Updates to Rule 64D-2, F.A.C.; Technical Assistance Guideline 345-9-13 (formerly TA-9); and Model Protocols for HIV Testing

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Division of Disease Control and Health Protection
Bureau of Communicable Diseases
HIV/AIDS and Hepatitis Section
This webinar is intended to update Early Intervention Consultants and county health department testing staff on changes to Florida’s HIV testing rule, model protocols, and technical assistance guidelines.
Background

- 2006, CDC released *Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health-Care Settings*:
  - Intended for all health-care providers in the public and private sectors
  - Does NOT apply to HIV testing in nonclinical settings (e.g. community-based organizations, outreach settings, CHD non-clinical testing programs)

*MMWR; September 22, 2006 / 55(RR14);1-17
Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health-Care Settings

- HIV screening is recommended for patients in all health-care settings
- Persons at high risk for HIV infection should be screened for HIV at least annually.
- HIV screening for patients should be done after the patient is notified that testing will be performed unless the patient declines (opt-out screening*)
- Separate written consent for HIV testing should not be required.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.

*Only allowed with certain populations in Florida
Rule 64D-2, Florida Administrative Code (F.A.C.)

- Revised and became effective January 2013.
- Streamline HIV counseling and testing in CHD clinics and healthcare settings as much as possible within existing laws.
Major changes include:

- CHD clinics are no longer required to provide pre- and post-test counseling but must provide the opportunity.
- While not required, face-to-face post-test counseling is recommended when an individual tests positive.
- Written consent is not required if the person conducting the test documents that informed consent was obtained.
“Clinical” or “Healthcare Settings”

- Clinical or healthcare settings are defined as “any setting devoted to both the diagnosis and care of persons, such as CHD clinics, hospital emergency departments, urgent care clinics, substance abuse treatment clinics, primary care settings, community clinics, mobile medical clinics, and correctional healthcare clinics.”
Clinical or Healthcare Settings in Your County Health Department

Examples of Clinical or Healthcare Settings in County Health Departments Include:

- STD Clinics
- TB Clinics
- Family Planning Clinics
- Adult Health Clinics
- Mobile Medical Units
Non-Clinical or Non-Healthcare Settings in Your County Health Department

- Examples of Non-Clinical or Non-Healthcare Settings in County Health Departments Include:
  - Stand-alone testing program that is not a part of any other clinical service
  - Mobile unit used for non-healthcare such as community education, condom distribution, and outreach
  - Health fairs
  - Community outreach/screening events
Wait - What Were Those Changes Again...?

- CHD clinics are **no longer required** to provide pre- and post-test counseling but **must provide the opportunity**
- While not required, face-to-face post-test counseling is **recommended when an individual tests positive**
- Written consent is not required if the person conducting the test documents that **informed consent** was obtained
What is Pre-Test Counseling?

- Pre-test counseling is a continuation of the risk assessment and includes:
  - Reason for testing
  - More in-depth conversation about HIV transmission
  - Establish or improve client’s perception of risk
  - Develop a plan for risk reduction/elimination

- Completing the DH1628 is NOT pre-test counseling
How can CHDs Provide the Opportunity for Pre-Test Counseling?

- To ensure that healthcare settings provide the opportunity for pre-test counseling, clinical sites could do the following:
  - Post signs and posters in the lobby encouraging HIV testing and stating that pre-test counseling is available upon request.
  - Provide information (verbal, brochure, info sheet, etc.) to clients at the time of the test.
  - Present informational or fact sheets to clients prior to the test (information at check-in, etc.).
  - Have HIV informational videos playing in the lobby.
Pre-Test Counseling

Even though it is not required some clients benefit from pre-test counseling.

As public health professionals we have an obligation to be adequately trained and prepared to provide pre-test counseling.
Post-Test Counseling

- Test results provided in same manner as results from other screening tests
  - Phone Call, Text, E-mail
    - Must ensure client confidentiality (password, PIN, etc.)
- While not required, face-to-face post-test counseling is strongly recommended when an individual tests positive
Informed Consent

Clinical or healthcare settings must still get informed consent, but consent can be verbal

- Person conducting the test documents in the medical record that the test was explained and informed consent was obtained.
- DH1818 can still be used
Informed Consent

When obtaining informed consent, explain that:

- HIV test results and the fact that a person is tested are confidential and protected by law.
- Positive test results, along with identifying information, will be reported to the county health department for follow-up.
- Information regarding anonymous test sites is available at www.floridaaids.org or the local health department.
What *Hasn’t* Changed?

- Risk Assessment
  - Help better understand client’s risk
  - Determine if test is necessary
Risk Assessment

- Assessment includes:
  - Introduction and purpose of session
  - Explanation of confidentiality
  - Assess reason for testing
  - Assess client’s history of testing
  - Assess client’s knowledge of HIV/AIDS
  - Assess client’s perception of risk
  - Assess risk factors (substance use/abuse; STD/hepatitis/TB history; condom use; etc.)
Risk Assessment

- Much of the information is obtained when completing the DH1628
- Sites must complete DH1628
  - Primary form in assessing risk
  - MUST be completed for all HIV tests processed through the state lab or any test paid for by the HIV Prevention program, including all rapid HIV tests
Questions?
Changes to Model Protocols

- Formerly two protocols
- Did not distinguish between CHD clinical and non-clinical settings
  - Model Protocol for HIV Counseling and Testing Conducted Outside County Health Departments and Registered Testing Programs
  - Model Protocol for HIV Counseling and Testing for County Health Departments and Registered Testing Programs
Model Protocol for HIV Testing in Non-Healthcare Settings

- Any site that conducts HIV testing for the sole purpose of identifying infection
- No medical treatment provided
  - CBOs; outreach settings; CHD HIV testing programs; mobile vans
- Consider this “testing as usual”
  - Pre- and post-test counseling required; signed informed consent
Model Protocol for HIV Counseling and Testing in Healthcare Settings

- Divided into three sections
  - HIV Testing in CHD Clinics
  - HIV Testing in Other Healthcare Settings
  - HIV Testing in CHD Clinics and Other Healthcare Settings (applies to testing conducted under sections 1 and 2)
Model Protocol for HIV Counseling and Testing in Healthcare Settings

- Section 1 – HIV Testing in CHD Clinics
  - Provide the opportunity for pre-test counseling
  - Informed consent is required, but does not have to be separate, signed consent
    - Document in medical record
  - Provide opportunity for face-to-face post-test counseling
Model Protocol for HIV Counseling and Testing in Healthcare Settings

Section 2 – HIV Testing in Other Healthcare Settings

- Pre-test counseling is not required
- Informed consent is required, but does not have to be separate, signed consent
  - Document in medical record
- Notification of test results
  - Must make a reasonable effort to return results
- Physician Reporting
Model Protocol for HIV Counseling and Testing in Healthcare Settings

- Section 3 - HIV Testing in CHD Clinics and Other Healthcare Settings
  - Release of Preliminary HIV Test Results
    - 381.004(3)(d), F.S.
    - Results may be released to healthcare providers when decisions about medical care and treatment cannot wait on confirmatory results
Model Protocol for HIV Counseling and Testing in Healthcare Settings

Section 3 - HIV Testing in CHD Clinics and Other Healthcare Settings

- Special Provisions for Pregnant Women
  - 381.34, F.S. and 64D-2.004, F.A.C. requirement for testing for HIV and STDs at first visit and again at 28-32 weeks
  - Opt-out testing
    - Written statement of objection if testing is refused
Section 3 - HIV Testing in CHD Clinics and Other Healthcare Settings

- Repeat Testing

- Healthcare providers should test all persons likely to be at high risk for HIV at least annually

- Use the following to help individual determine their risk
  - Sexual behavior; substance use/abuse; needle sharing; occupational exposure; blood/blood products/transplants; high-risk partners; STD history; etc.
Changes to TAG 345-9-13 (formerly TA-9)

- Provision of HIV Counseling, Testing, and Linkage Services
  - Updated to keep up with technology (e.g. E-mailing site re-registration) and emphasis on linkage rather than referral services
  - Protocols for:
    - HIV prevention counseling; partner services; linkages to medical care and social/support services; quality assurance.
Questions?
Thank You!

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