OUTPATIENT/AMBULATORY MEDICAL CARE STANDARDS OF CARE

FOR

RYAN WHITE ACT-FUNDED SERVICES IN ORANGE COUNTY

Effective March 1, 2013

COUNTY OF ORANGE
HEALTH CARE AGENCY

Ryan White Act

Outpatient/Ambulatory Medical Care Standards of Care

TABLE OF CONTENTS

SECTION 1: INTRODUCTION

The goal of outpatient/ambulatory medical care 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 consisted with the US Public Health Service Guidelines. In addition, outpatient/ambulatory medical care 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 Ryan White-funded outpatient/ambulatory medical care services:

- Are accessible to all persons infected with HIV 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 persons living with HIV/AIDS
- Increase patient self sufficiency and quality of life
- Provide a framework to foster ethical and nondiscriminatory practices

SECTION 2: DEFINITION OF OUTPATIENT/AMBULATORY MEDICAL CARE SERVICES

Outpatient/ambulatory medical care services are therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist, or nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where patients do not stay overnight. Emergency room services are not outpatient settings.

Primary activities for outpatient/ambulatory medical care services include:

- Diagnostic testing
- Early intervention and risk assessment
- Preventative care and screening
- Practitioner examination
- Medical history taking
- Diagnosis and treatment of common physical and mental conditions
- Prescribing and managing medication therapy
- Education and counseling on health issues
- Continued care and management of chronic conditions
- Medication adherence
- Referral and provision of specialty care, including all medical subspecialties

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 http://www.aidsinfo.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 http://hab.hrsa.gov/law/0702.htm .

SECTION 3: STAFFING REQUIREMENTS AND QUALIFICATIONS

Quality medical care services starts with well-prepared and qualified staff. To ensure this, Ryan White 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 2168[1]:

(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 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)

[1] Assembly Bill (AB) 2168 definition of "HIV Specialist" effective as of January 16, 2003

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**
  - **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.

[2] California Board of Registered Nursing

- **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. dieticians, 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/AIDS-related issues. Education can include round table discussion, training, one-on-one educational sessions, in-service, or literature review. Topics may include: 1) Medical issues; 2) HIV/AIDS transmission; 3) Psychosocial issues related to HIV/AIDS; and/or 4) Cultural issues related to communities affected by HIV/AIDS.

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 secured[3].
- **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 diseases[4]
- **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, child/elder abuse and, in some cases, domestic violence.
- **Duty to warn:** Serious threats of violence against a reasonably identifiable victim must be reported. However, at present, in California, a person living with HIV engaging in behaviors that may put others at risk for HIV infection is not a circumstance that warrants breaking of confidentiality. Only certain physicians may notify identified partners who may have been infected within specific guidelines[5].
- Practitioners are advised to seek legal advice when they are unsure about particular issues and the legal/ethical ramifications of their actions.

Standard	Measure
Provider will ensure that all practitioners providing medical care services will be	Documentation of licensure on file

[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
[5] As specified in California Health and Safety Code Section 121015

Standard	Measure
appropriately licensed through their respective licensing body	
Non-licensed outpatient/ambulatory medical care professionals receive initial and annual education regarding HIV/AIDS in any of the following categories: 1) Medical issues; 2) HIV/AIDS transmission; and 3) Psychosocial issues; and 4) Cultural issues	Training/education documentation on file including: • Date, time, and location of the education • Education type • Name of the agency and medical care practitioner(s) receiving education • 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: • Documentation of ethics training/education • Documentation of legal consultation, as applicable • Grantee review of grievances and patient complaints

SECTION 4: CULTURAL AND LINGUISTIC COMPETENCE

Providers 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 persons living with HIV/AIDS. Although an individual's ethnicity is generally central to his/her identity, it is not the only factor. Other relevant factors include gender; language; religious beliefs; disability; sexual orientation; the totality of socially transmitted behavior patterns, arts, beliefs, institutions; and other products of human work and thought characteristic of a community or population. In 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 he/she is not able to provide culturally or linguistically appropriate services, he/she must be willing to refer the patient to another practitioner or provider that can meet the patient's needs.

Culturally and linguistically appropriate services:

- Respect, relate, and respond to a patient's culture in a non-judgmental, respectful manner

- Match the needs and reflect the culture and language of the patients being served, including providing written materials in a language accessible to patients
- Recognize the significant power differential between provider and patient and work toward developing a more collaborative interaction
- Consider each patient as an individual, not making assumptions based on perceived membership in any group or class

Standard	Measure
Providers will recruit a diverse staff that reflects the culture (including gender, sexual identity, and disability) of the community served	Providers have a written strategy on file
All staff (including administrative staff) will receive initial and annual training to build cultural and linguistic competence	Training/education documentation on file including: • Date, time, location, and provider of education • Education type • Name of staff receiving education • Certificate of training completion or education outline, meeting agenda, and/or minutes
Provider shall have posted and written materials in appropriate languages for the patients served	Site visit will ensure
Providers will maintain a physical environment that is welcoming to the populations served	Site visit will ensure
Provider shall maintain visible suggestion box or other client input mechanism.	Site visit and/or audit will ensure
Agency complies with American Disabilities Act (ADA) criteria	Completed form/certification on file
Services are accessible to community served	Site visit to review hours of operation, location, accessibility with public transportation

SECTION 5: PATIENT INTAKE

Patient intake is required for all patients who request outpatient/ambulatory medical care services and shall be initiated at the time a patient presents for services. Intake is a time to gather registration information and provide basic information about outpatient/ambulatory medical care and other HIV services, as appropriate. It is also a pivotal moment for establishment of trust and confidence in the care system. Practitioners shall provide an appropriate level of information that is helpful and responsive to patient need. Medical care provider staff shall conduct the patient intake with respect and compassion.

If a patient is receiving multiple Ryan White services with the same provider, intake need only be conducted one 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.

5.1. Timeframe. Intake shall take place as soon as possible, at maximum within five 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, the intake process will be expedited and appropriate intervention may take place prior to formal intake.

5.2. Eligibility Determination. The provider shall obtain the necessary information to establish the patient's eligibility. This includes verifying documentation of the patient's HIV status, lack of medical care coverage, income, and residency within Orange County (See Eligibility Requirements and Checklist Spreadsheet under separate cover for complete list of eligibility requirements).

5.3. Demographic Information. The 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 provider may also determine the patient's share-of-cost for services.

5.4. Provision of Information. The provider shall provide information to the patient about the medical services he/she is receiving. The 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 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:** Patients shall be informed of the AIDS Regional Information and Evaluation System (ARIES). The ARIES consent must be signed at intake prior to entry into the ARIES database and every three years thereafter. The signed consent form shall indicate (1) whether the patient agrees to the use of ARIES in recording and tracking their demographic, eligibility and service information and (2) whether the patient 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 a Release of Information 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 intake prior to the actual need for 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 provider's policy regarding privacy rights based on the provider's confidentiality policy. For agencies and information covered by HIPAA, 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.

Standard	Measure
Intake process began within five business days of initial contact with patient.	Intake tool is completed and in patient service record
Eligibility for services is determined	Patient's service record includes • Proof of HIV diagnosis • Proof of income • Proof of Orange County residence • Proof of no other source of medical care (Medi-Cal, MSI, private insurance)
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

Standard	Measure
Release of Information 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

SECTION 6: SERVICE MANAGEMENT

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

6.1. Service Delivery

- Services shall be delivered in a manner that promotes continuity of care.
- Providers shall refer patients to other providers if they cannot provide a level of service that is medically, culturally, linguistically, or otherwise appropriate for the needs of the patients.

6.2. Confidentiality

- 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, providers shall comply with HIPAA guidelines and regulations for confidentiality.

6.3. 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.

6.4. 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 between two (2) to five (5) business days as specified in contract or scope of work.
- Providers shall document and keep accurate records of units of services for use in reporting units of service for reimbursement and community planning.

- Providers shall gather and document data (e.g. demographic, eligibility, and risk factor information) for the Ryan White Services Report.

6.5. 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
Provider shall have procedure to address walk-ins, telephone triage, and emergencies and after-hour care	Written procedure in place
Provider shall have procedure for making referrals to offsite services	Written procedure in place
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
Provider shall ensure patient information is in a secured location	Site visit will ensure
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	• Written procedure in place • Documentation of patient screening and determination on file • Site visit will ensure
Provider shall regularly review patient charts to ensure proper documentation including progress notes	Written procedure in place
Providers shall document and keep accurate records of units of services	Site visit and/or audit will ensure
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	Site visit and/or audit will ensure

Standard	Measure
must be certified, licensed, or FDA approved	

SECTION 7: MEDICAL EVALUATION

Proper assessment/evaluation of patient need is fundamental to medical care services. Outpatient/ambulatory medical care 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.

7.1. 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 months or more frequently as medically indicated.

7.2. 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

7.3. 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 Antibody (Elisa/IFA and EIA/Western Blot) Lymphocyte Panel
- Complete Blood Count with Differential and Platelet Count
- Chemistry Panel
- Cytomegalovirus (CMV)
- CD4 Count
- Viral Load
- Venereal Disease Research Laboratory Test / Fluorescent Treponemal Antibody (VDRL/FTA)
- Toxoplasmosis Titer
- Mantoux interdermal PPD skin test or IGRA
- Chest x-ray (if indicated)
- Hepatitis A antibody
- Hepatitis B antibody
- Hepatitis C antibody
- Pap Smear (females)

7.4. 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. Women shall receive pregnancy tests at time of initial medical visit and/or when indicated. Female patients shall receive pap smears based on medical necessity, at a minimum of annually. Physical examination findings in addition to course of treatment shall be documented in patient progress notes and/or treatment plan.

7.5. 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.

7.6. Reassessments. Reassessments shall be conducted at a minimum of every six 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.

7.7. 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 practitioner conducting the evaluation	Documentation in patient service record
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
CD4 tests conducted every 3-4 months to: (1) Determine when to start ART in untreated patients; (2) Assess immunologic response to ART; and (3) Assess the need for initiation or discontinuation of prophylaxis for opportunistic infections For patients whose CD4 count has increased well above the threshold for opportunistic infection risk, CD4 count can be monitored every 6-12 months.	Documentation of lab report in patient service record or documentation if not clinically indicated
Viral load tests conducted:	Documentation of lab report in patient service

Standard	Measure
(1) Every 3-4 months or as clinically indicated; and (2) At initiation or change in therapy 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.	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 with differential and platelet count conducted at a minimum annually	Documentation of lab report in patient service record
Pap smear conducted based on medical necessity or a minimum of annually	Documentation in patient service record
Allergy status documented at each visit	Documentation in patient service record
Documentation of each medical evaluation/assessment	Signed and dated note in patient service record to 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, procedures, and medications • Other observations
Problem list updated as appropriate	Signed and dated problem list in patient service record includes: • 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: • 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: • Date of visit • Outcomes of evaluation and or physical examination

Standard	Measure
	• Signature of the medical practitioner conducting the evaluation
Patient education is provided	Documentation of education provided in patient service record includes: • Date of education • Type of education provided

SECTION 8: PSYCHOSOCIAL ASSESSMENT

Patients living with HIV infection 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 providers of outpatient/ambulatory medical care annually.

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

Mental Health Issues
◦ History of and current mental health issues ◦ Mental health treatment history ◦ Resources/referrals for mental health issues, if applicable
Nutritional Assessment
◦ 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
◦ Visual assessment/exam of oral cavity ◦ Referral to oral health care services, if applicable
Substance Use
◦ 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: • Mental health assessment	Documentation of annual psychosocial assessment in patient service record

Standard	Measure
• Nutrition assessment • Oral health assessment • Substance use assessment	

SECTION 9: 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
Treatment plans must be completed and/or reviewed and revised at each routine medical visit and must be signed and dated by the medical care practitioner who completed the assessment/evaluation	Signed and dated treatment plan documented in patient service record

SECTION 10: 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 11: 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 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 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 clinic for ongoing primary HIV medical care.

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 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
Treatment is consistent with the United States Public Health Service Guidelines	Chart review will ensure
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: • 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 12: 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 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 medical care 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 medical care provider's established range of services. Outpatient/ambulatory medical care 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
As needed, providers will refer patients to a full range of services including but not limited to: • 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 13: OUTPATIENT/AMBULATORY MEDICAL CARE 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 died
- The client has become ineligible for services (e.g., due to relocation outside Orange County or other eligibility requirements)
- The client chooses to terminate services
- The client's needs would be better served by another agency
- The client demonstrates pervasive unacceptable behavior that violates client rights and responsibilities
- The client cannot be located

13.1. Efforts to Find Client. The 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 attempts to contact the patient are made over a period of three 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.

13.2. Closure Due to Unacceptable Behavior. The provider may decide to first verbally and/or in writing give the patient a warning of service termination if pervasive unacceptable behavior (which is described to the client) that violates patient rights and responsibilities including excessive missed appointments continues. Termination may be immediate if the client or family member has threatened provider staff with violence or has exhibited threatening behavior. If it is decided that closure is necessary, the 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 provider shall notify the patient in writing that his/her 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 include[6]

- The last day the physician 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 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, 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 provider is not authorized to send mail to the patient, the 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, he/she shall be informed of the provider's grievance procedure.

13.3. .Outpatient/Ambulatory Medical Care Service Closure Summary. A outpatient/ambulatory medical care 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 medical care service closure summary shall include the following:

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

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

13.4. 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 medical care service closure. For patients receiving services other than outpatient/ambulatory medical care 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
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 pervasive 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 notification or attempt at notification in patient service record.
A outpatient/ambulatory medical care 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: • 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 14: QUALITY MANAGEMENT

Ambulatory medical care providers shall have in place a Quality Management (QM) Plan. The QM Plan is a written document that outlines how the QM program will be implemented, including a clear indication of responsibilities and accountability, performance measurement strategies and goals, and processes for ongoing evaluation. The following paragraphs describe components of a QM Plan. Sections 11.1 through 11.4 (Quality Statement, Quality Infrastructure, Capacity Building, and Evaluation) describe components that can be developed by the provider agency for all services under the QM program. Sections 11.5 and 11.6 (Annual Quality Goals and Performance Measurement) describe components that are developed for each Ryan White service.

14.1. Quality Statement: A quality statement is a brief declaration that provides a vision for the QM program. This component shall include the following elements:

- A brief purpose: Describe the end goal of the agency's HIV quality program.

- Shared vision: Takes into account the agency's internal and external expectations for which all activities will be directed.

14.2. Quality Infrastructure: The quality infrastructure outlines how the QM program is organized. This component shall include the following elements:

- Leadership: Identify who is responsible for QM activities.
- Quality committee(s) structure: Document who serves on the quality committee, who chairs the committee, and how often the committee will meet. If the agency currently does not have a quality committee, document a plan to establish a committee.
- Roles and responsibilities: Define all key persons within the organization, community partners, and major stakeholders, including patients, to clarify expectations for the QM program.
- Quality committee reporting: Document the relationship of the quality committee to the program at large. Document how the quality committee will communicate its progress to staff, consumers, other key persons, and stakeholders. Identify who is responsible for reporting quality committee progress.

14.3. Capacity Building: Capacity building identifies resources and training needs required to assist staff in implementing a QM program. This component shall include the following elements:

- Orientation: Description of how all staff will be oriented to the agency's QM plan.
- Training: Description of the identified training topics and plan for documenting attendance at trainings/conferences to improve quality of service.

14.4. Evaluation: Quality improvement evaluation provides a systematic way for which QM program successes, challenges, and strategies for improvement are measured. This component shall include the following elements:

- Evaluation of the QM/QI infrastructure: Document plan to evaluate infrastructure to decide if changes are required to ensure that QI work gets done.
- Performance measures: Document plan for reviewing performance measures.
- QI activities: Identify process, including time line, to evaluate if QI activities have contributed to the annual quality goals.

14.5. Annual Quality Goals: Quality goals are endpoints or conditions toward which the quality program will direct its efforts and resources. Quality goals shall be developed for mental health services. This component shall include the following elements:

- Measurable and realistic goals: Include at least one annual goal per service category. The first goal is defined by the HCA. An *optional* goal may be selected for an agency specific to the agency's QM plan.

14.6. Performance Measurement: Performance measurement provides a tool to assess progress toward reaching annual goals for mental health services. This component shall include the following elements:

- Outcomes: Outcomes are the desired result for each goal, generally associated with a health outcome.

- Indicators/Targets: Each outcome shall have at least one indicator that specifies what will be measured to determine whether the outcome has been met. Each indicator shall be associated with a target that shows the goal for the indicator.
- Staff responsible: Indicate the staff who will collect, analyze, and review data.
- Dissemination strategy: Identify strategies on how to report and disseminate QM results and findings.
- New Quality Improvement (QI) activities: Describe processes in place to use data to develop and implement new QI activities to address identified gaps.

The following are HRSA-recommended QM outcomes and measurable indicators for Outpatient/Ambulatory Medical Care services:

- **Outcome 1: Improvement in client's health.**
  - Indicators TBD.

Standard	Measure
Providers shall develop a QM Plan annually to continuously assess whether a program is meeting its mission, goals, and objectives	QM Plan submitted to the Grantee and on file at provider agency
Providers shall form a QM Committee to review patient feedback and outcome data, as well as develop plans for corrective actions	Documentation of Committee meetings on file at provider agency
Programs develop a process to measure and monitor outcomes and indicators	QM Plan to detail process

Appendix A. Glossary of Terms

Patient: Individual receiving outpatient/ambulatory services services.

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

Practitioner: An individual who provides outpatient/ambulatory medical care services. This may include licensed and unlicensed individuals under the supervision of a licensed medical care professional who provides medical care services to clients.

Provider: An institution or entity that provides outpatient/ambulatory medical care services. This includes a group of practitioners, clinic, or other institution that provide outpatient/ambulatory medical care services and the agency at which services are provided.