.myflorida.com/disease ctrl/aids/</a>
Centers for Disease Control	<a href="http://www.cdc.gov">http://www.cdc.gov</a>
World Health Organization	<a href="http://www.who.int">http://www.who.int</a>
HTV Insite	<a href="http://hivinsite.ucsf.edu/">http://hivinsite.ucsf.edu/</a>
The Body	<a href="http://www.thebody.com/index.shtml">http ://www.thebody .com/index . shtml</a>

Center for AIDS Prevention Studies      <http://www.caps.ucsf.edu/index.html>

John Hopkins AIDS Service - Infectious Diseases      [j http://www.hopkins-aids.edu/](http://www.hopkins-aids.edu/)

JAMA HTV/AIDS Information Center      <http://www.ama-assn.org/special/hiv/hivhome.htm>

PAHO: AIDS/Sexually Transmitted Diseases      <http://www.paho.org/english/aid/aidstd.htm>

The American Social Health Organization      <http://www.ashstd.org/>

UNAIDS      <http://www.unaids.org/>

National Alliance of State and Territorial AIDS Directors      [http ://www.nastad .org/](http://www.nastad.org/)

International Association of Physicians in AIDS Care	<a href="http://www.iapac.org/">http://www.iapac.org/</a>
Nat'l Academy Press, No Time To Lose (2000)	<a href="http://www.nap.edu/books/0309071372/html/">http://www.nap.edu/books/0309071372/html/</a>

**Statement for the Record**

by

**Linda Rosenstock, M.D., M.P.H.  
Director, National Institute for  
Occupational Safety and Health  
Centers for Disease Control and Prevention**

**Before the**

**Subcommittee on Workforce Protections  
Committee on Education and the Workforce  
U.S. House of Representatives**

**June 22, 2000**

As the Director of the National Institute for Occupational Safety and Health (NIOSH), I thank you, Chairman Ballenger, and members of the Subcommittee, for the opportunity to submit this statement, which discusses the science and public health issues that pertain to needlestick injuries among health care workers.

NIOSH is a research institute within the Centers for Disease Control and Prevention (CDC), a part of the Department of Health and Human Services. CDC, through NIOSH, is the federal agency mandated to conduct research to identify and prevent workplace safety and health hazards. In addressing needlestick injuries, NIOSH works closely with the National Centers for Infectious Disease (NCID), also part of CDC.

This statement summarizes the scientific issues related to needlestick injuries, including what we know about the number of workers affected, what can happen to a worker's health as a result of such an injury, how these injuries occur, and ways to prevent them. In addition, it describes what CDC is doing to address this serious public health problem.

First, it is important to provide some context about health care workers in general. Over 10 million workers are now employed in health care industries. They cover a range of occupations, from nurses and doctors to pharmacists to laboratory technicians to dental assistants. Health care services are growing at twice the rate of the overall economy.

## The Number of Needlestick Injuries

We know that needlestick injuries are contributing to the overall burden of health care worker injuries. Although we do not know exactly how many work-related needlesticks occur each year across the country, estimates indicate that 600,000 to 800,000 such injuries occur annually, about half of which go unreported. A recent CDC study estimates that an average of 385,000 needlestick injuries occur annually in U.S. hospital settings. At an average hospital, workers incur approximately 30 reported needlestick injuries per 100 beds per year. Most reported needlestick injuries involve nursing staff; but laboratory staff, physicians, housekeepers, and other health care workers are also injured. Health care workers outside the hospital setting are also at risk. Others at clinics, private medical and dental offices, nursing homes, correctional facilities, and in the community, such as emergency medical response workers, are also at risk of exposure to contaminated blood.

## Needlestick Injuries and the Risk of Disease

Fortunately, most needlestick injuries do not result in exposure to an infectious disease, and of those that do, the majority do not result in the transmission of infection. Nevertheless, needlestick injuries may expose workers to bloodborne pathogens such as human immunodeficiency virus (HIV), hepatitis B virus, and/or hepatitis C virus. A health care worker's risk of infection depends on several factors, such as the pathogen involved, the severity of the needlestick injury, and the availability and use of pre-exposure vaccination and post-exposure prophylaxis (i.e., protective treatment for the prevention of disease once exposure has occurred).

### HIV

HIV infection is a complex disease that can be associated with many symptoms. The virus attacks part of the body's immune system, eventually leading to severe infections and other complications - a condition known as AIDS. Despite current therapies that delay the progression of HIV disease, many individuals who become infected with HIV are likely to develop AIDS.

As of December 1999, CDC received reports of 56 "documented" cases and 136 "possible" cases of occupationally acquired HIV infection in the U.S. Most involved nurses and laboratory technicians. Percutaneous injury - such as needlesticks - was associated with 89% of the documented occupationally acquired infections. Studies that followed health care workers with occupational HIV exposures indicate that the

as a needlestick or a cut with a sharp object, to HIV-infected blood is approximately 0.3%. To say this another way, three of every 1,000 health care workers stuck with a needle contaminated with HIV-positive blood will become infected with HIV.

An epidemiologic study of health care workers who had percutaneous exposures to HIV found that the risk of HIV transmission was increased in certain circumstances: when the worker was exposed to a larger quantity of blood from the patient, a procedure that involved placing a needle in a patient's vein or artery, a deep injury, or when the patient was in a phase of the illness associated with higher viral levels.

### **Hepatitis B Virus**

Hepatitis B virus (HBV) infection is another risk associated with needlestick injuries. About one-third to one-half of persons with acute HBV infection develop symptoms of hepatitis such as jaundice, fever, nausea, and abdominal pain. Most acute infections resolve, but 2% to 6% of patients develop chronic infection with HBV that carries an estimated 15% lifetime risk of dying from cirrhosis of the liver or from liver cancer.

CDC national hepatitis surveillance indicates that, in 1997, an estimated 500 health care workers became infected with HBV. This figure represents a greater than 95% decline from the 17,000 new infections estimated in 1983, largely due to the widespread immunization of health care workers with the hepatitis B vaccine and the use of universal precautions.

Most health care workers "are immune to HBV due to pre-exposure vaccination. However, studies done before the availability of hepatitis B vaccine showed rates of HBV transmission ranging from 6% to 30% after a single needlestick exposure to an HBV-infected patient.

### **Hepatitis C Virus**

Health care workers with needlestick injuries are also at risk for infection with the Hepatitis C virus (HCV). The precise number of health care workers who have acquired HCV occupationally is not known. However, epidemiologic studies of health care workers exposed to HCV through a needlestick or other percutaneous injury have found that the incidence of infection averages 1.8% per injury. Of the total new HCV infections that have occurred annually (declining from 112,000 in 1991 to 38,000 in 1997), 2% to 4% have been in health care workers exposed to blood in the workplace.

HCV infection often occurs with no symptoms or only mild symptoms. But unlike HBV, with only 2% to 6% of adults

develops in 75% to 85% of patients. Seventy percent of those with chronic HCV develop active liver disease, with 10% to 20% of patients then developing cirrhosis and 1% to 5% developing liver cancer over a period of 20 to 30 years.

### **Prophylaxis and Post-Exposure Treatments**

Postexposure prophylaxis is available for hepatitis B and HIV exposures but not for hepatitis C. However, preventing the needlestick injury in the first place is the best approach to preventing these diseases in health care workers, and it is an important part of any bloodborne pathogen prevention program in the workplace.

### **Emotional Impact**

Another serious effect of needlestick injuries is the emotional toll on health care workers. With each needlestick incident, workers face the possibility of having been exposed to a bloodborne pathogen, in which case they face difficult decisions about undergoing medical treatment with both short-term and long-term side effects. In addition, the worker is advised to use barrier contraception and to postpone decisions on childbearing.

Studies have shown that the emotional impact of a needlestick injury can be severe and long lasting, even when a serious infection is not transmitted. This impact is particularly severe when the injury involves exposure to HIV. In one study of 20 health care workers with an HIV exposure, 11 reported acute severe distress, 7 had persistent moderate distress, and 6 quit their jobs as a result of the exposure. Other stress reactions requiring counseling have also been reported. Not knowing the infection status of the source patient can accentuate the health care worker's stress. In addition to the exposed health care worker, colleagues and family members may suffer emotionally.

### **How Needlestick Injuries Occur: Devices and Activities**

Health care workers use many types of needles and other sharp devices to provide patient care.

Whenever one of these "sharps" is exposed in the work environment there is an opportunity for injury. Data from two surveillance programs, the CDC National Surveillance System for Healthcare Personnel (NaSH) and EPINet, a project developed by Dr. Janine Jagger at the University of Virginia, provide descriptive epidemiological evidence of how such injuries occur, including under what circumstances, with what devices and during what types of procedures. The picture that

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patients, workers, devices and the environment. Approximately 38% of percutaneous injuries occur during use, when a needle or other sharp being manipulated in a patient becomes accidentally dislodged. Other injuries occur after use during cleanup, or in association with the disposal of a sharp device.

The circumstances leading to a needlestick injury depend partly on the type and design of the device used. In addition to risks related to device characteristics, needlestick injuries have been related to certain work practices such as recapping, transferring a body fluid between containers, and failing to properly dispose of used needles in puncture-resistant "sharps" containers.

### Preventing Needlestick Injuries

Based on a review of the science, CDC recommends a hierarchical approach for implementing strategic measures to prevent needlestick injuries. Among these measures is eliminating the use of needles wherever possible through changes in how medications are delivered or specimens obtained, and by using engineered technologies, such as non-needle connectors for intravenous delivery systems. If safe and effective alternatives to needles are not available, devices with engineered sharps injury prevention features such as shields and sheaths should be used. In addition to the changes in the use of medical devices, other factors that must be addressed in the prevention of needlestick injuries include modification of hazardous work practices, administrative changes to address needle hazards in the environment (e.g., prompt removal of filled sharps disposal boxes), safety education and awareness, feedback on safety improvements, and action taken on continuing problems. Each health care setting should have its own carefully tailored program, developed with front line worker input and review.

### Effectiveness of Medical Devices with Safety Features

Research has shown that devices with safety features, especially when used as part of a comprehensive prevention program are effective in preventing needlestick injuries.

For example, some studies have shown that needleless or protected-needle IV systems decreased needlestick injuries related to IV connectors by 62% to 88%. In a CDC study, phlebotomy injuries (i.e., those involving the letting of blood) were reduced by 76% with a self-blunting needle, 66% with a hinged needle shield, and 23% with a sliding-shield, winged-steel (butterfly-type) needle. Another study concluded that phlebotomy injuries were reduced by 82% with a needle shield, but a recapping device had minimal impact. Other research concluded that safer IV catheters that encase the needle after use reduced needlestick injuries related to IV insertion by 83%

in three hospitals.

A number of sources have identified the desirable characteristics of safety devices, which can be used as a guideline for device design and selection. These are included, along with a description of their limitations, in CDC's *Alert, Preventing Needlestick Injuries in Health Care Settings* (November 1999) (at pp. 10-11), attached to this testimony.

### Comprehensive Safety Programs

Although medical safety devices are key in the prevention of needlestick injuries, as already mentioned, they are most effective when used in the context of a comprehensive safety program that considers all aspects of the work environment and that has employee involvement and management commitment. Several studies document substantial reductions in needlestick injuries with the proper use of needleless systems or newer safety needle devices used in a comprehensive program to prevent needlestick injuries.

CDC believes that a comprehensive strategy to prevent percutaneous injuries is necessary and should include the following:

- occupational injury and disease surveillance to identify procedures, devices and injury mechanisms for targeting prevention efforts;
- development and implementation of a prevention plan that includes 1) elimination of unnecessary use of needles, 2) implementation of devices with safety features, 3) modification of procedures and work practices, 4) health care worker education, and 5) safety promotion in the work environment; and
- outcome evaluation.

The critical role of appropriate training has been emphasized by several recent reports of increased patient bloodstream infections associated with improper care of needleless IV systems, primarily in the home health care setting. These data emphasize the need for patient safety surveillance and thorough training as well as occupational injury surveillance when implementing the use of a new medical device.

One recent study tracked phlebotomy services at a major institution and found that from 1993 to 1996, the needlestick injury rate among its 200 full-time phlebotomists decreased almost 90% (from 1.5 to 0.2 per 10,000 venipunctures performed). The low rate achieved is almost 80% below an

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services included changes in worker education and work practices, the implementation of devices with safety features, and encouragement of injury reporting. These interventions as well as the implementation of CDC published guidelines and the Occupational Safety and Health Administration's (OSHA) bloodborne pathogens standard were associated with the observed steady decline in the injury rate. The authors also noted that an important factor contributing to this success was a thorough understanding among the institution's staff of the injuries that had occurred.

Another recently published study, funded by CDC, examined needlestick injuries in an acute-care community hospital in Greater Washington, D.C., from 1990 to 1998. The study found that implementation of a multi-faceted intervention program led to a significant and sustained decrease in the overall rate of sharps injuries. Annual sharps injury incidence rates decreased from 82 sharps injuries/1,000 full-time workers to 24 sharps injuries/1,000 full-time workers, representing a 70% decline in incidence rate overall. The hospital's interventions included an intensive training effort, expanded employee health programs, and an expedited injury reporting process with a focus on confidentiality issues, an anti-needlesticks and sharps task force, and the implementation of new work practices, as well as the use of medical safety devices.

#### CDC Efforts to Address Needlestick Injuries

CDC has had a long-standing interest and involvement in the prevention of needlestick exposures dating back to its 1987 guidelines for universal precautions that included recommendations for the safe handling of sharp devices, including proper disposal. In a 1998 report, CDC reviewed the proper location, use, and benefits of sharps disposal containers, which play a key role in needlestick injuries. Last November, after reviewing the available scientific research, CDC—with a broad range of review from diverse stakeholders—published a national *Alert on Preventing Needlestick Injuries in Health Care Settings* (mentioned previously herein and attached hereto), which was distributed to every hospital in the country. The *Alert* contains public health recommendations for preventing needlestick injuries, as reflected in my previous comments. CDC is now conducting an evaluation of the impact of the *Alert*.

CDC is currently funding and conducting a wide variety of extramural and intramural projects aimed at reducing the occurrence of needlestick injuries and exposure to bloodborne pathogens. Current research on exposure prevention is focused on the following:

- evaluating safer blood collection devices;

- developing evaluation criteria for selecting medical devices;
- developing benchmarks for needlestick exposure frequencies that could be used for local prevention efforts to protect health care personnel;
- funding hospitals to demonstrate the use of data-driven strategies for the prevention of needlestick injuries; and
- developing a workbook on the prevention of needlestick injuries to guide health care organizations in developing, implementing, and evaluating a prevention plan.

An extramural project beginning later this year will work to provide new data on health care workers who work outside of hospitals, reflecting the changing environment of health care delivery. CDC has also worked on a number of projects with universities to examine safety climate and work organization factors that have an impact on needlestick injuries and to evaluate training programs for health care workers.

In terms of postexposure management, CDC is monitoring the use and side effects of postexposure prophylaxis after occupational exposures, assessing immune responses of health care personnel, and assessing factors that influence selection of postexposure measures. CDC has also joined the Health Resources and Services Administration in funding the PEPLine, an 800 number that provides treatment advice to clinicians treating workers who have been occupationally exposed to blood.

Also of note, coordinated national efforts to address needlestick injuries are occurring through *Healthy People 2010*, the Department of Health and Human Service's national health promotion and disease prevention initiative (*Objective 20-10*, Reduce occupational needlestick injuries among health care workers to 420,000 annual needlestick exposures) and the National Occupational Research Agenda, or NORA™, a national research framework created and implemented by a broad group of stakeholders. Several of NORA's 21 priority research areas, including Infectious Diseases and Intervention Effectiveness Research, are addressing needlestick injury issues.

#### Areas for Further Research

As with any emerging public health problem, there are several important areas in which our knowledge about needlestick injuries and their prevention can be improved. Because most of the medical devices are in the first generation stage, ongoing of current devices and options will be necessary.

devices. Evaluation studies to provide improved information on what does and does not work will similarly continue to improve the effectiveness of comprehensive safety programs. Because training for employers and health care workers is a vital part of a comprehensive prevention program, especially as new and safer devices are introduced, model training curriculums need to be developed and evaluated at regular intervals.

There is a need to improve national surveillance and to build institutional capacity for measuring the impact of prevention efforts. The two existing systems in the U.S. that collect information on needlestick injuries have certain limitations. CDC's NaSH surveillance system, mentioned earlier, is comprised of 60 hospitals around the country that voluntarily report blood exposures to the CDC. The EPINet system, also mentioned previously, counts needlestick injuries at 84 hospitals. Neither system surveys a random selection of hospitals, and the participating hospitals may not be representative of all hospitals across the U.S. Also, we do not have data available to tell us whether the problem of needlestick injuries is occurring uniformly across the country, or if there are pockets where the situation is worse.

In addition, there is no system in place to track the millions of health care workers employed outside of hospitals, or exposed workers who are not health care workers. Needlestick injuries at public health sector facilities are also not counted by current reporting requirements. Moreover, from observational studies, we estimate that approximately half of all needlestick injuries are never reported by employees.

Accurately tracking needlestick injuries is critical. Tracking - or public health surveillance - involves a continuous and systematic process of collecting, analyzing, interpreting, and disseminating descriptive information to monitor health problems. Surveillance is used to guide disease prevention and control activities and provides a basis for public health policy. Some have called surveillance the eyes and ears of public health. Without surveillance, we don't know how big a problem is, whether it's getting bigger or smaller, where it is, or whether our attempts at prevention are effective.

Improved surveillance could be used to identify potential risk factors associated with needlestick injuries, such as high-risk occupations, settings, or procedures, and detect the emergence of new problems. We could also use enhanced surveillance systems to track whether interventions put into place significantly help reduce injuries; for example, whether changes in staffing ratios or the use of newer medical safety devices has an impact on these injuries. Individual facilities could use surveillance to identify problem areas and solutions within their own organization and could use the national data as

a benchmark for comparison with their own data. Any

GDC Washington Office: Linda Rosenstock

enhanced surveillance systems would include appropriate privacy and confidentiality protections for those being monitored.

### Conclusion

While the science base on needle stick injuries continues to grow, completed research indicates that such injuries are an important and continuing cause of exposure to serious and sometimes fatal infections among health care workers. Greater collaborative efforts by all stakeholders are needed to prevent needle stick injuries and the consequences that can result. Such efforts are best accomplished through a comprehensive program that addresses institutional, behavioral, and device-related factors that contribute to the occurrence of needle stick injuries in health care workers. Critical to this effort is the elimination of needle use where safe and effective alternatives are available and the continuing development, evaluation, and use of needle devices with safety features. All such approaches must include serious initial and ongoing training efforts. Monitoring systems are also needed to provide accurate information on the magnitude of needles stick injuries and trends over time, potential risk factors, emerging new problems, and the effectiveness of interventions in all health care settings.

<http://www.cdc.gov/washington/legislative/OB222000.htm>

Washington, DC Office Centers for Disease  
Control and Prevention

Name \_\_\_\_\_ Date \_\_\_\_\_

HIV/AIDS INITIAL TRAINING POST TEST Answer True (T) or False

(F) to the following questions:

1. \_\_\_\_\_ HIV is the virus that causes AIDS, (pg.3 of 28)
2. \_\_\_\_\_ Casual contact with an HIV infected person can put you at risk of contracting the disease, (pg.8 of 28)
3. \_\_\_\_\_ Florida is second in the nation in the number of pediatric AIDS cases, (pg.3 of 28)
4. \_\_\_\_\_ HIV can be cured through new and improved drugs, (pg.8 of 28)
5. \_\_\_\_\_ The most common way of transmitting HIV is through unprotected sex. (pg. 3 of 28)
6. \_\_\_\_\_ HIV cannot be transmitted through the shared use of a needle, (pg. 3 of 28)
7. \_\_\_\_\_ If properly used, any condom is an effective barrier against HIV and other sexually transmitted disease, (pg. 7 of 28)
8. \_\_\_\_\_ Plastic gloves should be changed after contact with patients or residents and hands washed frequently, (pg.8 of 28)
9. \_\_\_\_\_ The first AIDS case was reported in the U.S. in June 1981. (pg.3 of 28)
10. \_\_\_\_\_ It usually takes two to twelve weeks from the point a person becomes infected with HIV to the point that his/her antibody blood test is positive, (pg. 7 of 28)
11. \_\_\_\_\_ HIV attacks and destroys the T-4 helper lymphocytes of T4 cells, (pg. 5 Of 28)

12. In most cases, Florida law prohibits HW testing without the informed consent of the person being tested, (pg. 2 of 28)
13. \_\_\_\_\_ Persons who do not engage in homosexual activity have little or no chance of contracting HIV. (pg.4of28)
14. \_\_\_\_\_ HIV can be detected through an ELISA test within a few days of contamination, (pg. 6 of 28)
15. \_\_\_\_\_ **The only drug that has shown to reduce the risk of HIV transmission from a pregnant women to her baby is ZDV.** (pg.9of28)
16. \_\_\_\_\_ All positive HIV antibody tests must by law be reported to the Florida Department of Health, (pg.10 of 28)
17. \_\_\_\_\_ Recommendations for post exposure prophylaxis have been modified to include a basic four week regimen of two drugs (zidovudine and lamivudine) (pg.15of28)
18. \_\_\_\_\_ On November 6,2000 then President Clinton signed the Needlestick Safety And Prevention Act to reduce the number of needlestick injuries suffered by healthcare workers and patients, (pg. 21 or 28)
19. \_\_\_\_\_ HIV is becoming increasingly more common among older people who are sexually active, (pg. 4 of 28)
20. \_\_\_\_\_ Potentially infectious fluids include but not limited to: blood, semen, vaginal secretions, and pleural fluid, (pg. 16 of 28)

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## PROGRAM EVALUATION

COURSE TITLE: HIV/AIDS

DATE & LENGTH: \_\_\_

COURSE LOCATION:

PLEASE EVALUATE BY CIECLING THE APPROPRIATE RATING: 5-  
EXCELLENT 4-BETTER THAN AVERAGE 3-AVERAGE 2-FAIR 1-POOR

1. OVERALL QUALITY OF THE PROGRAM 54321
2. OVERALL CONTENT OF THE PROGRAM
- a. Content and/or skills demonstrated can improve my ability to perform my job 54321
  - b. Content reflected knowledge level and needs of learner** **54321**
  - c. The material was current 54321
  - d. Time was allowed for questions 54321
3. ACHIEVED STATED OBJECTIVES
- a. Total number of objectives in program \_\_\_\_\_
  - b. Circle the number of objectives that were met 12345678910
  - c. Circle the number of objectives that were not met 12345678910
  - d. The test material reflected the objectives listed 54321
4. Audio Video Portion was appropriate to learning 54321
- OVERALL ORGANIZATION OF THE PROGRAM
- a. Material was organized to facilitate learning 54321
  - b. The amount of material covered was adequate and accurate 54321
6. OVERALL QUALITY OF THE LECTURER 54321
7. OVERALL QUALITY OF THE FACILITY, REGARDING PHYSICAL LEARNING ENVIRONMENT
- a. The facilities and classroom were adequate 54321

WHAT DID YOU LIKE BEST ABOUT THE PROGRAM?

SUGGESTIONS FOR IMPROVEMENT OF THIS PROGRAM

TOPIC IDEAS FOR FUTURE IN-SERVICE PROGRAMS