Minnesota Ryan White HIV/AIDS Program
Service Area Standards: Outpatient / Ambulatory Health Services

HRSA Definition: 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. 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

Program Guidance: Treatment adherence activities 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.

Non-HIV related visits to urgent care facilities are not allowable costs within the Outpatient/Ambulatory Health Services Category.

Emergency room visits are not allowable costs within the Outpatient/Ambulatory Health Services Category.

Universal Standards: All subrecipients must meet universal standards requirements in addition to service area standards for which they are funded.

Council Approved: December 9, 2014
Amended: December 14, 2021, January 31, 2024

Standard	Measure	Data Source
1. Initial encounter 1.1. Patient's medical care initial encounter and subsequent visit shall be in compliance with the current U.S. Department of Health & Human Services Guidelines and/or the International Antiviral Society General Medicine Primary Care Guide. https://clinicalinfo.hiv.gov/en/guidelines https://www.iasusa.org/guidelines	1.1 See section on Provision of Services and Patient records	File reviews/site visits
2. Provider Qualifications 2.1. All clinicians and staff maintain appropriate licensesand credentials. 2.2. Clinicians must be HIV-experienced and have treated50 or more individuals living with HIV. For areas of MN with low HIV prevalence, any clinician providing HIV medical care with a patient load of <50 has a formal consulting relationship with an HIV specialty provider.	2.1-2.2 Completed forms on file for all participating clinicians, including Minnesota Medical License and other appropriate licenses and certifications.	File Reviews/Site Visits

Standard	Measure	Data Source
3. Coordination: Rapid Response Treatment and specialty care. 3.1. Rapid ART: To engage and link those newly diagnosed with HIV into same-day care and treatmentwithin 7 days of diagnosis. • Agencies shall have a written policy for Rapid ART,expediting care and treatment for referral of newly diagnosed and out of care clients. Coordination andreferral including HIV appointments, labs, and treatment. • Agencies shall have memorandums of understandings and maintain relationships with local Ryan White Funded Early Intervention Servicesproviders and/or other testing providers. 3.2. Specialty Care: Appropriate specialty care services shall be provided as indicated. • Agencies shall have a written policy for makingspecialty care referrals. • Agencies shall develop and maintain relationshipwith specialty care providers.	3.1-3.2 Copy of MOU on file. Policies and procedures in place	File Reviews/Site Visits

Standard	Measure	Data Source
4. Documentation 4.1 Agencies shall ensure that required documentation is obtained and maintained. 4.2 Provision of Services and Consumer Records shall include: o The initial comprehensive assessment that includes physical, sociocultural, and emotional assessments and may require two to three outpatient visits to complete. (See Appendix I) o Follow-up visits for patients receiving ARV therapy should be scheduled every three to four months, except at the practitioner's discretion when a patient has demonstrated long term stability and adherence in their medical regime. Follow-up visits should be scheduled every three to six months for patients who are not receiving ARV therapy. U.S. Public Health Guidelines require at least two visits annually. Follow-up visits should be scheduled more frequently at entry to care, when starting or changing ARV regimens, or for management of acute problems. (See Appendix II)	4.2 Documentation in patient files.	File Review/Site Visits

Appendix I

From Los Angeles County Commission on HIV Standards of Care Medical Outpatient Services
Medical Outpatient.pdf (kc-usercontent.com)

Initial Assessment and Reassessment. The initial assessment of an individual with HIV 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 OAHS practitioners (physician, NP, PA, or RN) responsible for completing the initial assessment and reassessments will utilize 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 coordination programs, as appropriate. An initial assessment and annual reassessment for a patient with HIV should include a general medical history; a comprehensive HIV-related history, including a psychosocial history; sexual 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.

General Medical Histories should include (at minimum):

□ History of present illness □ Past hospitalizations, past and current illnesses □ Past immunizations □ Travel history and place of birth □ Current treatment, prescription, and non-prescription medicines (including complementary and alternative therapies, illicit substances, and hormones)	□ Pets/animal exposures □ Allergies □ Full review of systems □ Mental health □ Health Literacy □ Occupational history and hobbies

Comprehensive HIV-related histories should include (at minimum):

- □ HIV treatment history and staging
- □ Most recent viral load and CD4 count
- □ Nadir CD4 and peak viral load
- □ Current and previous ARV regimens
- □ Previous adverse ARV drug reactions
- □ Previous adverse reactions to drugs used for opportunistic infection prophylaxis
- □ History of HIV-related illness and opportunistic infections
- □ History of sexually transmitted diseases
- □ History of tuberculosis
- □ History of hepatitis and hepatitis vaccines
- □ Psychiatric history
- □ Diagnosed psychiatric diseases
- □ Previous/current treatment for psychiatric diseases
- □ Disability related to psychiatric disease
- □ Homicidality and suicidality
- □ Socio-cultural assessment
- □ Transfusion or blood product history, especially before 1985
- □ Review of sources of past medical care (obtaining past medical records whenever possible)
- □ Sexual history
  - Sexual activity
  - Sexual practices
  - Gender identity
  - Past and current partners
  - Risk behavior assessment
- □ HIV-specific review of systems
  - Skin
  - Eyes
  - Ear, nose, and throat
  - Stomatognathic
  - Pulmonary
  - Cardiovascular
  - Gastrointestinal/Hepatic
  - Endocrine
  - Genitourinary
  - OB/GYN
  - Dermatologic
  - Musculoskeletal
  - Neurologic
  - Hematopoietic
  - Metabolic
- □ Substance use history
  - Past and current use and types of drugs, including alcohol
  - Frequency of use and usual route of administration
  - Risk behavior assessment
  - History of treatment
- □ Tobacco use history

Comprehensive Physical Exams should include (at minimum):

- □ Temperature, vital signs, height, and weight
- □ Pain assessment
- □ Ophthalmologic examination
- □ Ears, nose, and throat examination
- □ Dermatological examination
- □ Lymph node examination
- □ Oral examination
- □ Pulmonary examination
- □ Cardiac examination
- □ Abdominal examination
- □ Genital examination
- □ Rectal examination
- □ Neurological examination

Appendix II

From Los Angeles County Commission on HIV Standards of Care Medical Outpatient Services
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Follow-up Visits. At minimum, a medical visit for a returning patient will include a problem focused history, problem focused examination and straightforward medical decision-making. OAHS providers should follow the most recent HHS guidelines, which contain detailed recommendations on laboratory tests for initial assessment and treatment monitoring, including appropriate testing intervals. Tests should be ordered by a licensed provider and may include, as clinically indicated:

- □ Temperature, vital signs, height, and weight
- □ Problems list status and updates including sexual history
- □ Pain assessment
- □ Treatment plan adherence
- □ Viral load measurements (see Laboratory Assessment and Diagnostic Screening below), viral load should be measured according to prevailing medical standards and current guidelines
- □ Resistance testing should be performed (if necessary) for ARV viral failure (see more detailed discussion in Drug Resistance Testing below)
- □ Laboratory tests as outlined in Laboratory Assessment and Diagnostic Screening below
- □ Prophylaxis for opportunistic infections offered to each patient as indicated by immune status. Refer to current guidelines and prevailing standards for prophylaxis of opportunistic infections from DHHS Guidelines for Opportunistic Infections (www.aidsinfo.nih.gov). Documentation of current therapies should be maintained on all patients receiving prophylaxis.
- □ Cervical cancer screen (following the most current clinical recommendations) for patients who have a cervix:
    - Patients Aged 21-29 Years:
        - Patients aged 21-29 should have a Pap test at the time of initial HIV diagnosis. Pap should be done at baseline and every 12 months. If the results of 3 consecutive Pap tests are normal, follow-up Pap tests can be performed every 3 years.
    - Patients Aged 30 Years or Older:
        - Pap test or Pap test with human papillomavirus (HPV) co-testing should be done at baseline and every 12 months. If results of 3 consecutive Pap tests are normal, follow-up Pap tests can be performed every 3 years.
- □ Medical providers should discuss family planning with patients and provide contraception counseling, including information about hormonal contraception, as applicable.
- □ There are currently no national guidelines regarding screening for anal cancer and dysplasia. The HHS Clinical Practice Guidelines do not endorse routine anal cytology testing (anal Pap) but note that some specialists do recommend anal cytology for people living with HIV. Annual digital anal rectal examination (DARE) and screening for symptoms of anal dysplasia (anorectal pain, bleeding, masses, or nodules) may also be useful in the early detection of anal cancers. HHS and the Infectious Disease Society of America both recommend against offering anal cytology if resources are not available for appropriate referral and follow-up of abnormal results, including high-resolution anoscopy (HRA). For clinicians who opt to conduct screenings for anal dysplasia and cancer, the New York State Department of Health offers detailed guidelines (https://www.hivguidelines.org/guideline/hiv-anal-cancer).

- □ Tuberculosis (TB) screening at time of diagnosis and when clinically indicated.
    - Chest x-ray should be performed for any patient with a newly positive tuberculin skin test or IGRA, or with any clinical concern for tuberculosis.
- □ Advance directives, durable powers of attorney, living wills and other planning documents, including POLST (Physician's Orders for Life Sustaining Treatment) and DNR (Do Not Resuscitate) status, should be addressed at the beginning of treatment and at any appropriate time in the course of the illness.
- □ Patients with CD4 counts below 50 should be referred for ophthalmic examination by a trained retinal specialist for screening or as recommended by that specialist, according to prevailing medical standards and current guidelines. Follow-up should be conducted as recommended by the specialist or clinical judgment.
- □ Documentation of discussions of safer sex practices for all patients. Patients in sero-discordant relationships should be educated about options for HIV pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) for their partners. Referrals for PrEP and PEP should be made for these partners.
- □ Following standards of care for HIV prevention and treatment, OAHS practitioners must include the following in each patient encounter:
    - Providing brief HIV prevention messages (asking patients about risk behaviors, and positively reinforcing patient's report of risk reduction behavior)
    - Asking patients about problems and concerns with treatment adherence and making suggestions to support adherence (such as pill boxes, setting alarms)
    - Screening patients' nutritional needs and referring them for Medical Nutrition Therapy services when and as needed.
    - Asking patients about their social living conditions, ensuring that lack of housing, food, or other social needs do not become a barrier to treatment adherence
    - Providing patient education on HIV disease, symptoms, medications, and treatment regimens to increase patient participation in treatment decision-making (see www.IHI.org for Institute for Healthcare Improvement guidelines on "Self-Management"). Patient education on medications will include instructions, risks and benefits, compliance, side effects, and drug interaction.
    - Building and maintaining patient relationships, increasing the likelihood that patients may ask for needed emotional support, or talk with practitioners about substance abuse issues.

Laboratory Assessment and Diagnostic Screening (including Drug Resistance Screening). OAHS programs must have access to all laboratory services 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.

Baseline lab tests (preferably at fasting) for all HIV positive persons should include:

□ Complete Blood Count (CBC) Liver function tests □ Basic Metabolic Panel (BMP) □ Protein □ Albumin □ Glucose □ Triglycerides □ Cholesterol □ Pregnancy test (for patients of childbearing potential) □ Cervical Pap smear (if not done in past year) □ Chest x-ray, when clinically indicated	□ Syphilis serology, urine Gonorrhea Chlamydia (GC)/Chlamydia and rectal/throat swabs for GC/Chlamydia *Toxoplasma gondii* antibody screening for those with CD4 < 200 □ CMV IgG Antibody screening for those with CD4 < 200Urinalysis □ CD4 count and HIV-RNA viral load □ Purified Protein Derivative (PPD) or IGRA (Quantiferon) □ Hepatitis A screening for those not previously vaccinated □ Hepatitis B and C serology*

*If the serology for Hepatitis C is reactive, then tests to determine whether the patient has chronic hepatitis C infection should be done. If a quantitative Hepatitis C viral load is indicated, and if the virus is present, the patient should be counseled and evaluated for hepatitis treatment and, as appropriate, treatment should be initiated.

Follow-up and ongoing lab tests for patients should be based on the most current U.S. Department of Health and Human Services (HHS) guidelines. For patients on ARV this should include: CBC, liver function tests, Basic Metabolic Panel, glucose, cholesterol, triglycerides (preferably fasting), CD4, HIV-RNA. Syphilis serology, urine Gonorrhea Chlamydia/Chlamydia, and rectal/throat swabs for GC/Chlamydia should be offered for sexually active patients based on risk behavior.

Drug Resistance Testing. When appropriate, OAHS practitioners may order drug resistance testing to measure a patient'spattern 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.
Drug resistance testing services will be based upon most recent established guidelines and standards of care including the PHS Guidelines and the Infectious Disease Society of America Guidelines, as well as the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents with HIV (https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/drug-resistance-testing)

Counseling and education about drug resistance testing must be provided by the patient's medical practitioner, registered nurse and/or other appropriate licensed healthcare 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.