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Public Comment Period for Draft Ambulatory Outpatient Medical Service Standards

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The Los Angeles County Commission on HIV (COH) announces an opportunity for the public to submit comments for the draft Ambulatory Outpatient Medical (AOM) service standards revised by the Standards and Best Practices Committee. Comments from consumers, providers, HIV prevention and care stakeholders, and the general public are welcome. A draft of the revised AOM service standards is posted to the COH website and can be found at: https://hiv.lacounty.gov/service-standards

Consider responding to the following questions when providing public comment:

- 1. Are the standards presented up-to-date and consistent with National standards of high-quality HIV prevention and care services?
- 2. Are the standards reasonable and achievable for providers? Why or why not?
- 3. Do the services meet consumer needs? Why or why not?
- 4. Is there anything missing from the standards related to HIV prevention and care?
- 5. Do you have any additional comments related to the AOM service standards and/or AOM services?

All comments are to be emailed to <u>HIVCOMM@LACHIV.ORG</u> by August 5, 2024.

DRAFT AMBULATORY OUTPATIENT MEDICAL (AOM) SERVICE STANDARDS

IMPORTANT: Service standards must adhere to requirements and restrictions from the federal agency, Health Resources and Services Administration (HRSA). The key documents used in developing standards are as follows:

- <u>Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of</u> <u>Funds Policy Clarification Notice (PCN) #16-02 (Revised 10/22/18)</u>
- <u>HIV/AIDS Bureau, Division of Metropolitan HIV/AIDS Programs National Monitoring</u> <u>Standards for Ryan</u> White Part A Grantees: Program – Part A

INTRODUCTION

Service standards for the <u>Ryan White HIV/AIDS Part A Program</u> (RWHAP) outline the elements and expectations a service provider should follow when implementing a specific service category. The purpose of the standards is to ensure that all RWHAP service providers offer the same fundamental components of the given service category. Additionally, the standards set the minimum level of care Ryan White-funded service providers may offer clients, however, service providers are encouraged to exceed these standards.

The Los Angeles County Commission on HIV (COH) developed the Ambulatory Outpatient Medical (AOM) service standards to establish the minimum service necessary to provide HIV specialty medical care to people living with HIV. The developed of the standards included review of current clinical guidelines, as well as feedback from service providers, people living with HIV, members of the COH's Standards and Best Practices (SBP) Committee, COH caucuses, and the public-at-large. All service standards approved by the COH align with the <u>Universal Service</u> <u>Standards and Client Bill of Rights and Responsibilities</u> (Universal Standards) approved by the COH on January 11, 2024. AOM providers must also follow the Universal Standards in addition to the standards described in this document.

AMBULATORY OUTPATIENT MEDICAL (AOM) OVERVIEW

AOM Services are evidence-based preventive, diagnostic and therapeutic medical services provided through outpatient medical visits by California-licensed health care professionals. Clinics shall offer a full-range of health services to HIV-positive RWP eligible clients with the objective of helping them cope with their HIV diagnosis, adhere to treatment, prevent HIV transmission, and identify and address co-morbidities.

Ambulatory Outpatient Medical (AOM) services include, but are not limited to:

- Medical evaluation and clinical care including sexual history taking
- AIDS Drug Assistance Program (ADAP) enrollment services
- Laboratory testing including disease monitoring, STI testing, viral hepatitis testing, and other clinically indicated tests

- Linkage and referrals to medical subspecialty care, oral health, medical care coordination, mental health care, substance use disorder services, and other service providers
- Secondary HIV prevention in the ambulatory outpatient setting
- Retention of clients in medical care.

The goals of AOM services include:

- Provide patients with high-quality care and medication even if they do not have health insurance and connect patients to additional care and support services as applicable.
- Help patients achieve low or suppressed viral load to improve their health and prevent HIV transmission (Undetectable=Untransmittable)
- Prevent and treat opportunistic infections
- Provide education and support with risk reduction strategies

SERVICE COMPONENTS

HIV/AIDS AOM services form the foundation for the Los Angeles County HIV/AIDS continuum of care. AOM services are responsible for assuring that the full spectrum of primary and HIV specialty medical care needs for patients are met either by the program directly or by referral to other health care agencies. Services will be provided to individuals living with HIV who are residents of Los Angeles County and meet Ryan White eligibility requirements.

AOM services will be patient-centered, respecting the inherent dignity of the patient. Programs must ensure that patients are given the opportunity to ask questions and receive accurate answers regarding services provided by AOM service providers and other professionals to whom they are referred. Such patient-practitioner discussions are relationship building and serve to develop trust and confidence. Patients must be seen as active partners in decisions about their personal health care regimen.

AOM services must be provided consistent with the following treatment guidelines:

- Clinical Practice Guidance for Persson with Immunodeficiency Virus: 2020
- American Academy of HIV Medicine HIV Treatment Guidelines
- Guidelines for the Use of Antiretrovirals Agents in Adults and Adolescents with HIV

The core of the AOM services standard is medical evaluation and clinical care that includes:

- Initial assessment and reassessment
- Follow-up treatment visits
- Additional assessments
- Laboratory assessment and diagnostic screening (including drug resistance testing)
- Medication service
- Antiretroviral (ART) therapy
- Treatment adherence counseling

- Health maintenance
- Clinical trials
- Primary HIV nursing care
- Medical specialty services
- Nutrition screening and referral
- Referrals to other Ryan White Program services and other publicly funded healthcare and social services programs.

MEDICAL EVALUATION AND CLINICAL CARE

AOM programs must confirm the presence of HIV infection and provide tests to diagnose the extent of immunologic deficiency in the immune system. Additionally, programs must provide diagnostic and therapeutic measures for preventing and treating the deterioration of the immune system and related conditions that conform to the most recent clinical protocols. At minimum, these services include regular medical evaluations; appropriate treatment of HIV infection; and prophylactic and treatment interventions for complications of HIV infection, including opportunistic infections, opportunistic malignancies and other AIDS defining conditions.

The following core services must be provided onsite or through referral to another facility offering the required service(s). Qualified health care professionals for these services include physicians, Nurse Practitioners (NPs) and/or Physician Assistants (PAs). Except where indicated, licensed nurses may provide primary HIV nursing care services and linkage to other <u>Ryan White</u> <u>Services</u> as needed.

STANDARD	DOCUMENTATION
AOM medical visits/evaluation and treatment	Medical record review to confirm.
should be scheduled based on acuity and viral	
suppression goals. Once a patient has	
demonstrated long-term durability of viral	
suppression, the patient should have at	
minimum 1 medical visit per year and have labs	
done 2 times per year. The patient's other	
comorbidities may require additional medical	
visits and should consult with provider for	
treatment plan adjustments.	
AOM core services will be provided by	Policies and procedures manual and
physicians, NPs, and/or PAs. Licensed nurses will	medical chart review to confirm.
provide primary HIV nursing care services and	
linkage to other <u>Ryan White services</u> as needed.	

INITIAL ASSESSMENT AND REASSESSMENT

Every effort should be made to accommodate timely medical appointments for patients newly diagnosed with HIV or newly re-engaging in HIV medical care. Clinics may receive requests for appointments from patients directly, from HIV test counselors, or from "linkage" staff such as patient navigators and/or peer navigators, whose role is to refer and actively engage patients back in medical care. If possible, patients should see their medical provider on their first visit to the clinic to help improve their success in truly engaging in their medical care.

The initial assessment of HIV-infected individuals must be comprehensive in its scope, including physical, sociocultural, and emotional assessments and may require two to three outpatient visits to complete. Unless indicated more frequently by a patient's changing health condition, a comprehensive reassessment should be completed on an annual basis. The AOM practitioners (physician, NP, PA, or licensed nurse) responsible for completing the initial assessment and reassessments will use assessment tools based on established HIV practice guidelines. While taking steps to ensure a patient's confidentiality, the results of these assessments will be shared with medical care coordination staff to help identify and intervene on patient needs. An initial assessment and annual reassessment for HIV-infected patient should include a general medical history; a comprehensive HIV-related history, including a psychosocial history; sexual health history, mental health, and substance abuse histories; and a comprehensive physical examination. When obtaining the patient's history, the practitioner should use vocabulary that the patient can understand, regardless of education level. AOM providers must follow and use the most current clinical guidelines and assessment tools for general medical and comprehensive HIV medical histories.

STANDARD	DOCUMENTATION
Comprehensive baseline assessment will be	Medical record review to confirm.
completed by physician, NP, PA, or licensed nurse	
and updated, as necessary.	

FOLLOW-UP TREATMENT VISITS

Patients should have follow-up visits scheduled following established clinical guidelines. If the patient is clinically unstable or poorly adherent, a more frequent follow-up should be considered. Visits should be scheduled more frequently at entry to care, when starting or changing ART regimens, or for management of acute problems. Due to the complex nature of HIV treatment, ongoing AOM visits must be flexible in duration and scope, requiring that programs develop practitioner clinic schedules allowing for this complexity. Follow-up should be conducted as recommended by the specialist or clinical judgment.

STANDARD	DOCUMENTATION
Patients should have follow-up visits scheduled	Patient medical chart to confirm
following established clinical guidelines.	frequency.

OTHER ASSESSMENTS - OLDER ADULTS WITH HIV

According to the Health Resources and Service Administration (HRSA), the RWHAP client population is aging. Of the more than half a million clients served by RWHAP, 46.1 percent are aged 50 years and older and this continues to grow. While Ryan White clients in Los Angeles County show higher engagement and retention in care, and viral suppression rates, within the 50+ population there exists disparities by racial/ethnic, socioeconomic, geographic, and age groups stratification.

AOM providers must at minimum assess patients 50 years and older for mental health, neurocognitive disorders/cognitive function, functional status, frailty/falls and gait, social support and levels of interactions, vision, dental, and hearing. Additional recommended assessments and screenings for older adults living with HIV can be found on page 6 of the <u>Aging</u> <u>Task Force Recommendations</u>.

Other specialized assessments leading to more specific services may be indicated for patients receiving AOM services. AOM programs must designate a member of the treatment team (physician, NP, PA, or licensed nurse) to make these assessments in the clinic setting.

STANDARD	DOCUMENTATION
Other assessments based on patient needs will	Assessments and updates noted
be performed.	documented in patient's medical record.

LABORATORY ASSESSMENT AND DIAGNOSTIC SCREENING (INCLUDING DRUG RESISTANCE SCREENING)

AOM programs must have access to all <u>laboratory services</u> required to comply fully with established practice guidelines for HIV prevention and risk reduction and for the clinical management of HIV disease. Programs must assure timely, quality lab results, readily available for review in medical encounters.

DRUG RESISTANCE TESTING

When appropriate, AOM practitioners may order drug resistance testing to measure a patient's pattern of resistance of HIV to antiretroviral medications. Genotypic testing looks for viral mutations, and is expected for all naïve patients, and phenotypic testing measures the amount of drug needed to suppress replication of HIV. By using resistance testing, practitioners can determine if the virus is likely to be suppressed by each antiretroviral drug. This information is used to guide practitioners in prescribing the most effective drug combinations for treatment.

Counseling and education about drug resistance testing must be provided by the patient's medical practitioner, RN and/or other appropriate licensed health care provider (if designated by the practitioner). Patients must be fully educated about their medical needs and treatment options according to standards of medical care. Patients must be given an opportunity to ask questions about their immune system, antiretroviral therapies, and drug resistance testing. All patient education efforts will be documented in the patient record.

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STANDARD	DOCUMENTATION
Baseline lab tests based on current clinical	Record of tests and results on file in
guidelines.	patient medical chart.
Ongoing lab tests based on clinical guidelines and	Record of tests and results on file in
provider's clinical judgement.	patient medical chart.
Appropriate health care provider will provide	Record of drug resistance testing on file in
drug resistance testing as indicated.	patient medical chart.
Drug resistance testing providers must follow	Program review and monitoring to
most recent, established resistance testing	confirm.
guidelines, including genotypic testing on all	
naïve patients.	

MEDICATION SERVICES

Medications should be provided to interrupt or delay the progression of HIV-disease, prevent, and treat opportunistic infections, and promote optimal health. Patients should be referred to an approved AIDS Drug Assistance Program (ADAP) enrollment site and, as indicated, to medical care coordination programs for additional assistance with public benefit concerns. Patients eligible for ADAP will be referred to a participating pharmacy for prescriptions on the ADAP formulary. If the patient requires medications that are not listed on the ADAP formulary or that can be reimbursed through other local pharmacy assistance resources, the AOM program is responsible for making every effort possible to link them to medications and exercise due diligence for that effort consistent with their ethical responsibilities.

STANDARD	DOCUMENTATION
Patients requiring medications will be referred to	ADAP referral documented in patient
ADAP enrollment site.	medical chart.
AOM programs must exercise every effort and due diligence consistent with their ethical responsibilities to ensure that patients can get necessary medications not on the ADAP and local formularies.	Documentation in patient's medical chart.

ANTIRETROVIRAL THERAPY (ART)

Antiretroviral therapy will be prescribed in accordance with the established guidelines based upon the <u>DHHS Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and</u> <u>Adolescents</u> Decisions to begin ART treatment must be collaborative between patient and AOM practitioner.

STANDARD	DOCUMENTATION
ART will be prescribed in accordance with DHHS	Program monitoring to confirm.
Guidelines for the Use of Antiretroviral Agents in	
HIV-infected Adults and Adolescents.	

Patients will be part of treatment decision-	Documentation of communication in
making process.	patient medical chart.

MEDICATION ADHERENCE ASSESSMENT

Medication adherence assessment should be performed for patients at every medical visit. Providers should refer patients challenged by maintaining treatment adherence to <u>Medical Care</u> <u>Coordination</u> (MCC) services and other Ryan White services as needed.

STANDARD	DOCUMENTATION
Medical providers or treatment adherence counselors will provide direct treatment adherence counseling or refreshers to all patients.	Notes in medical file indicating that counseling was provided, by whom and relevant outcomes.
Medical providers or treatment adherence counselors will develop treatment adherence assessments of patients where need is indicated.	Assessment on file in patient chart signed and dated by medical staff or treatment adherence counselor responsible, indicating, at a minimum, any follow-up intended.
Medical providers will refer patients with more acute treatment adherence needs to specialized treatment adherence or treatment education programs.	Referral(s) noted in assessment and/or patient chart, as applicable.

PATIENT EDUCATION AND SUPPORT

Medical providers and treatment adherence counselors will provide patient education and support to make information about HIV disease and its treatments available, as necessary.

STANDARD	DOCUMENTATION
 Medical providers and/or Treatment Adherence Counselors may provide patient education and support. Support can include: Accompanying patients to medical visits and clinical trials visits and/or providing transportation support Helping patients understand HIV disease and treatment options Helping patients with adherence issues Providing emotional support 	 Progress notes on file in patient chart to include (at minimum): Date, time spent, type of contact What occurred during the contact Signature and title of the person providing the contact Referrals provided, and interventions made (as appropriate) Results of referrals, interventions and progress made toward goals in the individual service plan (as appropriate)

STANDARD HEALTH MAINTENANCE

AOM practitioners will discuss general preventive health care and health maintenance with all patients routinely, and at a minimum, annually. AOM programs will strive to provide preventive health services consistent with the most current recommendations of the <u>U.S. Preventive</u> <u>Health Services Task Force</u>. AOM practitioners will work in conjunction with other Ryan White service providers to ensure that a patient's standard health maintenance needs are being met.

STANDARD	DOCUMENTATION
Practitioners will discuss health maintenance with patients annually (at minimum), including:	Annual health maintenance discussions will be documented in patient medical
 with patients annually (at minimum), including: Cancer screening (cervical, breast, rectal – per American Cancer Society guidelines) Vaccines Pap screening Hepatitis screening, vaccination TB screening Family planning Counseling on sexual health options and STI screening including discussions about Pre-Exposure Prophylaxis (PrEP), Post- Exposure Prophylaxis (PEP), and Doxy PEP Counseling on nutrition, exercise, and diet 	will be documented in patient medical chart.
 Harm reduction for alcohol and drug use Smoking cessation Mental health and wellness including 	
substance use disorder support and social isolation resources	

COMPLEMENTARY, ALTERNATIVE AND EXPERIMENTAL THERAPIES

AOM practitioners must be aware if their patients are accessing complementary, alternative, and experimental therapies. Providers are encouraged to discuss at regular intervals complementary, alternative, and experimental therapies with patients, discussing frankly and accurately both their potential benefits and potential harm. Practitioners may consult the National Institutes of Health (NIH) National Center for Complementary and Alternative Medicine (http://nccam.nih.gov) for more information.

STANDARD	DOCUMENTATION
Practitioners must know if their patients are	Record of therapy use and/or discussion
using complementary and alternative therapies and are encouraged to discuss these therapies	on file in patient medical record.
with their patients regularly.	

PRIMARY HIV NURSING CARE

AOM programs will provide primary HIV nursing care performed by a licensed nurse and/or appropriate licensed health care provider. If available, services will be coordinated with <u>Medical</u> <u>Care Coordination</u> programs to ensure the seamless, non-duplicative, and most appropriate delivery of service.

STANDARD	DOCUMENTATION
Licensed nurses and/or other appropriate	Documentation of primary HIV nursing
licensed health care providers in AOM programs	care service provision on file in patient
will provide primary HIV nursing care to include	medical chart.
(at minimum):	
 Nursing assessment, evaluation, and 	
follow-up	
Triage	
 Consultation/communication with 	
primary practitioner	
Patient counseling	
 Patient/family education 	
• Services requiring specialized nursing skill	
 Preventive nursing procedures 	
 Service coordination in conjunction with medical care coordination 	

MEDICAL SPECIALTY SERVICES HIV/AIDS AND REFERRALS

AOM service programs are required to provide access to specialty and subspecialty care to fully comply with the DHHS Guidelines.

HIV-related specialty or subspecialty care include (but are not limited to):

- Cardiology
- Dermatology
- Ear, nose, and throat (ENT)
- Gastroenterology
- Gender affirming care
- General surgery
- Gerontology
- Gynecology
- Infusion therapy
- Mental Health
- Nephrology
- Neurology

- Nutrition Therapy
- Obstetrics
- Oncology
- Ophthalmology
- Oral health
- Orthopedics
- Podiatry
- Proctology
- Pulmonary medicine
- Substance Use Disorder Treatment
- Urology

Referrals to medical specialists are made as complications occur that are beyond the scope of practice of primary HIV medical and nursing care. Such complications require referral to specialty and subspecialty physicians for consultation, diagnosis, and therapeutic services. In some cases, the AOM practitioner may need only to consult verbally with a medical specialist for clarification and confirmation on an approach to HIV clinical management. In other cases, the physician may need to refer a patient to a medical specialist for diagnostic and therapeutic services. Medical specialty services are considered consultative; patients will be referred back to the original AOM clinic for ongoing primary HIV medical care.

AOM programs must develop written policies and procedures that facilitate referral to medical specialists. All referrals must be tracked and monitored. The results of the referrals must be documented in the patient's medical record.

STANDARD	DOCUMENTATION
AOM programs must develop policies and	Referral policies and procedures on file at
procedures for referral to all medical specialists.	provider agency.
All referrals will be tracked and monitored.	Record of linked referrals and results on
	file in patient medical record.
In referrals for medical specialists, medical	Record of referral activities on file in
outpatient specialty practitioners are responsible	patient medical record.
for:	
 Assessing a patient's need for specialty 	
care	
 Providing pertinent background clinical 	
information to medical specialist	
 Making a referral appointment 	
 Communicating all referral appointment 	
information	
 Tracking and monitoring referrals and 	
results	
Assuring the patient returns to the AOM	
program of origin	

COORDINATION OF SPECIALTY CARE

It is imperative that AOM programs and medical specialists coordinate their care to ensure integration of specialty treatment with primary HIV medical care. As noted above, AOM programs must provide pertinent background clinical information in their referrals to medical specialists. In turn, specialists within the County-contracted system must provide to AOM programs a written report of their findings within two weeks of seeing a referred patient. Medical specialists within the County-contracted system must contact the referring medical provider within one business day in the event that urgent matters arise, to follow up on unusual findings or to plan a required hospitalization.

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STANDARD	DOCUMENTATION
Specialists within the County-contracted system	Specialty report on file at provider agency
must provide written reports within two weeks	
of seeing a referred patient.	
Specialists within the County-contracted system	Documentation of communication in
must contact AOM programs within one business	patient file at provider agency.
day:	
When urgent matters arise	
To follow up on unusual findings	
To plan required hospitalization	

NUTRITION SCREENING AND REFERRAL

Nutrition is a component of the Public Health Service standards of care in order to guard against malnutrition and wasting. The physician, NP, PA, RN, or RD should screen all patients for nutrition concerns and provide a written prescription for all at-risk patients for medical nutrition therapy within six months of an individual becoming an active patient in the AOM program.

AOM programs may provide medical nutrition therapy onsite or may refer patients in need of these services to specialized providers offsite. All programs providing nutrition therapy (including AOM services sites) must adhere to the American Academy of Nutrition and Dietetics guidance Evidence-Based Nutrition Practice Guidelines (eatrightpro.org)

STANDARD	DOCUMENTATION
AOM service providers should screen all patients	Record of screening for nutrition related
for nutrition-related concerns for all at-risk	problems noted in patient's medical
patients.	chart.
AOM service providers will provide a written	Record of screening for nutrition related
prescription for all at-risk patients for medical	problems noted in patient's medical
nutrition therapy within six months of an	chart.
individual becoming an active patient.	
When indicated, patients will also be referred to	Record of linked referral on file in patient
nutrition therapy for:	medical chart.
 Physical changes/weight concerns 	
 Oral/GI symptoms 	
Metabolic complications and other	
medical conditions	
Barriers to nutrition	
Behavioral concerns or unusual eating	
behaviors	
Changes in diagnosis	
Referral to medical nutrition therapy must	Record of linked referral on file in patient
include:	medical chart.

- Written prescription, diagnosis, and desired nutrition outcome
- Signed copy of patient's consent to release medical information
- Results from nutrition-related lab assessments

MEDICAL CARE COORDINATION (MCC) SERVICES

To best address the complex needs of their patients, AOM providers are expected to either partner with <u>Medical Care Coordination (MCC</u>) team located at their clinics or refer to an MCC team at another agency. For additional details, please see the <u>Medical Care Coordination</u> <u>Standard of Care</u>, Los Angeles Commission on HIV, 2024.

HIV PREVENTION IN AMBULATORY/OUTPATIENT MEDICAL SETTINGS

HIV prevention is a critical component to ongoing care for people living with HIV. Prevention services provided in AOM clinics may include HIV counseling, testing and referral; partner counseling; prevention and medical care; and referral for intensive services. For additional details see the <u>HIV Prevention Service Standards</u> Los Angeles, Commission on HIV, 2024.