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I. Purpose: To prevent the transmission of HIV through the delivery of science-based, culturally sensitive HIV testing, and linkage services. The provision of linkages and/or referrals to needed prevention and medical psychosocial services, including but not limited to behavioral and biomedical interventions. Successful linkages of clients with HIV to partner services, expedited HIV treatment, case management, and support services as appropriate. Ongoing program evaluation and quality improvement to ensure that testing and linkage services are accessible, readily available, and of the highest quality.

II. Authority: Section 381.004, Florida Statutes; Florida Administrative Code (FAC) Rule 64D-2.

III. Scope: All Department personnel, contracted staff, and volunteers.

IV. Definitions

A. Centers for Disease Control and Prevention (CDC): The leading national public health institute of the United States. The CDC is a United States federal agency under the Department of Health and Human Services, headquartered near Atlanta, Georgia.

B. Community-Based Providers: Nonprofit groups that work at a local level to improve life for residents. Their focus is to build equality across society in all streams—health care, environment, quality of education, access to technology, access to spaces, and information for the disabled, to name a few.

C. Counselor: A health professional providing essential HIV counseling and testing services to clients and families who may be at risk of acquiring HIV or are affected by the disease. An HIV/AIDS counselor specializes in providing educational and medical information to help prevent the transmission of HIV.

D. County Health Department (CHD): CHDs work to preserve, protect, and enhance the general health and environment of the community by providing leadership in public health policy, ensuring access to quality health services and information, preventing disease, and enforcing health regulations.

E. Department: The Florida Department of Health and all 67 CHDs.

F. Early Intervention Consultant (EIC): Regional positions covering 15 jurisdictional areas across Florida. EICs ensure an effective HIV-testing training system exists in their area, participate in quality improvement, and technical assistance activities, ensure an adequate distribution of test sites (confidential and anonymous) that target high-risk and priority populations, and make informed decisions on programming by reviewing HIV testing data on a regular basis.

G. Health Care Setting: A setting devoted to the diagnosis and care of persons or the provision of medical services to persons, such as CHD clinics, hospitals,

urgent care clinics, substance abuse treatment clinics, primary care settings, community clinics, blood banks, mobile medical clinics, and correctional health care facilities.

H. **HIV/AIDS 500:** Basic HIV counseling and testing training course required for certification as an HIV counselor and tester in the state of Florida. Prerequisite to HIV 501 course. Online or classroom, two-hour requirement.

I. **HIV/AIDS 501:** Advanced HIV counseling and testing training course required for certification as an HIV counselor and tester in the state of Florida. Online or classroom, two-hour requirement. Face-to-face practicum, eight-hour requirement.

J. **HIV Test:** A test ordered on or after July 6, 1988, to determine the presence of the antibody or antigen to HIV or the presence of HIV infection**.**

K. **HIV Test Result:** A laboratory report of an HIV 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 an HIV test. The term does not include test results reported to a health care provider by a patient.

L. **Human Immunodeficiency Virus (HIV):** A lentivirus (subgroup of retroviruses) that causes HIV infection and, over time, acquired immunodeficiency syndrome (AIDS).

M. **Linkage to Care:** The process of engaging persons newly diagnosed with HIV into HIV primary care.

N. **Non-Health Care Setting:** A site that conducts HIV testing for the sole purpose of identifying HIV infection. Such setting does not provide medical treatment but may include community-based organizations, outreach settings, CHD HIV testing programs, and mobile vans.

O. **Partner Services (PS):** Provides an array of free services to persons diagnosed with HIV or other sexually transmitted diseases (STDs), such as syphilis, gonorrhea, and chlamydial infection, and their partners. PS is a function of CHD staff who help to identify and locate sex or drug-injection partners to inform them of their risk and to provide them testing, counseling, and referrals for other services.

P. **Pre-exposure Prophylaxis (PrEP)**: A biomedical HIV prevention method in which people who don't have HIV take medicine to reduce their risk of acquiring HIV if they are exposed to the virus. PrEP is prescribed to HIV-negative adults and adolescents who are at high risk for acquiring HIV. When taken as prescribed, PrEP reduces the risk of acquiring HIV through sex by more than 90 percent and through injection-drug use by more than 70 percent.

Q. **Trainer:** Department employees certified to train other individuals in the HIV 500 and 501 courses and/or other Department sponsored courses.

V. Procedures

A. Administrative Functions and Responsibilities

1. Registration and Reregistration of Testing Programs

(a) All CHDs and organizations that conduct or advertise as conducting an HIV testing program must register with the HIV/AIDS Section and receive a site number. Please refer to Rule 64D-2.006, FAC, for more information. Non-Department test sites are required to pay a processing fee. Fees established shall be an amount sufficient to meet all costs incurred by the Department in carrying out its registration, data collection, compliance monitoring, and administrative responsibilities under Section 381.004(9)(b), Florida Statutes, for all private HIV testing sites, but shall not exceed $100. The one-time registration fee of $100 can only be waived under the stipulations outlined in the FAC.

(b) HIV testing programs must reregister annually. All registered testing sites receive a Certificate of Registration with an expiration date of one year from the date of registration. Sites will be sent an application form for reregistration 60 days prior to their expiration date. Sites that fail to reregister with the HIV/AIDS Section by the expiration date are not authorized to continue operating an HIV testing program.

(c) The role of the physician, as it relates to HIV testing sites, is to ensure the operation of the center and to ensure that the site is adhering to best practices. This includes all medical standards, standard precautions, correct and accurate billing, and meeting protocols.

(d) If the Department laboratory is used for HIV testing, test sites must use the DH 1628 data collection form as specified in the *HIV Counseling, Testing and Linkage Forms Instruction Guide.* If a private lab is used, all sites must return confirmatory HIV test results with the reactive rapid yellow copies of the DH 1628 data collection forms to the Department monthly.

(e) HIV testing staff, as defined in IOP 360-07, “Minimum Standards for HIV Counselors, Trainers, and Early Intervention Consultants,” must have documentation of approved training in HIV counseling and testing prior to performing HIV testing sessions. Training includes the HIV/AIDS 500 and 501 courses and annual HIV/AIDS 501 updates.

(f) The CHD must agree to provide the HIV/AIDS 500 and HIV/AIDS

501 courses and annual HIV/AIDS 501 updates to registered test site staff free of charge. The CHD will also provide the applicable forms to the provider free of charge.

2. Confidential and Anonymous Test Sites

(a) Potential test sites should contact their local EIC for a new site application packet. The packet contains a copy of relevant statutes and administrative rules, the model protocols, a sample Memorandum of Agreement/Memorandum of Understanding (MOA/MOU), and DH Form 1781, *Application for Registration and Reregistration for HIV Testing Programs*. Prior to assigning a new registered HIV testing site number, the EIC shall do/ensure the following to determine the appropriateness and readiness of the site to conduct HIV testing:

(1) Site visit
(2) Completed Memo of Agreement/Memo of Understanding (MOA/MOU) between site and local CHD, as appropriate
(3) CLIA certificate and biohazard permit in place
(4) 500/501 training completed, and staff certified
(5) Rapid HIV testing training completed, and staff certified
(6) Verification of all paperwork at site
(7) Provision of additional technical assistance and supplies
(8) Submission of application to the HIV Counseling and Testing Team lead for approval

(b) Potential test sites must complete DH Form 1781, *Application for Registration and Reregistration for HIV Testing Programs,* and return it to the regional EIC. Non-Department sites are required to submit the one-time $100 registration fee (unless it has been waived) along with the application.

(c) If the Department is providing support for any portion of HIV testing services, including forms, test supplies, and laboratory support, to non-Department test site, an MOA/MOU should be negotiated between the local CHD and the provider. The potential test site must agree to follow all Department security and client confidentiality policies and procedures. The MOA/MOU must state that the potential provider will follow all applicable statutes, rules, policies, and procedures regarding HIV counseling and testing. It will be important for the CHD to include what they require of the site in the agreement, such as not turning clients away because of their inability to pay for testing, participation in quality improvement/technical assistance reviews by CHD and/or HIV/AIDS Section staff, following the appropriate model protocol, and following applicable technical assistance guidelines. The EIC will be available to provide technical assistance on the application process.

(d) Upon receipt of the completed DH Form 1781 by the state

office, the HIV Counseling and Testing Team Lead will review the DH Form 1781 for approval. Once approved, a provider site number will be assigned, and a certificate issued by the HIV/AIDS Section. The certificate should be posted in a location visible to clients.

(e) Anonymous sites must be approved by the HIV/AIDS Section.

(f) HIV counselors must meet minimum requirements, as outlined in IOP 360-07, “Minimum Standards for HIV Counselors, Trainers and Early Intervention Consultants,” and complete annual HIV/AIDS 501 updates. HIV counseling and testing should be included in performance standards of all persons providing these services. Qualified staff should monitor counselors at least annually or as needed and should provide immediate feedback.

(g) Services must be provided in accordance with all applicable laws, administrative rules, guidelines, policies, and procedures.

(h) Department staff should ensure that test sites are supplied with necessary forms and equipment to properly execute HIV prevention counseling, testing, and linkage services.

(i) Services must be provided in a manner that is appropriate for clients’ culture, language, gender, sexual orientation, and age. All persons providing HIV prevention counseling, testing, and linkage services should receive cultural diversity training.

(j) Barriers to clients accessing services must be assessed, identified, and eliminated or reduced on an ongoing basis. To increase accessibility for clients, HIV testing may be integrated with other clinical/program services. Services should be available on an appointment or walk-in basis. Hours of operation should be based on clients’ need for services, staffing levels, and available resources.

(k) HIV/AIDS printed informational materials and condoms with instructions must be readily available at test sites.

(l) Services must be provided in a confidential setting.

(m) Every effort must be made to ensure that clients who test positive receive their results (for example, via a post-test appointment at the time of testing, followed up with via a generic phone call, followed up with via letter, visited in the field).

(n) Documentation of services must be conducted as specified in the *HIV Counseling, Testing and Linkage Forms Instruction Guide*. A sampling of records should be randomly chosen and

reviewed annually by qualified staff. Qualified staff may include prevention program staff, EICs, clinic supervisors, HIV/AIDS program coordinators, and others who have been trained in how to review counseling, testing, and linkage records.

(o) Records must be maintained in a secured area with minimal access.

(p) Appointments for anonymous HIV counseling and testing services may not be scheduled in a way that will identify the client. An alternative method, such as a numerical appointment system, should be developed. Pseudonyms should not be used to identify clients in anonymous HIV test settings.

(q) Relationships with medical and social service providers should be established and maintained to facilitate successful linkages.

(r) No client should be denied services based on inability to pay. Fees can be charged on a sliding scale or by flat rate. In the case of an anonymous test, the client's verbal declaration of their inability to pay will be sufficient.

B. HIV Testing

1. HIV Testing in Health Care Settings

   (a) When providing HIV testing in CHD health care settings, staff must provide the opportunity for pre-test counseling and face-to-face post-test counseling. Pre- and post-test counseling is not required in other health care settings. While informed consent is no longer required, clients must be notified that they will be tested for HIV unless they decline (opt out). If a client declines, this must be noted in the client's medical record. Examples of notification include:
      (1) Signage in an exam room notifying the patient that HIV testing is performed as a routine part of medical care and that they have the right to refuse.
      (2) A patient brochure on HIV that explains that routine HIV screening is a practice of the facility and that they have the right to refuse.
      (3) Information about routine screening in the general medical consent/other consent form and about their right to refuse.
      (4) Verbal notice to the patient that an HIV test will be performed as a routine screening with all other tests and that they have the right to refuse.

2. HIV Testing in Non-Health Care Settings: When providing HIV testing in non-health care settings, staff must provide pre-test counseling and face-to-face post-test counseling and obtain informed consent. Informed consent to perform a test for HIV in a non-health care setting need not be in writing

if there is documentation in the medical record that the test has been explained and consent has been obtained. Informed consent must include notification that a positive HIV test result, along with identifying information, will be reported to the CHD and of the availability and location of sites at which anonymous testing is performed. For individual testing, CDC no longer supports extensive pre-test and post-test counseling. Instead, HIV testing providers should conduct brief, information-based sessions tailored to their clients.

3. HIV Risk Assessment: Risk information must be collected for all tests paid for with CDC HIV prevention funding. Risk assessment is an essential element of HIV testing in which the client and counselor work to understand and acknowledge the client's personal risk for HIV. Additional information on HIV risk assessment can be obtained in the HIV/AIDS 501 course and annual update.

   (a) All persons aged 13–64 should be screened for HIV at least once in their lifetime and more frequently based on their individual risk (per 2006 CDC recommendations).

   (b) When conducting the risk assessment, it is important to assure the client that all information is confidential under Florida law. All HIV counseling sessions should be conducted face-to-face, with the client and counselor behind a closed door. If sessions are conducted in an outreach setting, all precautions should be taken to ensure confidentiality. This could include the counselor and client moving away from other individuals and/or encouraging clients to meet with their counselor in the clinic. Partners, spouses, relatives, and others may only be permitted in the room or in the counseling area for translation purposes when no interpreters are available unless the test site is conducting the Couples HIV Counseling and Testing intervention (refer to the Couples HIV Counseling and Testing manual). With client permission, a third party may be allowed in the room for monitoring.

   (c) Risk assessment allows the counselor and client to identify, acknowledge, and understand the specific details of the client's own HIV risks and the contexts in which risk occurs (refer to the HIV/AIDS 501 manual).
      (1) Information from the risk assessment should be documented in the client record and on the DH 1628 data collection form, as specified in the *HIV Counseling, Testing and Linkage Forms Instruction Guide*.
      (2) Clients identified as being at risk should be strongly encouraged to accept testing.
      (3) Because clients' HIV risk may not always be identified by HIV counselors or acknowledged by clients, any client who requests a test should be given one.

4. HIV pre-test counseling should include:

   (a) Purpose of the HIV test, including medical indications.
   (b) Possibility of false-positive or false-negative result.
   (c) Possible need for confirmatory testing.
   (d) Possible need for retesting.
   (e) Availability, benefits, and confidentiality of partner notification services.
   (f) Need to eliminate high-risk behavior.
   (g) Advising all pregnant women of the need to know their HIV status, the risk to unborn children, and the treatment regimens that are available to reduce the risk of perinatal transmission. Florida law requires that all pregnant women receive opt-out testing for HIV, chlamydia, gonorrhea, syphilis, and hepatitis B at their first prenatal medical appointment and again at 28–32 weeks gestation. A DH Form 1631, *Statement of Objection,* must be completed when a pregnant woman declines HIV testing.
   (h) Documentation of information from the pre-test counseling session in client records and on the DH 1628 data collection form as specified in the *HIV Counseling, Testing and Linkage Forms Instruction Guide.*

5. Informed Consent (Non-Health Care Settings Only)

   (a) No person shall perform a HIV antibody test on an individual without first obtaining the consent of the test subject or their legal representative. Limited exceptions to obtaining informed consent can be found in section 381.004(2)(h), Florida Statutes. When written, informed consent is obtained, DH Form 1818, *Consent Form,* may be used. Documentation of informed consent must be recorded in the medical record. Specimen collection should only take place after informed consent has been obtained. This will eliminate the possibility of testing clients without consent. See model protocol for non-health care settings.

   (b) Clients who accept testing may complete the appropriate side of DH Form 1818, *Consent Form*, as specified in the *HIV Counseling, Testing and Linkage Forms Instruction Guide*. The counselor will assess the client's ability to read the consent form and will assist the client as needed. Reasonable accommodations should be made for those who need them.

   (c) When obtaining informed consent from the client, the counselor should explain the following:
      (1) The meaning of "confidential" and the client's right to confidential treatment of information identifying the subject of the test and the results of the test to the extent provided by law, and that Florida law provides penalties for breaches of confidentiality.
      (2) A positive test result is reported to the local CHD in a way

similar to other infection reporting. HIV infection reporting should not be presented in such a way as to deter confidential testing. HIV infection reporting allows Department staff to offer follow-up activities, including post-test counseling for those who do not return for test results, linkages to medical and psychosocial services, and voluntary PS.

(3) A list of anonymous test sites is available at the local CHD or at floridaaids.org.

6. HIV Post-Test Counseling

(a) Post-test counseling should include:
(1) The meaning of the test results.
(2) The possible need for additional testing.
(3) The need to reduce risk behavior.

(b) Negative and inconclusive post-test counseling should include:
(1) The availability of PrEP for persons at increased risk for HIV acquisition.
(2) The need for retesting due to recent possible exposure or inconclusive results. Most people who have acquired HIV will develop detectable HIV antibodies within three months of exposure. Persons with initial inconclusive results should be retested immediately. Persons with continued inconclusive results after one month are highly unlikely to have acquired HIV and should be counseled as though they are HIV negative, unless recent exposure is suspected, per the CDC Revised Counseling, Testing and Referral Guidelines. A specific return date should be given for all retesting.

(c) Positive post-test counseling should include:
(1) The importance of initiating immediate antiretroviral therapy (ART). Studies show the sooner treatment is initiated, the better the health outcomes. Research has also shown that the “test and treat” strategy has the potential to lower HIV incidence by reducing community viral load, a population-based measure of HIV virus levels within a local community. People with HIV who start treatment before their immune systems are moderately damaged are 96 percent less likely to transmit the virus to a partner.
(2) Information on the availability of medical and support services; on the importance of notifying partners that may have been exposed, including spouses from the past 10 years, of their potential exposure; and on preventing HIV transmission. Information should also be given on options for eliminating and/or reducing the transmission of HIV to the individual and/or partners.

Florida law imposes strict penalties upon those who knowingly transmit HIV infection to others (sections 384.24 and 384.34, Florida Statutes).

(3) Informing all pregnant women who test positive for HIV of the benefits of ART during pregnancy and where they can go to obtain medication and that breastfeeding can transmit HIV. In addition, all pregnant women who test positive for HIV antibodies should be referred to the local Targeted Outreach for Pregnant Women Act (TOPWA) program, Healthy Start Coalition, or medical case management. HIV testing should be encouraged for the baby's father and the woman's other children, as appropriate.

(4) Risk reduction planning, including for risk of additional infection exposure and transmission to others. This may include discussion of abstinence and/or safer sex practices, not sharing needles, proper cleaning of injection materials, and condom use. The client should also be informed of the penalties for criminal transmission of HIV (section 384.34, Florida Statutes); reasons not to donate blood, blood products, semen, tissues, and organs; and the importance of protecting their immune system.

(5) Client's past and present sex and/or needle-sharing partners who may have been exposed to HIV. All clients with HIV must be asked if they have or have had a spouse at any time within the 10-year period prior to their HIV diagnosis. If so, the client should be informed of the importance of notifying their spouse or former spouse(s) of the potential exposure to HIV. The client must be informed of the availability of confidential PS through the CHD STD Program for their spouse or former spouse(s) and any sex or needle-sharing partners.

C. Partner Services

1. PS is one of the most effective HIV prevention strategies and should always be done by trained staff and in accordance with TAG 360-11, "Field Services for Clients with a Diagnosed STD, a Positive STD Laboratory Finding or a Known or Suspected Exposure," and IOP 360-30, "Partner Services for Persons Infected with a STD by a Non-STD Epidemiologist."

2. Due to the sensitive nature of identifying and locating partners, PS should be performed by a qualified disease intervention specialist (DIS) who is trained in these techniques. Pursuant to section 384.26, Florida Statutes, only the Department and its authorized representatives may conduct PS. The CHD STD Program is responsible for all PS activities, regardless of where the client was originally tested. Other CHD staff may elicit information regarding partners, but only STD DIS can perform

notification of partners. Each test site should establish and maintain a good rapport with their local CHD STD Program to facilitate the provision of PS to clients who test positive.

3. If the client indicates they will not participate in PS and will not notify their spouse or ex-spouse(s), the tester has no authority to notify the spouse, former spouse(s) and/or other sex/needle-sharing partners, with the following exception: Pursuant to section 456.061, Florida Statutes, health care practitioners who are regulated through the Department's Division of Medical Quality Assurance can notify sex and/or needle-sharing partners of patients with HIV, under certain circumstances, in compliance with the "Partner Notification Protocol for Practitioners." Liability is not attached to the practitioner's decision to notify partners or not notify partners.

4. Clients who test positive for HIV anonymously need to be informed of the possibility that they may be named as a contact to a partner who has tested positive for HIV. This may result in the CHD STD Program offering the original client HIV counseling and testing and other services. The client will be informed that the DIS is acting on information obtained from a sex and/or needle-sharing partner who has acquired HIV. The counselor should assist the original client in determining the appropriate response.

D. Linkages to Medical Care and Social/Support Services

1. Clients who have tested positive for HIV should be linked immediately to medical care for initiation of ART.

2. Clients who have tested negative but are at increased risk for HIV should be linked to a medical provider for PrEP assessment and initiation.

3. Clients who have tested positive for HIV will be contacted by a DIS for PS.

4. Referral services should be offered to all clients of HIV test sites, particularly those who test positive, who need prevention and other supportive services.

5. Linkages differ from referrals. Linkages require providers to take steps to ensure the client accesses needed services. This may mean the provider makes a phone call to an agency to make an appointment for the client and a follow-up call to the agency to ensure that the appointment was kept. This could also happen through a form that is given to the client with the address and phone number of the agency and a specific contact person. The agency can then send a copy of the form back to the provider with documentation that services were/are being provided to the client. Clients should be provided with assistance in accessing and completing linkages, and completion of linkages should be verified.

6. Other linkage and/or referral needs may include:

(a) TB testing
(b) Case management
(c) Substance abuse prevention and treatment
(d) TOPWA and/or Healthy Start
(e) Prenatal care
(f) Domestic violence counseling
(g) Family planning services
(h) Mental health services
(i) STD and viral hepatitis screening and treatment
(j) Behavioral interventions

E. Quality Assurance

1. Documentation

(a) Proper documentation provides evidence that services were offered and/or provided and that the site is in compliance with Department policies. Appropriate documentation can also minimize the risk of future legal action.

(b) Services should be documented in client records and on HIV testing forms, as specified in the *HIV Counseling, Testing and Linkage Forms Instruction Guide.*

2. Quality Improvement Reviews

(a) EICs are responsible for conducting quality improvement site visits annually to assess the following (refer to IOP 360-07, "Minimum Standards for HIV Counselors, Trainers and Early Intervention Consultants"):
(1) Accessibility of services, including hours of operation, location, availability of supplies and materials such as brochures, posters, forms, and condoms.
(2) Compliance with written policies, procedures, protocols, guidelines, rules, regulations, and laws.
(3) Cultural, linguistic, gender, and age appropriateness of services and materials.
(4) Staff performance/proficiency, such as competence, skills, training, and record keeping procedures, including confidentiality and security.

(b) Test sites should develop their own written quality assurance protocols and should make them available to all staff providing testing and linkage services.

VI. Supportive Data and References

A. Section 381.004, Florida Statutes:

leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0381/Sections/0381.004.html

B. Chapter 384, Florida Statutes:
leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0300-0399/0384/0384ContentsIndex.html

C. Florida Administrative Code, Section 64D-2.004:
flrules.org/gateway/RuleNo.asp?title=HUMAN%20IMMUNODEFICIENCY%20VIRUS%20(HIV)&ID=64D-2.004

D. HIV Counseling and Testing Forms Instruction Guide:
floridaaids.org/prevention/_documents/Counseling_testing/_documents/2016-forms-instruction-guide.pdf

E. IOP 360-07, Minimum Standards for HIV Counselors, Trainers, and Early Intervention Consultants, is available from the DOH SharePoint Central Library.

F. National HIV/AIDS Strategy for the United States:
hiv.gov/federal-response/national-hiv-aids-strategy/overview

G. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*; Revised Guidelines for HIV Counseling, Testing, and Referral; November 9, 2001/50(RR19);1-58:
cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm

H. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*; Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings; September 22, 2006/55(RR14);1-17:
cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

VII. History Notes: Replaces IOP 360-09-16; effective date 09/01/2016.

VIII. Signature and Effective Date

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Date