



HIV Planning and Coordination
Health Care Agency

**OUTPATIENT/AMBULATORY HEALTH
SERVICES
STANDARDS OF CARE**

FOR

HIV SERVICES IN ORANGE COUNTY

Approved by Planning Council 3/13/24

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SECTION 1: INTRODUCTION

The goal of Outpatient/Ambulatory Health Services is to ensure accessible HIV/AIDS primary and specialty medical care, including family-centered care, and to enable adherence to treatment plans, that is consistent with the US Public Health Service Guidelines. In addition, outpatient/ambulatory medical health services are designed to interrupt or delay the progression of HIV disease, prevent and treat opportunistic infections, and promote optimal health. All services and interventions must be based on proven clinical methods and in accordance with legal and ethical standards. The services delivered shall reflect a philosophy of service delivery that affirms a patient's right to privacy, confidentiality, self-determination, nondiscrimination, compassionate and non-judgmental care, dignity, and respect.

Goals of the Standards. These standards of care are provided to ensure that Orange County's outpatient/ambulatory health services:

- Are accessible to all persons living with HIV (PLWH) who meet eligibility requirements
- Promote continuity of care, patient monitoring, and follow-up
- Enhance coordination among service providers to eliminate duplication of services
- Provide opportunities and structure to promote patient and provider education
- Maintain the highest standards of care for patients
- Protect the rights of PLWH
- Increase patient self sufficiency and quality of life
- Provide a framework to foster ethical and nondiscriminatory practices

SECTION 2: DEFINITION OF OUTPATIENT/AMBULATORY HEALTH SERVICES

Outpatient/Ambulatory Health Services provide diagnostic and therapeutic-related activities directly to a client by a licensed healthcare provider in an outpatient medical setting. Outpatient medical settings may include: clinics, medical offices, mobile vans, using telehealth technology, and urgent care facilities for HIV-related visits.

Treatment Adherence services provided during an Outpatient/Ambulatory Health Service visit are considered Outpatient/Ambulatory Health Services, whereas treatment adherence activities provided during a Medical Case Management visit are considered Medical Case Management services.

Allowable activities include:

- Medical history taking
- Physical examination
- Diagnostic testing (including HIV confirmatory and viral load testing), as well as laboratory testing
- Treatment and management of physical and behavioral health conditions
- Behavioral risk assessment, subsequent counseling, and referral
- Preventive care and screening
- Pediatric developmental assessment
- Prescription and management of medication therapy
- Treatment Adherence
- Education and counseling on health and prevention issues
- Referral to and provision of specialty care related to HIV diagnosis, including audiology and ophthalmology

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the Public Health Service's Health Services Guidelines. Such care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies. Current Public Health Service Guidelines are available online at: <https://hivinfo.nih.gov>

Diagnostic testing includes only testing procedures and applications as approved by the Health Resources and Services Administration (HRSA) for funding under the Ryan White Act. The policy describing the use of Ryan White Act Program funds for HIV diagnostics and laboratory tests is available online at:

<https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/hivdiag-test-pn-0702.pdf>

SECTION 3: STAFFING REQUIREMENTS AND QUALIFICATIONS

Quality medical care services starts with well-prepared and qualified staff. To ensure this, outpatient/ambulatory health services providers must meet all of the following requirements and qualifications:

- 3.1. Licensure.** Practitioners of medical care services include licensed practitioners and unlicensed practitioners who practice under the supervision of a licensed medical

professional and as mandated by their respective licensing boards. All licenses must be valid and in good standing.

- **Licensed Practitioners**

- **Physicians (MDs or DOs):** Physicians must have a valid license to practice medicine in the State of California (Medical Board of California or California Board of Osteopathic Examiners). Certification by the American Academy of HIV Medicine (AAHIVM) is strongly encouraged.

Physicians providing routine primary HIV medical care shall meet any one of the following four criteria consistent with the definition of “HIV Specialist” as defined by California Assembly Bill 2168¹:

- (1) Is credentialed as an “HIV Specialist” by the AAHIVM; **or**
 - (2) Is board certified, or has earned a certificate of Added Qualification, in the field of HIV medicine granted by a member board of the American Board of Medical Specialties, should a member board of that organization establish board certification, or a Certificate of Added Qualification, in the field of HIV medicine; **or**
 - (3) Is board certified in the field of infectious diseases by a member board of the American Board of Medical Specialties and meets the following qualifications:
 - (A) In the immediately preceding 12 months has clinically managed medical care to a minimum of 25 patients who are infected with HIV; **and**
 - (B) In the immediately preceding 12 months has successfully completed a minimum of 15 hours of category 1 continuing medical education in the prevention of HIV infection, combined with diagnosis, treatment, or both, of HIV-infected patients, including a minimum of 5 hours related to antiretroviral therapy per year; **or**
 - (4) Meets the following qualifications:
 - (A) In the immediately preceding 24 months, has clinically provided medical care to a minimum of 20 patients who are infected with HIV; **and**
 - (B) Has completed any one of the following:
 - In the immediately preceding 12 months has obtained board certification or re-certification in the field of infectious diseases; **or**
 - In the immediately preceding 12 months has successfully completed a minimum of 30 hours of “Category 1 Continuing Medical Education” in the prevention, diagnosis, and treatment of HIV-infected patients; **or**
 - In the immediately preceding 12 months has successfully completed a minimum of 15 hours of “Category 1 Continuing Medical Education” in the prevention, diagnosis, and treatment of HIV-infected patients **and** successfully completed the “*HIV Medicine Competency Maintenance Examination*” administered by the *American Academy of HIV Medicine*
- **Resident Physicians:** Physicians must have a valid license to practice medicine in the State of California (Medical Board of California or California Board of

¹ Assembly Bill (AB) 2168 definition of “HIV Specialist” effective as of January 16, 2003

Osteopathic Examiners) and will receive supervision in accordance with state requirements.

- **Physician Assistants (PAs):** PAs must have graduated from a medical training program approved by the California Physician Assistant Committee, and must have passed the Physician Assistance National Certifying Examination (PANCE) offered by the National Commission on Certification of Physician Assistants (NCCPA). PAs must complete continuing education as required by the appropriate licensing board. PAs authorized by supervising physicians to issue prescriptions for medication and medical devices must do so in compliance with the Physician Assistant Practice Act.

It is highly recommended that PAs routinely providing HIV medical care become certified as an HIV Specialist by the AAHIVM.

- **Nurse Practitioners (NPs):** Nurse Practitioners must possess licensure as a Registered Nurse certified to practice in the State of California, a Nurse Practitioner certificate, or Master's degree from a school accredited by the California Board of Registered Nursing. NPs must complete continuing education as required by the appropriate licensing board. In order to prescribe medicine, the NP must complete a pharmacology course and work six (6) months under a physician's supervision and hold a Drug Enforcement Administration (DEA) license.

It is highly recommended that NPs routinely providing HIV medical care become certified as an HIV Specialist by the AAHIVM

- **Clinical Nurse Specialist (CNS):** Clinical Nurse Specialists must achieve successful completion of a master's program with a clinical field of nursing which conforms with the standards set forth in the California Business and Professions Code or must possess certification by a national organization/association whose standards are equivalent to those set forth in the California Business and Professions Code. National organizations/associations that have met such CNS certification requirements include: 1) American Association of Critical-Care Nurses; 2) American Nurses Association – American Nurses Credentialing Center; and 3) Oncology Nursing Certification Corporation.²
- **Registered Nurses (RNs):** RNs must hold a license from the California Board of Registered Nurses (BRN), be a graduate from an accredited nursing program with a bachelor's (BSN) or two year nursing associate's degree, and must practice within the scope of practice defined in the California Business and Professions Code.
- **Licensed Vocational Nurses (LVNs):** LVNs must hold a license from the California Board of Vocational Nursing and Psychiatric Technicians (BVNPT), must be a graduate of a vocational nursing program that is accredited by the BVNPT, and must practice within the scope of practice defined in the California Business and Professions Code.

- **Unlicensed Practitioners**

² California Board of Registered Nursing

- **Medical Assistants (MAs):** MAs must receive certification from one of following certifying agencies approved by the Medical Board of California: 1) American Association of Medical Assistants; 2) American Medical Technologists; 3) California Certifying Board of Medical Assistants.
- **Medical Students:** Medical students/interns will practice within the scope of practice as defined by a university affiliation agreement and will receive supervision in accordance with state and federal requirements.
- **Additional Professional Staff**
 - Other staff providing services to patients in a primary medical care setting (e.g. dietitians, health educators, pharmacists, pharmacy assistants, case managers, social workers, etc.) shall provide services in accordance with their respective professional and/or licensing organizations.
 - Non-licensed medical care staff providing services to patients shall have initial and annual training/education on HIV/ related issues. Education can include round table discussion, training, one-on-one educational sessions, in-service, or literature review. Topics may include: 1) HIV disease process and current medical treatments; 2) Privacy Requirements and Health Insurance Portability and Accountability Act (HIPAA) regulations; 3) Human sexuality, gender, and sexual orientation affirming care; 4) Cultural issues related to communities affected by HIV/AIDS; and/or 5) Transmission of HIV and other communicable diseases

3.2. Legal and Ethical Obligations. Practitioners must be aware of and able to practice under the legal and ethical obligations as set forth by California state law and their respective professional organizations. Obligations include the following:

- **Continuity of Care:** Physicians have an obligation to support continuity of care for their patients and should not neglect a patient once a physician-patient relationship has been established. While physicians have the option of withdrawing from a case, they cannot do so without giving advanced notice to the patient sufficiently long in advance to permit another medical attendant to be secured³.
- **Potential Patients:** Physicians cannot refuse to care for patients based on race, gender, sexual orientation, gender identity, or any other criteria that would constitute invidious discrimination, nor can they discriminate against patients with infectious diseases⁴.
- **Confidentiality:** Maintenance of confidentiality is a primary legal and ethical responsibility of the practitioner. Limits of confidentiality include danger to self or others, grave disability, and child/elder/dependent adult abuse. Domestic violence must be reported according to California mandated reporting laws.
- **Duty to warn:** Serious threats of violence (including physical violence, serious bodily harm, death, and terrorist threats) against a reasonably identifiable victim must be reported to authorities. However, at present, in California, a PLWH engaging in behaviors that may put others at risk for HIV infection is not a circumstance that warrants breaking of confidentiality. Only certain healthcare practitioners may notify

³ As specified in Opinion 8.115 of the American Medical Association (AMA) Code of Medical Ethics

⁴ As specified in Opinion 10.05 of the AMA Code of Medical Ethics

identified partners who may have been infected within specific guidelines⁵. Staff should follow their agency’s policies and procedures in relation to duty to warn.

- Practitioners are advised to seek legal advice when they are unsure about particular issues and the legal/ethical ramifications of their actions.

| Standard | Measure |
|---|---|
| Service providers will ensure that all practitioners providing medical care services will be appropriately licensed through their respective licensing body | Documentation of licensure on file |
| Non-licensed outpatient/ambulatory health services professionals receive initial and annual education regarding HIV/AIDS in any of the following categories: 1) HIV disease process and current medical treatments; 2) Privacy requirements and HIPAA regulations; 3) Human sexuality, gender, and sexual orientation affirming care; 4) Cultural issues related to communities affected by HIV; and 5) Transmission of HIV and other communicable diseases | Training/education documentation on file including: <ul style="list-style-type: none"> • Date, time, and location of the education • Education type • Name of the agency and staff receiving education • Certificate of training completion or education outline, meeting agenda and/or minutes |
| Medical care practitioners will have a clear understanding of job responsibilities | Written job description on file signed by medical care practitioner and supervisor |
| Medical care practitioners will possess skill, experience, and licensing qualifications appropriate to provision of medical care and treatment modalities utilized | Résumé and current license on file |
| Licensed medical care practitioners are encouraged to seek consultation as needed | Documentation of consultation on file, as needed |
| Unlicensed Medical Assistants will receive supervision in accordance with state requirements | Documentation of supervision on file |
| Medical care practitioners will practice according to California state law and the code of ethics of their respective professional organizations | Documentation on file including: <ul style="list-style-type: none"> • Documentation of ethics training/education • Documentation of legal consultation, as applicable • Grantee review of grievances and patient complaints |

SECTION 4: CULTURAL AND LINGUISTIC COMPETENCE

Staff must participate in a process of training and education that increases cultural and linguistic competence and improves their ability to provide culturally and linguistically appropriate services to all PLWH. Although an individual’s ethnicity is generally central to their identity, it

⁵ As specified in California Health and Safety Code Section 121015

is not the only factor that makes up a person’s culture. Other relevant factors include gender, language, religious beliefs, disability, sexual orientation, beliefs, and institutions. When providing culturally and linguistically competent services, it is important to acknowledge one’s personal limits and treat one’s patient as the expert on their culture and relation to it. If a practitioner determines that they are not able to provide culturally or linguistically appropriate services, they must be willing to refer the patient to another practitioner or service provider that can meet the patient’s needs in accordance with their agency’s referral policy and procedure .

Based on the Health and Human Services’ National Standards for Culturally and Linguistically Appropriate Services (CLAS Standards), culturally and linguistically appropriate services and skills include:

- Effective, equitable, understandable, and respectful services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.
- The ability to respect, relate, and respond to a client’s culture in a non-judgmental, respectful manner.
- Meeting the needs and providing services unique to our clients in line with the culture and language of the clients being served, including providing written materials in a language accessible to all clients.
- Recognizing the significant power differential between provider and client and work toward developing a collaborative relationship.
- Considering each client as an individual, not making assumptions based on perceived memberships in any specific group or class.
- Translation and/or interpretation services to individuals who have limited English proficiency and/or other communication needs, at no cost to them, to facilitate timely access to all services.
- Ensure the competence of individuals providing language assistance, recognizing that the use of untrained individuals and/or minors as interpreters should be avoided.
- Being non-judgmental in regards to people’s sexual practices.
- Create conflict and grievance resolution processes that are culturally and linguistically appropriate to identify, prevent, and resolve conflicts or complaints.

| Standard | Measure |
|---|--|
| Service providers shall recruit a diverse staff that reflects the culture (including gender, sexual identity, and disability) of the community served | Service providers shall have a written strategy on file |
| All staff (including administrative staff) will receive initial training within 60 days of hire and annual training to build cultural and linguistic competence | Training/education documentation on file including: <ul style="list-style-type: none"> • Date, time, location, and provider of education • Education type • Name of staff receiving education |

| Standard | Measure |
|--|---|
| | <ul style="list-style-type: none"> • Certificate of training completion or education outline, meeting agenda, and/or minutes |
| Service providers shall have posted and written materials in appropriate languages for the patients served | Site visit will ensure |

SECTION 5: CLIENT REGISTRATION

Client registration is required for all patients who request Outpatient/Ambulatory Health Services and shall be initiated at the time a patient presents for services. It is a time to gather registration information and provide basic information about Outpatient/Ambulatory Health Services and other HIV services, as appropriate. It is also a pivotal moment for establishment of trust and confidence in the care system. Service providers shall provide an appropriate level of information that is helpful and responsive to patient need. Outpatient/Ambulatory Health Services staff shall conduct the client registration with respect and compassion.

If a patient is receiving multiple Ryan White or EHE services with the same provider, registration only needs to be conducted one (1) time. *With the exception of Releases of Information specific to medical information and Mental Health Consent for Treatment*, it is acceptable to note that eligibility, registration, and required documents discussed in this section were verified and exist in another patient service record at the same provider agency.

If a client has been referred by another Ryan White or EHE provider to receive services and the client has opted to share their AIDS Regional Information and Evaluation System (ARIES) data, the provider receiving the referral does not have to collect registration information. The provider shall review ARIES to ensure all registration data has been collected and is documented in ARIES. If the client is non-share in ARIES, the referring provider may provide registration information or the provider receiving the referral shall gather registration information from the client. Provision of information regarding Client Rights and Responsibilities and Client Grievance Process may be conducted one-time at the referring provider agency. To document the provision of this information, the referring provider may send the provider receiving the referral a signed document indicating that they have provided this information to the client.

5.1. Timeframe. Registration shall take place as soon as possible, at maximum within five (5) business days of initial patient contact. If there is an indication that the patient may be facing imminent loss of medication or is facing other forms of medical crisis, registration will be expedited and appropriate intervention may take place prior to formal intake.

5.2. Eligibility Determination. The service provider shall obtain the necessary information to establish the patient’s eligibility. See Requirements to be Eligible and Qualify for Services document: <https://ohealthinfo.com/about-hca/public-health->

[services/services/diseases-conditions/disease-information/hiv-planning/services/resources/hiv-pcs.](#)

- 5.3. Demographic Information.** The service provider shall obtain the appropriate and necessary demographic information to complete registration; this includes basic information about the patient's HIV medical history, living situation, employment and financial status, service linkages, and emergency contact information. Based on this information, the service provider may also determine the patient's share-of-cost for services.
- 5.4. Provision of Information.** The service provider shall provide information to the patient about the medical services they are receiving. The service provider shall also provide the patient with information about resources, care, and treatment (this may include the county-wide HIV Client Handbook) available in Orange County.
- 5.5. Required Documentation.** The service provider shall develop the following forms in accordance with state and local guidelines. The following forms shall be signed and dated by each patient.
- **ARIES Consent:** Service providers shall inform clients of ARIES and obtain ARIES consent. The ARIES consent must be signed at registration prior to entry into the ARIES database and every three (3) years thereafter. The signed consent form shall indicate (1) whether the client agrees to the use of ARIES in recording and tracking their demographic, eligibility, and service information and (2) whether the client agrees to share select information contained in ARIES with other agencies in the Ryan White system of care.
 - **Confidentiality and Release of Information:** When discussing patient confidentiality, it is important *not* to assume that the patient's family or partner knows the HIV-positive status of the patient. Part of the discussion about patient confidentiality should include inquiry about how the patient wants to be contacted (at home, at work, by mail, by phone, etc). If there is a need to disclose information about a patient to a third party, including family members, patients shall be asked to sign an Authorization to Disclose (ATD)/ Release of Information (ROI) form, authorizing such disclosure. A Release of Information form describes the situations under which a patient's information can be released and includes the name of the agency and/or person with whom information will be shared, the specific information to be shared, duration of the release consent, and the patient's signature. This form may be signed at registration prior to the actual need for disclosure. Information disclosed will be limited to the narrowest scope of information that meets the immediate need of disclosure. Releases of information may be cancelled or modified by the patient at any time. For agencies and information covered by the Health Insurance Portability and Accountability Act (HIPAA), the Release of Information must be a HIPAA-compliant disclosure.
 - **Consent for Treatment:** Signed by the patient, agreeing to receive medical care services/treatment.

The following forms shall be signed and dated by each patient receiving medical care services and posted in a location that is accessible to patients. For documents available in the HIV Client Handbook, completed forms may indicate that the patient has received the HIV Client Handbook.

- **Notice of Privacy Practices (NPP):** Patients shall be informed of the service provider’s policy regarding privacy rights based on their confidentiality policy. For agencies and information covered by HIPAA, service providers shall comply with HIPAA guidelines and regulations for confidentiality.
- **Client Rights and Responsibilities:** Patients shall be informed of their rights and responsibilities (included in the HIV Client Handbook).
- **Client Grievance Process:** Patients shall be informed of the grievance process. The grievance process is included in the HIV Client Handbook and applies to grievances that are administrative in nature. Grievance appeals specifically related to medical, clinical, and/or HIPAA issues should be filed with the Orange County Health Care Agency’s Office of Compliance.

5.6 Resources: Each new client receiving Outpatient/Ambulatory Health Services will receive information on available resources/services at the facility and within the county that is applicable to them.

| Standard | Measure |
|---|---|
| Registration process began within five (5) business days of initial contact with patient. | Intake tool is completed and in patient service record |
| Eligibility for services is determined | Client’s record includes proof of eligibility and qualification |
| Registration information is obtained | Patient’s service record includes data required for Ryan White Services Report |
| ARIES Consent signed and completed prior to entry into ARIES | Signed and dated by patient at initial visit and every three years thereafter and in patient service record |
| Authorization to Disclose (ATD)/Release of Information (ROI) is discussed and completed as needed | Signed and dated by patient and in patient service record as needed |
| Consent for Treatment completed | Signed and dated by patient and in patient service record |
| Patient is informed of Notice of Privacy Practices | Signed and dated by patient or documented patient refusal to sign and in patient service record |
| Patient is informed of Rights and Responsibilities | Signed and dated by patient or documented patient refusal to sign and in patient service record |
| Patient is informed of Grievance Procedures | Signed and dated by patient or documented patient refusal to sign and in patient service record |
| Client receives information on available resources/services at the facility and within the | Documented in the patient service record |

| Standard | Measure |
|------------------------------------|---------|
| county that is applicable to them. | |

SECTION 6: SCREENING

Ryan White Outpatient/Ambulatory Health Services

Ryan White service providers shall conduct a screening of the client’s needs and eligibility/qualification for Ryan White funded Outpatient/Ambulatory Health Services. For Ryan White funded Outpatient/Ambulatory Health Services the client must meet the following:

- Meet eligibility screening (HIV positive and Orange County resident), income, and payer of last resort criteria
- Be re-screened for eligibility/service qualification annually or when a change has occurred that impacts a client’s eligibility for services

| Standard | Measure |
|--|--------------------------------|
| Eligibility /service qualification screening conducted annually or when a change has occurred that impacts a client’s eligibility for services | Documentation in client record |

EHE Initiative Outpatient/Ambulatory Health Services

EHE service providers shall conduct a screening of the client’s needs and eligibility/qualification for EHE funded Outpatient/Ambulatory Health Services. For EHE funded Outpatient/Ambulatory Health Services the client must meet the following:

- Meet eligibility screening criteria (HIV positive)
- Meet payer of last resort criteria

| Standard | Measure |
|---|--------------------------------|
| Client meets eligibility screening (HIV positive) and payer of last resort criteria | Documentation in client record |

SECTION 7: SERVICE MANAGEMENT

Once patient intake and assessment has been conducted, the service provider may offer the appropriate range of services to the patient. Service management shall be consistent with the following principles.

7.1 Service Delivery

- Services shall be delivered in a manner that promotes continuity of care.

- Service providers shall refer patients to other agencies if they cannot provide a level of service that is medically, culturally, linguistically, or otherwise appropriate for the needs of the patients.

7.2 Confidentiality

- Service provider agencies shall have a policy regarding informing patients of privacy rights, including use of Notice of Privacy Practices. For agencies and information covered by HIPAA, service providers shall comply with HIPAA guidelines and regulations for confidentiality.

7.3 Service Planning

- Where service provision options are substantially equivalent, the least costly alternative shall be used in meeting the needs of patients.
- Services shall be planned, managed, and monitored to avoid the need for urgent or emergency services, the interruption of services, and need for emergency or unplanned appropriations of funding to continue services during contract periods.

7.4 Documentation and Data Collection

- Program and administrative staff shall provide adequate data collection in a timely manner and documentation of all services provided for accounting, reporting compliance, and evaluation purposes.
- Program data shall be entered into ARIES within five (5) business days as specified in contract or scope of work.
- Service providers shall document and keep accurate records of units of services for use in reporting units of service for reimbursement and community planning.
- Service providers shall gather and document data (e.g. demographic, eligibility, and risk factor information) for the Ryan White Services Report.

7.5 Compliance with Standards and Laws

- Service directors and managers shall ensure compliance with all relevant laws, regulations, policies, procedures, and other requirements designed to enforce service standards and quality.
- Services shall be consistent with standards set forth in this document.
- Laboratories from which tests were ordered must be certified, licensed, or FDA approved.

| Standard | Measure |
|--|--|
| Service provider shall have procedure to address walk-ins, telephone triage, and emergencies and after-hour care | Written procedure in place |
| Service provider shall have procedure for making referrals to offsite services | Written procedure in place |
| Service provider shall have policy regarding informing patients of privacy rights, including use of Notice of Privacy Practices; for covered agencies and information, policy shall be consistent with HIPAA regulations | Written policy on file |
| Staff shall be aware of confidentiality policy via training upon employment and annually thereafter | Documentation of education or training on file |

| Standard | Measure |
|--|--|
| Service provider shall ensure patient information is in a secured location | Site visit will ensure |
| Service provider shall screen patients to ensure the least costly service is used as appropriate to patient needs; screening shall occur at minimum when patient is accessing a new service and periodically as the patient's needs change | <ul style="list-style-type: none"> • Written procedure in place • Documentation of patient screening and determination on file • Site visit will ensure |
| Service provider shall regularly review patient charts to ensure proper documentation including progress notes | Written procedure in place |
| Service providers shall document and keep accurate records of units of services | Site visit and/or audit will ensure |
| Required client data and services shall be entered in ARIES | Required data fields will be validated by the RSR |
| Service directors and managers shall ensure compliance with all relevant laws, regulations, policies, procedures, and other requirements designed to enforce service standards and quality | Site visit and/or audit will ensure |
| Laboratories from which tests were ordered must be certified, licensed, or FDA approved | Site visit and/or audit will ensure |

SECTION 8: MEDICAL EVALUATION

Proper assessment/evaluation of patient need is fundamental to medical care services. Outpatient/Ambulatory Health Services providers shall provide a thorough evaluation of all patients to determine the appropriate level of care and to develop a therapeutic treatment plan. Each HIV-infected patient entering into care should have a complete medical history, physical examination, laboratory/diagnostic evaluation, and counseling regarding the implications of HIV infection. The purpose is to confirm the presence of HIV infection, obtain appropriate baseline historical and laboratory data, assure patient understanding about HIV infection, and initiate care as recommended by the HIV primary care guidelines and by the opportunistic treatment and prevention guidelines. Baseline information then is used to define management goals and plans.

8.1 Timeframe. The medical evaluation process shall begin at the patient's initial visit with a medical practitioner and may take more than one session, depending on the patient's medical and emotional state. Medical evaluations shall be conducted at a minimum of every six (6) months or more frequently as medically indicated.

8.2 Medical History. The medical history is a time to gather information regarding the patient's past medical conditions. Items that may be included in the medical history include but are not limited to:

- History of HIV illness, including date of HIV diagnosis and AIDS diagnosis, if applicable
- History of HIV medical care including most recent medical visit
- Current and previous HIV medication regimen and adherence to previous/current medication regimens
- Difficulties tolerating prescribed treatment regimens
- Most recent cluster of differentiation 4 (CD4) and viral load counts (if available)
- Results of prior resistance testing (if any)
- History of previous opportunistic infections
- History of sexually transmitted diseases (STDs)
- History of comorbidities including any other acute or chronic medical conditions (e.g., asthma, diabetes, heart problems, etc.)
- History of positive purified protein derivative (PPD) skin test or interferon-gamma release assay (IGRA)
- Allergies and information about previous allergic reaction(s)
- Vaccination history

8.3 Diagnostic Tests.

Unless medically contraindicated, patients should receive the following diagnostic tests at the time treatment is initiated in order to obtain a baseline for the patient. After baseline test results are obtained, diagnostic testing should be conducted based on the time frames provided in the table provided below and more frequently if medically indicated. Copies of diagnostic lab results should be included in the patient service record.

- HIV Antigen/Antibody, HIV 1 or HIV 2 antibody, and/or HIV RNA
- Complete Blood Count (CBC) with Differential and Platelet Count
- Chemistry Panel
- CD4 Count
- Viral Load
- RPR and/or Enzyme Immunoassays/Chemiluminescent immunoassay/Treponema Pallidum Particle Agglutination assay(EIA/CIA/TPPA)
- Toxoplasmosis Titer
- Mantoux interdermal PPD skin test or IGRA
- Chest x-ray (if indicated)
- Hepatitis A antibody
- Hepatitis B antibody
- Hepatitis C antibody
- Pregnancy Test when indicated
- Pap Smear scheduled according to ACOG guidelines when indicated

8.4 Physical Examination. A comprehensive physical examination shall be conducted at the time of the patient's first visit with a medical practitioner. Physical examinations should be conducted as medically indicated and should include a complete systems assessment. Physical examination findings in addition to course of treatment shall be documented in patient progress notes and/or treatment plan.

8.5 Education. Medical care is patient centered and therefore, information regarding diagnostic results, prognosis, risks and benefits of treatment, instructions for treatment management and follow-up, and treatment adherence shall be discussed with the patient. Additionally, HIV risk reduction and prevention education shall be provided utilizing the state model for Early Intervention and Prevention services that are designed to reduce high-risk drug and sexual behaviors and promote positive health actions. Patient education is ongoing and is the responsibility of all ambulatory/outpatient medical care practitioners.

8.6 Partner Services: Partner Services information should be offered and referrals should be made for clients according to established processes.

8.7 Reassessments. Reassessments shall be conducted at a minimum of every six (6) months or more frequently whenever health and situational changes make it helpful and necessary to do so. Significant changes noted through reassessments may signal changes in the progression of HIV, which may necessitate changes in treatment. Reassessments may also be indicated when a patient presents with a new or exacerbated complaint and/or symptoms. Allergy status shall be documented at each visit and the problem and medication lists shall be appropriately updated.

8.8 Documentation. Patient service records shall include documentation of all patient contacts, evaluation findings, observations, procedures, diagnoses, education provided, and other information pertinent to patient care. The following are required documentation of the medical evaluations/examinations:

- Progress notes shall include:
 - Date and reason for visit
 - Interventions and referrals provided
 - Results of interventions and referrals
 - Progress towards treatment plan outcomes
 - Newly identified issues/objectives
 - Patient’s responses to interventions and referrals
 - Other observations
 - Signature of medical practitioner conducting the evaluation and date of visit
- Problem lists shall be based on identified issues and must include acute and chronic medical conditions. For each problem, the date of onset and the date the problem was resolved shall be documented.
- Medication lists shall include current medications and shall be updated as medications are prescribed and/or discontinued
- Documentation of patient education (risk reduction, prevention, adherence to treatment regimens, nutrition, health maintenance, etc.)

| Standard | Measure |
|---|---|
| Medical evaluations are conducted based on medical necessity or a minimum of every six (6) months | Documentation in patient service record |
| Progress notes are signed and dated by medical | Documentation in patient service record |

| Standard | Measure |
|--|--|
| practitioner conducting the evaluation | |
| Medical history is obtained at initial medical visit | Documentation in patient service record |
| Comprehensive physical examination is conducted on initial medical visit with practitioner and as medically indicated | Documentation in patient service record |
| Allergy status is documented at each medical visit. | Documentation in patient service record |
| TB screening since diagnosis | Documentation of TB screening in patient service record |
| <p>CD4 tests conducted every 3-6 months to:</p> <p>(1) Assess immunologic response to ART; and</p> <p>(2) Assess the need for initiation or discontinuation of prophylaxis for opportunistic infections</p> <p>For patients whose CD4 count has increased well above the threshold for opportunistic infection risk, CD4 count can be monitored every 6-12 months.</p> | Documentation of lab report in patient service record or documentation if not clinically indicated |
| <p>Viral load tests conducted:</p> <p>(1) Every 3-4 months or as clinically indicated; and</p> <p>(2) At initiation or change in therapy</p> <p>Interval may be extended to every 6 months for adherent patients who have suppressed viral loads for more than 2-3 years and whose clinical and immunologic status is stable.</p> | Documentation of lab report in patient service record or documentation if not clinically indicated |
| Chemistry Panel is conducted at a minimum annually | Documentation of lab report in patient service record |
| Complete Blood Count (CBC) with differential and platelet count conducted at a minimum annually | Documentation of lab report in patient service record |
| Pap smear conducted based on ACOG guidelines | Documentation in patient service record |
| Allergy status documented at each visit | Documentation in patient service record |
| Documentation of each medical evaluation/assessment | <p>Signed and dated note in patient service record to include:</p> <ul style="list-style-type: none"> • Date and reason for visit • Interventions and referrals provided • Results of interventions and referrals • Progress towards treatment plan outcomes • Newly identified issues/objectives |

| Standard | Measure |
|--|---|
| | <ul style="list-style-type: none"> • Patient’s responses to interventions, procedures, and medications • Other observations |
| Problem list updated as appropriate | Signed and dated problem list in patient service record includes: <ul style="list-style-type: none"> • Acute and chronic medical conditions • Date of onset of problem • Date problem was resolved (if applicable) |
| Medication list updated as appropriate | Signed and dated medication list in patient service record includes: <ul style="list-style-type: none"> • Current medications • Date medication(s) prescribed • Date medication discontinued (if applicable) |
| Practitioners shall document results and outcomes of visit | Signed and dated progress notes in patient service record include: <ul style="list-style-type: none"> • Date of visit • Outcomes of evaluation and or physical examination • Signature of the medical practitioner conducting the evaluation |
| Patient education is provided | Documentation of education provided in patient service record includes: <ul style="list-style-type: none"> • Date of education • Type of education provided |
| Partner services information is offered | Documentation that partner services information was offered and referrals were made if needed |

SECTION 9: PSYCHOSOCIAL ASSESSMENT

PLWH must often cope with multiple medical, social, and psychiatric issues that are best addressed through a multidisciplinary approach to the disease. The evaluation must also include assessment of mental illness, nutritional status, oral health, substance use, economic factors (e.g., unstable housing), social support, high-risk behaviors, and other factors that are known to impair the ability to adhere to treatment and that promote HIV transmission. Once evaluated, these factors should be managed accordingly. Psychosocial assessments shall be conducted by medical care practitioners of outpatient/ambulatory health services annually.

The Psychosocial Assessment shall, at a minimum, assess the following:

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| Mental Health Issues |
| <ul style="list-style-type: none"> ◦ History of and current mental health issues ◦ Mental health treatment history |

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| <ul style="list-style-type: none"> ◦ Resources/referrals for mental health issues, if applicable |
| Nutritional Assessment <ul style="list-style-type: none"> ◦ Assess for items such as loss of appetite, nausea, vomiting, diarrhea, difficulty chewing/swallowing ◦ Access to food ◦ Diet and exercise ◦ Recent weight changes ◦ Lipid screening if indicated ◦ Resources/referrals for nutritional services, if applicable |
| Oral Health Assessment <ul style="list-style-type: none"> ◦ Visual assessment/exam of oral cavity ◦ Referral to oral health care services, if applicable |
| Substance Use <ul style="list-style-type: none"> ◦ History and extent of current substance use ◦ Tobacco use assessment ◦ Resources/referrals for substance use issues, if applicable |

| Standard | Measure |
|--|---|
| Medical psychosocial assessment conducted annually and includes, but is not limited to: <ul style="list-style-type: none"> • Mental health assessment • Nutrition assessment • Oral health assessment • Substance use assessment | Documentation of annual psychosocial assessment in patient service record |

SECTION 10: TREATMENT PLAN

Once medical and psychosocial needs have been assessed, medical care practitioners shall work in collaboration with patients to identify and prioritize medical care needs that will be addressed through medical care services. This process is documented and included in the treatment plan. The plan provides a map for the medical care practitioner on how to address needs in a manner that best promotes the health and medical needs of the patient. The treatment plan shall be reviewed and/or revised and signed and dated at each routine medical visit.

The treatment plan shall include:

- Statement of the problems and/or symptoms to be addressed during treatment
- Changes in patient’s medical condition
- Interventions proposed
- Referrals and linkages to other needed services
- Signature and date by the medical care practitioner developing the treatment plan.

| Standard | Measure |
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| Treatment plans must be completed and/or reviewed and revised at each routine medical | Signed and dated treatment plan documented in patient service record |

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| visit and must be signed and dated by the medical care practitioner who completed the assessment/evaluation | |
|---|--|

SECTION 11: TREATMENT PROVISION

All medical care treatment will be consistent with the United States Public Health Service treatment guidelines (www.aidsinfo.nih.gov/) and will be guided by the care needs expressed in the treatment plan. Practitioners shall be knowledgeable about outcome research and utilize clinically proven treatment for their patient’s presenting problems. Medical treatment and the prescription of antiretrovirals and prophylactic medications shall conform to the standards of care recognized within the general community and supported by clinically published research for the patient’s condition.

Treatment provision is documented through progress notes, treatment plans, problem lists, and medication lists.

SECTION 12: SPECIALTY MEDICAL CARE

In order to fully comply with the Public Health Service Guidelines, specialty medical services are provided by tertiary care providers for medical services that are beyond the scope of Ryan White Outpatient/Ambulatory Health Services primary medical care clinics. Specialty medical care services include the provision of outpatient infectious disease and other specialty medical care, including but not limited to: Obstetrics, Hepatology, Neurology, Oncology, Immunology, Pulmonology, Ophthalmology, Dermatology, Radiation Oncology, and Psychiatry. A physician, physician’s assistant, clinical nurse specialist, or nurse practitioner must render these services. Specific services include diagnostic testing, preventative care and screening, practitioner examination, medical history, and treatment of common physical and mental conditions.

Outpatient/Ambulatory Health Services providers are responsible for assessing a patient’s need for specialty care and should provide appropriate referrals as needed. Specialty care services are considered consultative and as such, patients shall be referred back to the original outpatient/ambulatory health services clinic for ongoing primary HIV medical care.

For Ryan White funded Outpatient/Ambulatory Health Services, specialty medical care shall be limited to those services authorized by the Orange County Health Care Agency (HCA). A prior authorization form authorizing specialty medical care services shall be completed by the Medical Director of 17th Street Testing, Treatment and Care for each specialty referral. A copy of the specialty referral in addition to a copy of a signed prior authorization form shall be retained in each patient’s service record. All referrals to specialty medical care shall be tracked and monitored by both the referring provider and the specialty medical care administrator.

Specialty medical care appointments shall be provided within three (3) weeks of the request for service or sooner, if the medical condition warrants.

| Standard | Measure |
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| Treatment is consistent with the United States | Chart review will ensure |

| Standard | Measure |
|--|--|
| Public Health Service Guidelines | |
| Copies of the Specialty Medical Care referrals and the signed prior authorization form shall be retained in each patient's file | Signed documents in patient service record |
| All Specialty Medical Care referrals shall be tracked and monitored | Record of Specialty Medical referrals made and status of referral. Record should include: <ul style="list-style-type: none"> • Date of referral • Date of Specialty appointment • Status of Specialty treatment |
| Specialty Medical Care appointments and visits shall be provided within three (3) weeks of request for service or sooner, if warranted | Documentation of referral and service date on file |

SECTION 13: REFERRAL/COORDINATION/LINKAGES

In many cases, patients will require services in addition to those that a given agency is able to provide. For instance, referrals to specialty medical care services shall be provided to patients who require care beyond the scope of an outpatient/ambulatory health services primary care clinic. Similarly, if a patient's psychosocial assessment reveals that a patient requires mental health services, it is incumbent upon medical practitioners to refer the patient to additional mental health services including psychiatric evaluation. Referrals to other services including case management, dental treatment, and supportive services shall also be made as indicated.

It is imperative that outpatient/ambulatory health services providers collaborate and implement formal relationships with other providers in order to provide the full spectrum of HIV services for patients. Referrals to other health care and social service providers are made as the patient's health status indicates and/or when the needs of the patient cannot be met by the outpatient/ambulatory health services provider's established range of services. Outpatient/ambulatory health services providers must develop written policies and procedures that facilitate referral to other health and social service providers in the local HIV/AIDS Continuum of Care. All referrals must be documented in the patient service record.

| Standard | Measure |
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| As needed, service providers will refer patients to a full range of services including but not limited to: <ul style="list-style-type: none"> • Mental health services including psychiatric evaluation • Case management • Other supportive services as needed | Signed and dated note to document referrals in patient service record |

SECTION 14: OUTPATIENT/AMBULATORY HEALTH SERVICES SERVICE CLOSURE

Medical services are considered the most critical aspect to a patient's physical and psychological well-being and as such, closure from medical care services must be carefully considered and reasonable steps must be taken to assure patients who need medical care are maintained in services.

A client may be closed from outpatient/ambulatory medical care services due to the following conditions:

- The client has become ineligible for services.
- The client no longer contacts the provider for services and/or chooses to terminate services.
- The client's needs would be better served by another agency.
- The client demonstrates unacceptable behavior that violates client rights and responsibilities.
- The client cannot be located.
- The client has died.

14.1 Efforts to Find Client. The service provider shall periodically query data systems to identify patients who appear to be lost to care. If the patient is receiving case management, the medical provider may work with the case manager to locate the patient. It is recommended, but not mandatory, that at least three (3) attempts to contact the patient are made over a period of three (3) months. Efforts shall be made to locate and contact a patient who has not shown up for appointments or responded to provider's phone calls. These efforts shall include contacting last known provider(s) for which releases have previously been obtained. Patients who cannot be located after extensive attempts may be referred to available outreach services so that they may be linked back into the care system.

14.2 Closure Due to Unacceptable Behavior. The service provider may decide to first verbally and/or in writing give the patient a warning of service termination if unacceptable behavior (which is described to the client) violates patient rights and responsibilities including excessive missed appointments continues. Termination may be immediate if the client or family member has threatened service provider staff with violence or has exhibited threatening behavior. If it is decided that closure is necessary, the service provider shall provide notice regarding intent to terminate services in person, by phone and/or written notice as soon as possible after the determination to terminate has been made. The service provider shall notify the patient in writing that their services are being terminated. The notification shall state that termination is effective 30 days or more from the date of the letter (or it may state the termination is already in effect which may have been decided due to violence or threatening behavior). Within the limits of patient's authorization to receive mail, notification of closure shall be mailed to the patient using certified mail, return receipt requested. The letter does not have to specify

the reason for termination and phrases such as “inability to achieve or maintain rapport” or “the therapeutic clinician/patient relationship no longer exists” may be used. At a minimum, the letter shall include⁶

- The last day the physician/medical practitioner will be available to render medical care, assuring the patient has been provided at least 15 days of emergency treatment and prescriptions before discontinuing the physician's/medical practitioner’s availability.
- Remind the patient that continued clinical care is the client’s responsibility and should be pursued.
- Alternative sources of medical care, i.e., refer patient to other physicians/medical practitioners, by name, or to the local medical society's referral service.
- The information necessary to obtain the medical records compiled during the patient's care (whom to contact, how and where).
- A copy of the notification shall be placed in the patient’s chart. If the patient has no known address or the service provider is not authorized to send mail to the patient, the service provider shall document other types of notification of closure (e.g. phone calls, visit) or attempts to notify the patient of closure. If the patient does not agree with the reason for closure, they shall be informed of the service provider’s grievance procedure.

14.3 Outpatient/Ambulatory Health Services Service Closure Summary. An Outpatient/Ambulatory Health Services service closure summary shall be documented in the patient’s record and if applicable, documents related to the written notification of service termination shall be filed in the client’s record. The Outpatient/Ambulatory Health Services service closure summary shall include the following:

- Circumstances and reasons for closure
- Diagnosis at closure
- Referrals and linkages provided at closure

14.4 Data Collection Closeout. The provider shall close out the patient in the data collection system (ARIES) as soon as possible, but no later than thirty (30) days of outpatient/ambulatory health services service closure. For patients receiving services other than outpatient/ambulatory health services at the same provider agency, the provider shall coordinate efforts between services to ensure that data collection closeout occurs no later than thirty (30) days of closure from all Ryan White services at that provider agency.

| Standard | Measure |
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| Follow up will be provided to patients who have dropped out of treatment without notice | Signed and dated note to document attempt to contact in patient service record |
| Notify patient regarding closure if due to unacceptable behavior violating patient rights and responsibilities | Copy of notification in patient service record. If patient has no known address or is unable to receive mail, documentation of other types of |

⁶As specified by the Medical Board of California <http://www.medbd.ca.gov/licensee/terminate.html>

| Standard | Measure |
|--|---|
| | notification or attempt at notification in patient service record. |
| An Outpatient/Ambulatory Health Services service closure summary shall be completed for each patient who has terminated treatment | Patient service record will include signed and dated mental health service closure summary to include: <ul style="list-style-type: none"> • Diagnosis at closure • Referrals made • Reason for termination |
| Closeout of data collection shall be completed for each patient who has been closed from all Ryan White services at that provider agency | Data collection system (ARIES) will indicate patient's closure no later than thirty (30) days of service closure |

SECTION 15: QUALITY MANAGEMENT

Ryan White Part A providers, and other funded providers if applicable, shall have at least one (1) member on the Health Care Agency's Quality Management (QM) Committee. The QM Committee will oversee quality management activities for all funded services. Providers may continue to have their own QM committee if they desire and/or are required to do so under other funding streams. The intent of a centralized QM committee with representation from all providers is to ensure information between agencies is consistent, quality initiatives are undertaken by all funded agencies, and service delivery issues can be addressed system wide.

As providers participate in the centralized QM committee, the intent is for all providers to actively participate in and provide feedback on the following items:

- Providers shall participate in community-wide Quality Improvement initiatives as developed by the QM committee, if applicable.
- Providers will implement strategies that may lead to improvements in health outcomes as outlined in annual Performance Outcome Goals.
- Providers will implement quality assurance strategies that improve the delivery of services.

| Standard | Measure |
|--|--|
| Providers shall participate in annual quality Initiatives, if applicable | Documentation of efforts to participate in quality initiatives |

Appendix A. Glossary of Terms

The terms defined in the appendix are general terms used throughout all of the standards of care and may not appear in the each individual standard.

Americans with Disabilities Act of 1990 (ADA): The ADA is a civil rights law that prohibits discrimination against individuals with disabilities in all areas open to the general public. The purpose of the law is to make sure that people with disabilities have the same rights and opportunities as the general public.

ARIES: The AIDS Research Information and Evaluation System (ARIES) is a centralized HIV/AIDS client management system that allows for coordination of client services among medical care, treatment and support providers and provides comprehensive data for program reporting and monitoring. ARIES is used by Ryan White-funded service providers to automate, plan, manage, and report on client data.

Authorization to Disclose (ATD): Signed consent by client that wants to grant another individual or organization access to their protected health information (PHI).

Client: Individual receiving services.

Eligibility for EHE Services: Is based on Health Resources Services Administration (HRSA) requirements and is limited to proof of HIV status. Providers are responsible for verifying this information.

Eligibility for Ryan White/and or HOPWA Services: Is based on Health Resources Services Administration (HRSA) and/or Housing Opportunities for Persons with AIDS (HOPWA) requirements. It includes that a person must have proof of HIV status, proof of Orange County residency, and proof of payer of last resort. Providers are responsible for verifying this information.

Ending the HIV Epidemic (EHE) Initiative: Federal program whose purpose is to focus resources in areas most impacted by HIV to implement effective and innovative strategies to reduce new HIV infections in the United States by at least 75% in 2025 and by at least 90% in 2030.

Eligibility Verification Form (EVF): Form used to document a client's eligibility for Ryan White services. Information includes but is not limited to contact, income, household, and insurance information.

Grant Recipient: Government recipient of Ryan White Part A funds. In Orange County, the Orange County Health Care Agency acts as the Grant Recipient for Ryan White Part A funds.

Health Insurance Portability and Accountability Act of 1996 (HIPAA): Is the US federal legislation that provides data privacy and security provisions for safeguarding medical information. More information can be found through US Department of Health & Human Services at <https://www.hhs.gov/hipaa/for-professionals/index.html>.

HIV Planning Council (Council): Provides advice and makes recommendations to the County regarding HIV policy issues, service needs of the community, and allocates funds to each service funded under the Ryan White Act and advises the County on Housing Opportunities for People with AIDS (HOPWA) funds.

Notice of Privacy Practice (NPP): A notice to clients that provides a clear, user friendly explanation of client's rights with respect to their personal health information and the privacy practices of health plans and health care providers as required by HIPAA.

Payer of last resort: Funds are used to pay for care services that are not covered by other resources such as Medi-Cal or private health insurance.

Payer of last resort: Funds are used to pay for care services that are not covered by other resources such as Medi-Cal or private health insurance.

Protected Health Information (PHI): Under US law, any information about health status, provision of health care, or payment for health care that is created or collected by a covered entity such as a health plans, health care clearinghouses, and health care providers as defined by HIPAA rules that can be linked to a specific individual.

Provider: An institution or entity that receives funding to provide Ryan White services. This includes a group of practitioners, clinic, or other institution that provide Ryan White services and the agency at which services are provided.

Qualifying for a service: Based on Ryan White, EHE, and/or HOPWA eligibility and Planning Council determined requirements (for example, income less than 150% of Federal Poverty Level for Ryan White funded Medical Transportation Services), providers are responsible for ensuring that services provided adhere to qualifying requirements.

Release of Information (ROI): Signed consent by client that wants to grant another individual or organization access to their protected health information (PHI).

Ryan White Act: Federal legislation first authorized in 1990 that created Ryan White HIV/AIDS Program which provides a comprehensive system of care that includes primary medical care and essential support services for people living with HIV who are uninsured or underinsured.

Staff: An individual who directly provides Ryan White, EHE, and/or HOPWA funded services, oversees the provision of services, or perform administrative functions for services. This may include paid employees, subcontractors, volunteers, or interns.