Outpatient Ambulatory Medical Care
Standards of Care

Definition:

Outpatient/Ambulatory medical care (health services) is the provision of professional diagnostic and 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 generally do not stay overnight.

Limitations:

Services cannot be reimbursed if conducted in a hospital, hospital emergency room, or any other type of inpatient treatment center.

Services:

Services include diagnostic testing, early intervention and risk assessment, preventive 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, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties including ophthalmic and optometric services). As part of Outpatient and Ambulatory Medical Care, provision of laboratory tests integral to the treatment of HIV infection and related complications is included.

Care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies.

Early Intervention Services provided by Ryan White Part C and Part D programs should be included under Outpatient/Ambulatory Medical Care.

Diagnostic Laboratory Testing includes all indicated medical diagnostic testing including all tests considered integral to treatment of HIV and related complications (e.g. Viral Load, CD4 counts, and genotype assays). Funded tests must meet the following conditions:

- Tests must be consistent with medical and laboratory standards as established by scientific evidence and supported by professionals panels, associations or organizations;
- Tests must be (1) approved by the FDA, when required under the FDA Medical Devices Act and/or (2) performed in an approval Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified laboratory or State exempt laboratory; and
- Tests must be (1) ordered by a registered, certified or licensed medical provider and (2) necessary and appropriate based on established clinical practice standards and professional clinical judgment

Personnel and Staff Training

Staff Qualification	Expected Practice
Qualifications Providers shall have unconditional	All agency staff, contractors, and consultants who provide direct-care services, and who require

Staff Qualification	Expected Practice
licensure/certification in area of practice.	licensure, shall be properly licensed by the State of Texas, or documented to be pursuing Texas licensure while performing tasks that are legal within the provisions of the Texas Medical Practice Act (or in the case of a nurse, the Nursing Practice Act), including satisfactory arrangements for malpractice insurance.
Peer Review Agency/Provider will conduct peer review for all levels of licensed/credentialed providers (i.e. MD, NP, PA).	Provider will document peer review has occurred annually.
Staff Experience Service providers shall employ clinical staff who are experienced regarding their area of clinical practice as well as knowledgeable in the area of HIV/AIDS clinical practice.	Personnel records/resumes/applications for employment will reflect requisite experience/education. All staff without experience with HIV/AIDS shall be supervised by an employee with at least one (1) year of experience.
Staff Education Staff participating in the direct provision of services to patients must satisfactorily complete all appropriate Continuing Medical Education (CME)/Continuing Educational Units (CEUs) based on individual licensure requirements to include HIV-related courses.	Provider will document training received according to professional licensure requirements. Providers shall complete cultural competency to include cultural awareness of the aging population through participation in formal CME activities.
Standing Delegation Orders (SDO) Standing delegation orders provide direction to RNs, LVNs and, when applicable, Medical Assistants in supporting management of patients seen by a physician. Standing Delegation Orders must adhere to Texas Administrative Code, Title 22, Part 9; Chapter 193; Rule §193.1 and. must be congruent with the requirements specified by the Board of Nursing (BON) and Texas State Board of Medical Examiners (TSBME).	Standing Delegation Orders for a specific population shall be approved by the Medical Director for the agency or provider. Standing Delegation Orders will be reviewed, updated as needed and signed by the physician annually. Use of standing delegation orders will be documented in patient's primary record system.

Standards of Care

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Medical Evaluation/Assessment All HIV infected patients receiving medical care shall have a completed an initial comprehensive medical evaluation/assessment and physical examination that adheres to the current United States Public Health Service's (USPHS) guidelines within 3 months of HIV diagnosis or within 15 business days of initial contact with patient who has been in care. Primary medical care for the treatment of HIV infection includes the provision of care that is consistent with the USPHS guidelines.	The comprehensive assessment/evaluation will be completed by the MD, NP, or PA in accordance with professional and established HIV practice guidelines.
-Comprehensive HIV Related History	History shall include at a minimum, general medical history, a comprehensive HIV related history and psychosocial history to include: **Medical/surgery history** -Assess for presence of chronic diseases such as: • Diabetes • High blood pressure • Heart disease • Cholesterol problems • Asthma or emphysema • Sickle Cell Disease • Ulcers, acid reflux, or irritable bowel syndrome • Thyroid disorders • Kidney or liver problems • Obesity/BMI -History of Tuberculosis -History of Hepatitis and vaccines -Psychiatric/mental health history -Transfusion/blood products history -Past hospitalizations -Allergies -Drug reactions -Full review of systems -Travel history and place of birth -Medication adherence history -Past medical care -Past immunizations/vaccines

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	-Prescription and non-prescription medicines (over the counter) -Complementary and alternative therapies to include supplements/herbs **Psycho-social History** -Socio-cultural assessment -Occupational history and hobbies -Mental Health -Substance abuse **Lifestyle** -Tobacco use -Alcohol use -Illicit substances and hormones -Pets/animal exposures -Hobbies -Exercise -Stress Management -Spirituality **Sexual Health** -Partners -Practices -Past STIs -Protection used -Current contraception use -Contraceptive needs -Pregnancies -Births -Living children -Abortions/miscarriages -Date of last menstrual period -Date of last pap -Date of last anal pap **HIV-related health history** -Most recent CD4 counts and VL test results (Nadir CD4 and peak viral load) -Resistance testing and co receptor tropism assays as clinically indicated -Current and previous ARV regimens -Medication adherence -Previous adverse ARV drug reactions -Previous adverse reactions to drugs used for opportunistic infection prophylaxis -History of HIV related illness and infections

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	-HIV treatment history and staging Providers should monitor/treat/refer for all conditions identified during the health history.
-Physical Examination Providers should perform a baseline and annual physical examination, with particular attention to areas potentially affected by HIV	Physical examination will include a complete review of systems. Examination of the oral cavity should be included in both the initial and interim physical examination of all HIV-infected patients. Patients with lesions suspected to be oral manifestations of HIV disease should be referred to a dental health expert with experience in treating oral lesions associated with HIV/AIDS.
-Initial Laboratory Tests	Tests will include as clinically indicated: -CBC -Chemistry Profile: Electrolytes, Creatinine, eGFR (Estimated Glomerular Filtration Rate), Blood Urea Nitrogen (BUN) -Liver Transaminases, Bilirubin (Total and Direct) -Protein -Albumin -Fasting Glucose or hemoglobin A1C -Fasting Lipid Profile (Total Cholesterol, LDL, HDL, Triglycerides) -Syphilis serology, urine GC/Chlamydia, and extra-genital GC/CT is indicated (vaginal swab recommended for females) -Urinalysis Urine Protein and Creatinine -CD4 count and HIV-RNA viral load -Hepatitis B and C serology • If the HCV antibody test is reactive, then an HCV RNA should be done. If the HCV RNA test indicates the virus is present, then the patient should be counseled and evaluated for hepatitis treatment and, as appropriate, treatment should be initiated.
-Other Diagnostic Testing	Chest x-ray will be completed if pulmonary symptoms are present or LTBI test is positive.
Initial Screenings/Assessments	Screening should include at a minimum:

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Patients should receive screening for opportunistic infections and assessment of psychosocial needs initially and annually according to the current USPHS guidelines.	-Quantitative HCV RNA viral load testing is now recommended for HIV-infected patients to: • Confirm a reactive HCV ELISA antibody screen • Exclude HCV infection in those who are seronegative for HCV but have risk factors for HCV exposure and unexplained liver disease, including increased serum liver enzymes -TB screen at initial HIV diagnosis, then annually for high-risk individuals, as determined by their medical provider. • TST (Tuberculin Skin Test) or IGRA (Interferon- Gamma Release Assay) (if no history of TB or positive TB screening test in the past) (HRSA 2014 Guide) • Normal findings: o Repeat every 12 months if high risk of repeated or ongoing exposure o Repeat if CD4 count was <200 cells/μL on initial test but increases to >200 cells/μL on ART o Abnormal (TST induration ≥5 mm or positive IGRA): Evaluate for active TB -*Toxoplasma gondii* antibody screening • Positive results: Start toxoplasmosis prophylaxis if CD4 count drops to ≤100 cells/μL. • Negative results: Repeat if patient becomes symptomatic or when CD4 count drops to ≤100 cells/μL -Hepatitis A, B & C screens at initial intake. • Surface antigen test (HBsAG) should be used initially to determine if there is an acute or chronic HBV infection. Testing using additional HBV markers will be needed if positive. -Providers should screen all HIV-infected patients for anti-HCV antibodies at baseline. • Now recommended for HIV-infected patients who have continued high-risk behaviors but are seronegative for HCV; such individuals include: o Injection drug users o Men who have sex with men o Anyone with multiple sexual partners • In Texas, providers must report all acute

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	Hepatitis A, B, and C infections, to the local health department of the area where the patient resides. If a female is pregnant with HBV, Texas requires reporting whether acute or chronic.
	-Mental health assessment that includes screening.
	• Mental health screening in all HIV/HCV co-infected patients at baseline and at least annually according to standard guidelines for all HIV-infected patients (see the Mental Health Guidelines)
	  o Depression screening at initiation of anti-HCV treatment and at least every 4 weeks thereafter during treatment (see Section XII. Treatment Monitoring of HIV/HCV Co-infected Patients)
	  o Depression, anxiety, post-traumatic stress disorder, suicidal/violent ideation, and substance use
	  o Sleep habits and appetite assessment
	  o Psychiatric history, including psychotropic medications
	-Psychosocial assessment, including domestic violence and housing status
	-Substance use and abuse screening
	-Patients on ART receive lipid screening.
	-Tobacco use screening
	-Pediatric patients (14 years and younger) will be screened for child abuse as defined in Chapter 261 of the Texas Family Code and DSHS policy
	• Consider screening youth 14-17 for child abuse
	-Oral health assessment and screening
	-Ophthalmology screening
	-Cervical Cancer Screen
	• Women with HIV infection should have more frequent screening than uninfected women:
	  o Screen all HIV-infected women for cervical cancer (cervical Pap test) at initial visit, at 6 months, then annually unless abnormal.
	  o For HIV-infected women (any age) with ASCUS or higher-grade abnormality, colposcopy generally is recommended; alternatively, the Pap can be repeated in 6-12 months.

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	○ Consider anal cancer screening (anal Pap test) for all HIV-infected women if high resolution anoscopy is available to evaluate abnormal findings. ○ Colposcopy should be performed for females with abnormal cervical screen. Follow-up would then vary on a case-by-case basis. ○ Females with cervical HSIL also should be referred for high-resolution anoscopy and/or examination with biopsy of abnormal tissue. -Anal Pap tests (CIII recommendation) - Consider for examination for all HIV-infected adults, regardless of age at baseline and as part of the annual physical • Inquire about anal symptoms, such as itching, bleeding, diarrhea, or pain • Perform a visual inspection of the perianal region • Perform a digital rectal examination (CIII) -Providers should refer women with cervical HSIL and any patient with abnormal anal physical findings, such as warts, hypopigmented or hyperpigmented plaques/lesions, lesions that bleed, or any other lesions of uncertain etiology, for high-resolution anoscopy and/or examination with biopsy of abnormal tissue. -Providers should obtain anal cytology at baseline and annually in the following HIV-infected populations 60-74: • Men who have sex with men • Any patient with a history of anogenital condylomas • Females with abnormal cervical/vulvar history
Immunizations/Antibiotic Treatment Immunizations/vaccinations will be given according to the current USPHS guidelines. Providers will initiate prophylaxis for specific opportunistic infections	Patients will be given directly or through referral the following vaccinations: -Tetanus, Diphtheria, and Pertussis (Tdap) - every 10 years; if potential exposure (wound), after 5 years -Measles, Mumps, Rubella (MMR) - For all asymptomatic HIV-infected all no immune persons with CD4 counts of ≥200 cells/μL. & who are seronegative for MMR antibody;

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	• Live vaccine is contraindicated for use in patients with severe immunosuppression (CD4 count of <200 cells/µL). -Influenza (inactivated vaccine)- annually during flu season October 1st - March 31st (Not Flu Mist because it contains live virus & is not recommended for use in patients with HIV infection as the efficacy of the vaccine in this population has not been evaluated. • Vaccination is most effective among persons with CD4 counts of >100 cells/µL and HIV RNA of <30,000 copies/mL • Pneumococcal is recommended for all clients: • If CD4 count is <200 cells/µL, may be less effective; consider revaccination when CD4 count increases in response to ART. • Two types of pneumococcal vaccine: Pneumococcal (polysaccharide), (PPV23) & Pneumococcal 13-valent conjugate (PPV13) -Completion of hepatitis B vaccines series, unless otherwise documented as immune • Providers should administer the conventional HBV vaccination at 0, 1 month, and 6 months to patients with CD4 counts <500 cells/µL. -Completion of hepatitis A vaccines series, unless otherwise documented as immune. • Recommended, for persons with chronic liver disease, injection drug users, men who have sex with men, international travelers, and hemophiliacs. Consider for all, unless there is serologic evidence of previous disease. • Providers should administer HAV vaccination early in the course of HIV infection. If a patient's CD4 count is <200 cells/mm3, or the patient has symptomatic HIV disease, it is preferable to defer vaccination until several months after initiation of ARV therapy in an attempt to maximize the antibody response to the vaccine. However, vaccination should not be deferred in pregnant patients or patients who are unlikely to achieve an increased CD4 count.

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	• Providers should obtain a post-vaccination antibody measurement in patients who are at increased risk for hepatitis A infection • HBV-infected pregnant females who are not immune to hepatitis A should be vaccinated. -Human Papillomavirus (HPV) Not contraindicated for use in HIV-infected individuals • Females and males between ages 9-26 years. The vaccine is also recommended for gay and bisexual men (or any man who has sex with men) and men with compromised immune systems (including HIV) through age 26, if they did not get fully vaccinated when they were younger. • May be less effective if CD4 is <200 cells/µL. -Varicella-Zoster (VZV). Two doses • Live vaccine; contraindicated for use in patients with severe immunosuppression (CD4 count of <200 cells/µL) • Consider for HIV-infected, VZV-seronegative persons with CD4 counts of > 200 cells/µL -Zoster Vaccine. One dose • Live vaccine; contraindicated in persons with AIDS or other clinical manifestations of HIV infection • Consider for select patients aged >50 with CD4 counts of >200 cells/µL and with evidence of varicella immunity. -Meningococcal - two doses 8 weeks apart. • Recommended if risk factor is present Providers will obtain HIV viral load before vaccinations and not during intercurrent illness because these situations may lead to a transient elevation in viral load. Antibiotic treatment for opportunistic infection will be initiated if active infection has been ruled out and seropositive for: • Mycobacterium avium complex (MAC) if CD4<50 cells/µL. • Toxoplasmosis if CD4<100 cells/µL

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Antiretroviral Therapy and Pneumocystis jiroveci pneumonia (PCP) Prophylaxis Antiretroviral therapy will be prescribed in accordance with the established guidelines. Patients who meet current guidelines for ART are offered and/or prescribed ART. PCP Prophylaxis will be completed adhering to the current USPHS Guidelines.	Patients, regardless of age, with a diagnosis of HIV are prescribed antiretroviral therapy for the treatment of HIV infection. Patients aged 6 weeks or older with a diagnosed of HIV/AIDS, with CD4 counts of less than 200 cells/μL or a CD percentage below 15% will be prescribed PCP prophylaxis.
Drug Resistance Testing Drug resistance testing must follow most recent, established resistance testing guidelines, including genotypic testing on all naïve patients.	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). When appropriate, medical outpatient practitioners may order drug resistance testing to measure a patient's pattern of resistance of HIV to antiretroviral medications. Providers should perform resistance testing under the following circumstances: -At baseline, regardless of whether ART is being initiated (genotypic testing) -In all ART-naïve patients before initiation of ART (genotypic testing) -In patients experiencing treatment failure or incomplete viral suppression while receiving ART (genotypic and/or phenotypic testing) Providers should conduct the following to predict safety and efficacy of ARVs: -Coreceptor Tropism Test: Test before making decision to treat with CCR5 antagonist, or if virologic failure occurs while on a CCR5 antagonist (phenotypic assay preferred). -HLA-B*5701: Test before starting treatment with abacavir.
Health Education/Risk Reduction Health education will adhere to the most current	The following will be conducted initially and as needed: -Providers should discuss safer sexual practices so to decrease risk of transmitting HIV during HIV

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USPHS guidelines. Providers will provide routine HIV risk-reduction counseling and behavioral health counseling for HIV-infected patients. Since patients' behaviors change over time as the course of their disease changes and their social situations vary, health education providers will tailor routine risk-reduction counseling and behavioral health counseling not only to the individual patient but also to the particular point in time in the patient's life.	infection. -Providers should counsel HIV-infected patients about the risk of acquiring syphilis and other STIs from unprotected sexual contact, including all sites of possible transmission, such as anus, cervix, vagina, urethra, and oropharynx. -Providers should discuss family planning with patients, including: • Risks to the mother and fetus during pregnancy • Contraception counseling/hormonal contraception • Drug interaction counseling -Providers should assess smoking status and should encourage those who smoke to stop. -Providers should counsel patients on tobacco cessation annually (or document decline of tobacco use) • When current alcohol or other substance use is identified, providers should discuss the possible effects of such use on the patient's general health and HIV medications, as well as options for treatment if indicated. -Providers should routinely discuss with patients the importance of disclosure to partners. Patients should be educated about the options for voluntary partner notification. -Preconception care for HIV infected females of child bearing age. In accordance with the US Department of Health and Human Services recommendations (http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf), preconception care shall be a component of routine primary care for HIV infected females of child bearing age and should include preconception counseling and include: • General components of preconception counseling • Assessment of the female's pregnancy intentions on an ongoing basis and discuss reproductive options • Offer effective and appropriate contraceptive methods to females who wish to prevent unintended pregnancy • Counsel on safe sexual practices • Counsel on elimination of alcohol, illicit drugs and smoking

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	• Educate and counsel on risk factors for perinatal HIV transmission, strategies to reduce those risks, and prevention and potential effects of HIV and treatment on pregnancy course and outcomes
	• Inform females of interventions to prevent sexual transmission of HIV when attempting conception with an HIV-uninfected partner
	• Other preconception care consideration should include:
	  o The choice of appropriate antiretroviral therapy effective in treating maternal disease with no teratogenicity or toxicity should pregnancy occur
	  o Maximum suppression of viral load prior to conception
	  o Pre-fatherhood counseling
	-When HIV-infected patients are diagnosed with early syphilis (primary, secondary, or early latent), providers should intensify risk-reduction counseling, including discussions about the importance of condom use.
	• Refer to Disease Intervention Specialist (DIS) for follow-up on contacts
	-Nutritional Counseling regarding:
	• Quality and quantity of daily food and liquid intake
	• Exercise

Treatment Adherence Treatment adherence will be assessed and counseling will be provided according to current USPHS guidelines.	Patients are assessed for treatment adherence and counseling at a minimum of twice a year. -Those who are prescribed on-going ART regimen must receive adherence assessment and counseling on every HIV-related clinical encounter. • Should administer a reliable and valid standardized adherence assessment tool. If adherence issue is identified, referral to an appropriate health care professional for counseling and follow-up action is documented.
Referrals Providers will refer to specialty care in accordance	At a minimum, patients should receive referrals to specialized health care/providers/services as needed to augment medical care: -If CD4 count below 50 cells/mm^3 should be

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with current USPHS guidelines.	referred for ophthalmic examination by a trained retinal specialist for screening or as recommended by that specialist. -AIDS Drug Assistance Program (ADAP) -Medication Assistance Programs -Medical care coordination -Medical specialties -Mental health and substance use services • Mental health/substance use providers should be a part of the medical care coordination team -Treatment education services -Partner counseling and referral -Annual hygiene and intraoral examinations, including dental caries and soft-tissue examinations. -Medical Nutrition Therapy (MNT) -Health maintenance such as: • Cervical Cancer Screening - annually after 2 negative screens 6 months apart • Family Planning - annually • Colonoscopy - every 10 years unless patient condition indicates more frequent • Mammogram - annually unless patient condition indicates different frequency -Specialty medical care for any preexisting chronic diseases -Case Management Services or a Disease Investigation Specialist (DIS) for follow-up if missing appointments. Providers or staff is expected to follow-up on each referral to assess attendance and outcomes.
Follow-up Visits Outpatient Medical Care will adhere to the current USPHS guidelines for on-going health care. Patients will have at least one medical visit in each 6-month period with a minimum of 60 days between the first medical visit in prior 6-month period and last medical visit in the subsequent 6-month period.	Reassessment/reevaluation of health history, physical examination to include oral cavity, and annual laboratory testing should include at a minimum: -Assessment of vital signs and weight at each visit -Inquiry about new symptoms at each visit, to include new allergies and drug reactions -Noted changes in general appearance and body habitus -Syphilis, gonorrhea, Chlamydia screens annually -Hepatitis B and C screens if risk present -Ongoing lab tests for patients should include: • **Annual:** CBC, liver function tests, BUN,

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	cholesterol, triglycerides (preferably fasting) • **Every 3-6 months:** CD4 counts and HIV-RNA viral loads monitored every 3-6 months based on compliance and medication adherence. o For patients on a suppressive regimen whose CD4 cell count has increased well above the threshold for opportunistic infection risk, the CD4 count can be measured less frequently than the viral load. • **Every 3-6 months:** Syphilis serology, urine and extra-genital GC/Chlamydia for sexually experienced patients at increased risk • **Every 6-12 months:** CD4 count may be monitored every 6 to 12 months for patients on a suppressive regimen, unless there are changes in the patient's clinical status, such as new HIV-associated clinical symptoms or initiation of treatment with interferon, corticosteroids, or anti-neoplastic agents. Patients receiving ARV therapy should have follow-up visits scheduled every three to four months, except at the practitioner's discretion when a patient has demonstrated long-term stability and adherence. -Patients on ART receive lipid screening annually -In accordance with USPHS guidelines follow-up and ongoing lab tests for patients on ARV should include: • CBC, liver function tests, BUN, creatinine, glucose, cholesterol, triglycerides (preferably fasting), CD4, HIV-RNA and Syphilis serology. • Urine and extra-genital GC/Chlamydia (vaginal swabs recommended for females) should be offered for sexually active patients at increased risk. The USPHS guidelines require at least two visits a year. If clinically unstable or poorly adherent, follow-up should be considered monthly. Patients who are not receiving ARV therapy should have follow-up visits scheduled every three to six

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	months. Providers will continually evaluate patients for adverse outcomes and documents actions taken, outcomes, and follow-up.
Documentation in Patients Chart Providers will develop/update plan of care at each visit.	At a minimum, provider will document/update the following at each visit: -Chief complaint -Vital signs -Assessment/diagnosis -Proposed treatment -Problem list -Medical plan of care • A plan of care shall be developed for each identified problem and should address diagnostic, therapeutic and educational issues in accordance with the current USPHS treatment guidelines. -Current medications -Vaccinations -Referrals and recommendations -Any decline in services offered/referrals -Outreach efforts to bring patient who has missed appointments back into care. If a patient refuses a treatment, such as vaccinations, documentation of denial will be written in the patient's chart. The provider developing the plan will sign each entry.
Documentation of missed patient appointments and efforts to bring the patient into care.	Provider/staff will conduct the following: -Contact patients who have missed scheduled appointments using at least 3 different forms of contact (email, phone, mail, emergency contact phone call, referral to DIS for home visit) -Address any specific barriers to accessing services -Documentation includes number of missed patient appointments and efforts to bring the patient into care.

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