DOH-Orange: Area 7 Program Office
Protocol for Partnering Organizations to Obtain an MOA for Counseling and Testing

Overview:

Registered HIV test sites requesting an HIV Testing MOA with the DOH-Orange: Area 7 Program Office must initially comply with the below standards outlined in the FDOH IOP 360-09-17 "Provision of HIV Testing and Linkage" prior to review of required Programmatic documents submitted to the review committee:

1. Organizations should contact their local Early Intervention Consultant (EIC) for a new site application packet. The package contains a copy of relevant statutes and administrative rules; the model protocols; an Application to Request a CTL Memorandum of Agreement, and the DH Form 1781 Application Registration for HIV Testing Programs.

2. Organizations must complete the DH 1781 Application for Registration and Registration for HIV Testing Programs and return it to the Early Intervention Consultant (EIC). In addition, potential test sites must submit the Application to Request a CTL Memorandum of Agreement to the contract manager.

3. If DOH is providing support for any portion of HIV testing services, including forms, test supplies and laboratory support to non-DOH test site, a MOA must be negotiated between the Area 7 Program Office and the organization. The potential test site must agree to follow all DOH security and client confidentiality policies and procedures, complete annual rapid testing minimum, participate in Rapid Start treatment program, complete all required reporting for positive diagnosis for HIV and other Sexually Transmitted Infections, participate in quality improvement/technical assistance reviews by CHD and/or HIV/AIDS Section staff, and follow the appropriate model protocol and following applicable technical assistance guidelines. A MOA will not be issued to organizations without a Rapid Testing Site Number.

4. Only one MOA will be granted per organization. Organizations have the option to establish multiple service locations with multiple HIV testing site numbers, however only one MOA will be executed for the entire organization. In addition, the organization cannot have an additional MOA executed for other branches or departments under that original organization.

5. The decision to execute a MOA with an organization is at the discretion of the Department. Based on limited resources, the Department will award MOAs based on community needs and the Department's ability to manage these agreements.

Eligibility:

Potential or registered HIV Testing sites requesting a MOA with the DOH-Orange: Area 7 Program Office must meet the following requirements for the application to be considered by the review committee:

1. Organization applying for a MOA with the Department must be a Not-for-Profit Organization established for at least three years, verifiable through Sunbiz. Not-for-Profit Organizations who

have not been established for at least three years, however, have verifiable experience in providing HIV Prevention or HIV Patient Care services shall also be eligible. Verifiable experience is defined as: an executed contract for the provision of HIV Prevention or HIV Patient Care services, a purchase order for the provision of HIV Prevention or HIV Patient Care services, or have an existing HIV testing site with a completion of at least one hundred and twenty rapid HIV tests under an executed purchase orders or actual grant contract. Not-for-Profit Organizations with verifiable experience should be in good standing with the Department. Good standing shall be defined as, no pending corrective actions or at will terminations.

2. Organization applying for a MOA with the Department must be providing services in Area 7 (Orange, Osceola, Seminole, or Brevard Counties). Organization must provide a physical address of where services will be provided. All contact information and location information should be verifiable in Sunbiz. If an agency is using a DBA, this information must be provided on the application for a MOA with the Department.

3. Organization must provide a person of contact on file with the EIN, a person of contact for daily business, and a person who is authorized to sign a MOA. All positions can be filled by a sole person or multiple personal. Each person(s) of contact listed must be a hired employee of the agency. Consulting agencies or any other corporations hired by the agency for representation will not be accepted as person(s) of contact.

4. Organization must determine if they are a Community Based Organization (CBO) or a Clinical Location. Determination will be confirmed by an on-site inspection conducted by the EIC and another DOH-Orange representative.

    a. If the organization is determined to be a Community Based Organization (CBO), the location must conduct conventional HIV testing for one year. In accordance Florida Department of Health, HIV/AIDS Rapid HIV Testing Site Guidelines, during that one year the agency must reach a one percent positivity rate for newly identified HIV diagnosis. While a testing site number may be issued, the CBO will not be eligible for a MOA until the one year of conventional testing is completed and has reached a one percent positivity rate. This process can be waived if the location has verifiable experience conducting rapid HIV testing, which will be determined by the EIC, review committee, and HIV/AIDS Section staff.

    b. If the organization is determined to be a Clinic or a location providing medical services, the organization will provide a community outreach plan to the Department. Community outreach plan must at a minimum include: populations of focus that outreach will be towards, zip codes with a high co-morbidity for new HIV diagnosis of where outreach will take place, and a hypothesized amount of rapid HIV tests completed on a monthly basis. Outreach plan must be submitted with the application for a MOA and will be reviewed by the review committee for approval. Clinical organizations who do not have a community outreach plan will be guided to continue routine HIV screening and will not be eligible for a MOA.

Application:

Organizations requesting a MOA with the DOH-Orange, : Area 7 Program Office, must complete the following steps and submit the appropriate documentation to the Department for review. The review committee will determine if the location is eligible for a MOA:

1. The Department will accept applications from organizations requesting a MOA during quarterly application periods. Each year the quarterly application period will take place: January 1st through January 15th, April 1st through April 15th, July 1st through July 15th, and October 1st through October 15th. Applications will only be reviewed by the review committee if received before 5:00 PM on the final day of each quarterly application period. Agencies who submit partial applications and are unable to provide all required documentation before the deadline of the quarter in which they are applying, will be required to re-apply the following quarter.

Application Opens	Applications Closes	MOA Start Date	MOA End date (Two Years)
January 1	January 15	April 1	March 31
April 1	April 15	July 1	June 30
July 1	July 15	October 1	September 30
October 1	October 15	January 1	December 31

2. Submit the DH Form 1781 Application Registration for HIV Testing Programs and the Application to Request a CTL Memorandum of Agreement to the Department. Applications should also include all current License of Certificates or Numbers to practice in the State of Florida (NPI number) of all physicians, advanced registered nurse practitioners, physician assistants and other licensed or certified health professionals that provide any of the services set forth in MOA.

3. Submit the following documents in addition to the application(s):

    a. CLIA (Clinical Laborites Amendment Act) Certificate/Waiver
    b. Biomedical Waste Permit and Biomedical Waste Plan
    c. Exposure Control Plan and Needle-stick procedure (OSHA)
        i. Written control plan designed to eliminate or minimize employee exposures to occupation risks.
    d. Policies and Procedures relating to Confidentiality (HIPAA)
        i. Written procedure concerning protection and confidentiality of Protected Health Information (PHI) including but not limited to, the Health Insurance Portability Accountability Act of 1996(HIPAA).
        ii. Written procedure concerning the storage, retention, and disposal of PHI records.

e. Standard Operation Procedure (SOP) relating to Quality Assurance
    i. Written procedure concerning assessing or evaluating quality; identifying problems or issues with care delivery and designing quality improvement activities to overcome them.
f. SOP relating to participation in the Rapid Start Treatment Program
g. Community Outreach Plan (if applicable)
h. Linkage to Care Plan for New HIV Diagnosis (CBO only)
i. Linkage to PrEP and nPEP Services Plan (CBO only)

4. Organization applicants must complete a successful on-site inspection to be conducted by the EIC and an another DOH representative. The on-site inspection must be scheduled prior to the quarterly application period deadline, in which the organization is applying. The Department will schedule on-site inspection with the agency and will provide all expectations prior to the appointment. On-site inspection will ensure organization's physical location is aligned with the Florida Department of Health, HIV/AIDS Rapid HIV Testing Site Guidelines and will also confirm if the organization is a CBO or a clinic.

    a. EIC and DOH- Representative will determine if the Organization has successfully completed the on-site inspection.
        i. If the on-site inspection is not successful, the EIC will determine if the deficiencies can be resolved within a time frame that would allow the organization to maintain their eligibility during the quarter in which they are applying.
        ii. If deficiencies cannot be resolved within a time frame that would allow the organization to maintain their eligibility during the quarter in which they are applying, the organization will be required to reapply at the next quarterly application period from which the deficiencies have been resolved.

    Applications and all documentation must be submitted to:
    CHD48Area7Submissions@flhealth.gov

Review:

Upon completion of a successful on-site inspection and receipt of the DH Form 1781 Application Registration for HIV Testing Programs, the Application to Request a CTL Memorandum of Agreement, and all additional supporting documentation, the review committee will determine if the agency will be granted a MOA/MOU based on the criteria. The review committee will consist of: the EIC, HIV/AIDS Program Manager (HAPC), Area 7 Program Office Contract Manager, and a staff representative from the DOH-Orange Business Office; and will meet each quarter to review all applications received prior to the submission deadline. Based on the review committee's decision:

1. Organization applicants who are determined eligible and thus granted a MOA/MOU, the contract manager will follow the current DOH-Orange steps for executing a new agreement.

Upon execution of the MOA/MOU, EIC will submit supporting documentation to the HIV/AIDS Section for the issuance of a HIV Testing Site Number.

2. Organization applicants who are not determined to be eligible and thus denied a MOA/MOU will receive an official letter detailing the denial. In addition, the agency will be guided that they will be eligible to reapply after four quarters from the denial. It should be known that an agency can still receive a HIV Testing Site Number if they so choose, however, they will not be eligible for state support.

The review committee must unanimously agree to move forward with executing a MOA with a potential testing site. The committee will have thirty (30) days from the submission deadline to determine a final decision.

Organization Requirements:

Organizations who are granted a MOA with the DOH-Orange: Area 7 Program Office must agree to the following requirements to maintain their agreement with the Department:

1. Provide confidential HIV testing and counseling free of charge to all residents of Area 7. No clients shall be turned away due to financial situation. Organization must also maintain the annual testing minimum of one hundred and twenty (120) tests each year and maintain a one percent positivity rate for newly identified HIV diagnosis to remain in good standing.

2. Clinical locations must provide treatment, regardless of the client's ability to pay, to all clients with a positive HIV diagnosis. Clinical locations will also provide treatment for Sexually Transmitted Infections (STI), regardless of the client's ability to pay, to clients with a positive diagnosis.

3. CBOs, who do not have a clinic available, will be required to provide a linkage to care plan for persons with a positive HIV diagnosis. This plan must be approved by the Department prior to execution of the MOA.

4. Agencies must screen all clients who receive a rapid HIV test for PrEP and nPEP eligibility.

    a. Clinical organizations must initiate PrEP and nPEP services~~,~~ regardless of the client's ability to pay, to clients who are determined to be eligible. Agencies must maintain a 25% referral rate of clients referred into PrEP/nPEP services.

    b. Organizations must document all PrEP referrals to eligible clients on the quarterly progress report. In addition to receiving a negative test for HIV and showing a general interest in PrEP, referrals are required for clients who match the following specific eligibility of: receiving a positive diagnosis for a STI other than HIV, currently having a sexual partner who is living with HIV, currently completing and finishing a PEP regimen

for HIV, or has had more than one rapid HIV test in the past twelve months. A reason must be provided on the quarterly progress report for any clients, who match the specific eligibility, and are not referred into PrEP services.

c. Organizations will agree to be listed as PrEP and nPEP provider within the Area 7 service network. CBO's, who do not have a clinic available, will be required to provide a linkage to care plan for persons initiating PrEP and nPEP services. This plan must be approved by the Department.

5. Organizations must complete the DH1628 form for each rapid HIV test conducted either electronically through the CTLS system or manually. Manual forms must be sent to the or HIV/AIDS Section by the tenth of the following month. Manual forms must be mailed to: HIV/AIDS Section 4025 Esplanade Way Tallahassee, FL 32399 Attention: Rapid Testing Data/Room 304.

6. Organization must report all new HIV diagnosis to the DOH-Orange, HIV/AIDS Surveillance Program within seventy-two hours of the diagnosis. In addition, clinics must report all new STI diagnosis to DOH-Orange STD Surveillance within seventy-two hours of the diagnosis. Case reporting forms will be provided by the Department.

7. Organization will participate in the Area 7 Rapid Start Treatment Network. Rapid start shall be defined as the initiation of Antiretroviral Treatment (ART) no later than seven days of the initial HIV diagnosis or if previously diagnosed, the initial date of interaction with the client. Clinics must agree to be advertised as a member of this network and be available to provide treatment, regardless of the client's ability to pay, within the time frame to clients. Rapid Start SOP will be submitted with the application for a MOA/MOU. CBO's will be required to show proof of partnership with a Rapid Start location within the network if a clinic is not available, to be approved by the Department.

8. Organization will link pregnant women with risk factors for HIV or have a HIV positive diagnosis to their local Targeted Outreach for Pregnant Women Act (TOPWA) program. The current TOPWA contact information will be made available by the Department. Agency will also report each case of pregnant woman with an HIV diagnosis within seventy-two hours of diagnosis to the local TOPWA program, local perinatal HIV prevention program, DOH-Orange HIV/AIDS Surveillance Program, and the Department's Statewide Perinatal Coordinator.

9. Organization will agree to join DOH-Orange Area 7 Program Office email distribution list and ensure representation at quarterly provider meetings and engagements.

10. Organization will agree to , participate in quality improvement/technical assistance reviews by CHD and/or HIV/AIDS Section staff, and follow the appropriate model protocol and following applicable technical assistance guidelines.

11. Complete a quarterly report to indicate how many rapid tests were conducted, how many were linked to HIV medical care, outreach locations, and contact made through outreach. Quarterly reports will be sent to the contract manager by the 20th of the following month.

Execution Date	First Summary Due Date	Second Summary Due Date	Third Summary Due Date	Fourth/Year-End Summary Due Date
January 1	April 20	July 20	October 20	January 20
April 1	July 20	October 20	January 20	April 20
July 1	October 20	January 20	April 20	July 20
October 1	January 20	April 20	July 20	October 20

Renewal and Termination:

Organizations who are granted a MOA with the DOH-Orange: Area 7 Program Office will be held to the following regarding a renewal or termination of an agreement with the Department:

1. Organizations will be eligible for a renewal for their MOA agreement upon successful completion of the above requirements. Contract manager will review received quarterly reports, testing completed verified through CTLS, and ensure that there is no pending corrective action before initiating renewal process.

    a. Agencies must request a renewal in writing no later than sixty (60) days prior to the expiration of the current agreement. Failure for the agency to request a renewal prior to the specified deadline will result in the expiration of the MOA and the agency must reapply during the next quarterly application period.

    b. Department will review received quarterly progress reports from the agency and determine if the provider was able to maintain annual testing minimum, 25% Prep and nPEP referral rate, 1% positivity rate for newly identified HIV diagnosis, and successful compliance of all other tasks specified in the MOA. If the Department can determine that all tasks were completed, the MOA will be renewed for an additional term.

Execution Date	End Date (2 Years)	Deadline to Request a Renewal
January 1	December 31	November 1
April 1	March 31	February 1
July 1	June 30	May 1
October 1	September 30	August 1

2. Failure for an agency to adhere to the above requirements will result with a Corrective Action Plan (CAP) issued to the agency. Once a CAP has been issued, the agency must respond to the Department within five (5) business days and address all deficiencies, in addition, the agency must provide a timeline of when all deficiencies will be resolved within the next quarter. The CAP will be required to be approved by the Department before the agency can implement the appropriate corrections. The Department will review the CAP progress after one quarter and determine if the agency has successfully fulfilled the requirements of the CAP, or if MOA shall be terminated. Such termination will be reported to the Florida Bureau of Communicable Diseases and to HRSA 340B Program. Agencies with a terminated MOA will not be eligible to reapply for a MOA until after four quarters from the termination date and have successfully resolved all identified deficiencies.