POPS Chapter 12 — STI Clinical Standards

12.1 Accessibility and Clinic Environment

- 1. The clinic facility is physically accessible in accordance with the Americans with Disabilities Act.
- 2. The clinic is accessible from residential areas through public and private transportation. Signage is clear and easy to understand without being conspicuous.
- 3. Clinic hours and staffing are adequate to accommodate clients, with a minimal number of clients turned away. The clinic assesses demand for STI services periodically to adjust the hours of operation and staffing levels. The clinic is open during lunch and staggers staff arrival, departure, and lunchtimes.
- 4. Ninety percent of clients who come to the clinic during normal operating hours get exams, testing and/or treatment as medically appropriate.
- 5. The clinic documents number of clients not seen the day they seek services and periodically analyzes the documentation to determine appointment and staffing needs.
- 6. The clinic conducts a yearly client satisfaction survey and uses the information to improve services.
- 7. The clinic does not deny care to any client who is unable to pay. Clinic fees are minimal or based on a sliding scale.
- 8. The clinic bills third-party payers to the extent possible.
- 9. People referred by a Disease Intervention Specialist (DIS) do not pay a fee for evaluation and treatment if they are unable to pay.
- 10. The waiting area is welcoming. The clinic offers a variety of client education materials (e.g., posters, videos, pamphlets, etc.), including materials relevant to diverse communities (e.g., Spanish language materials, LGBTQ health related information, and other community specific brochures and publications).
- 11. The public and non-clinic staff do not have routine access to the clinic area. Non-clinic staff do not use the area to access other areas of the building.
- 12. Exam rooms are clean and private and have adequate equipment and supplies for physical exams and specimen collection for both male and female genitalia.
- 13. The number of exam rooms is adequate to accommodate the number of clinicians (at least one room per clinician) and to serve clients promptly.

12.2 Range of Services

- 1. Clinicians accurately diagnose and treat bacterial STIs (i.e., syphilis, gonorrhea and chlamydia). The clinic should be able to diagnose HIV through a lab test.
- 2. If a clinic has the ability and resources to perform microscopy, clinicians diagnose and treat, or provide prescriptions to treat, vaginitis and other common, non-reportable genital infections.
- 3. The clinic offers confidential opt-out HIV counseling and testing at the time of the STI visit in accordance with <u>DSHS HIV and STD Program Operating Procedures and Standards (POPS)</u>, <u>Chapter 4, HIV Testing in STI Clinics</u>, so clients do not have to visit separate clinics or make an additional appointment for an HIV test.
- 4. The clinic provides or administers medications for reportable bacterial infections, (e.g., syphilis, gonorrhea and chlamydia).
- 5. The clinic offers expedited STI services, including:
 - Express clinic visits (DSHS POPS Chapter 12, STI Clinical Standards, Section 12.5-2 Clinic Flow – Appointment and Walk-in Systems)
 - Expedited Partner Therapy (EPT):
 - DSHS POPS Chapter 12, STI Clinical Standards, Section 12.8.2-2, Medical Protocols, Management of Sex Partners
 - DSHS POPS Chapter 12, STI Clinical Standards, Section 12.3-5, Client Considerations
 - Field-delivered therapy (FDT) to health department clients and/or partner(s) (with or without testing) by DIS and/or other health care workers.
- 6. The clinic provides primary prevention counseling and condoms to all clients.
- 7. If clinicians perform Pap smears, protocols for follow-up of abnormal results conform to AASCCP Guidelines and ACOG recommendations, (most current versions).
- 8. If the clinic performs pregnancy tests, protocols for follow-up and referral are in place (e.g., prenatal care, family planning).
- 9. Management of Gonorrhea Treatment Failure:
 - The clinic provides adequate evaluation and management of possible ceftriaxone treatment failure when a client was appropriately treated for lab-confirmed *Neisseria gonorrhoeae* infection with ceftriaxone and reinfection is unlikely.
 - Clinicians collect a test-of-cure with culture for antibiotic sensitivity testing and nucleic acid amplification tests (NAATs) of relevant clinical sites of

- exposure/infection (if not already done) prior to retreatment. If the site of persistent gonorrhea infection is the penile urethra, a Gram stain is also obtained, if available.
- Clinicians consult with the <u>STD Clinician Consultation Network</u> at Denver Prevention Training Center or CDC Gonorrhea Treatment Failure Team (gcfailure@cdc.gov; 404-718-5447) for guidance on clinical management and retreat as indicated.
- The clinic has a relationship with a reference laboratory or public health laboratory that performs *N. gonorrhea* culture/antibiotic sensitivity testing and a procedure for submitting specimens for possible treatment failure.
- The clinic has a procedure for reporting cases with positive test-of-cure result(s) to the <u>local or regional health department</u> within 24 hours.
- 10. Trained and knowledgeable clinic staff promote adult immunizations (e.g., HPV, hepatitis A, hepatitis B immunizations, as appropriate). The clinic offers routine hepatitis B immunizations to unimmunized clients, regardless of risk factors. The clinic has a system to refer clients for next injections if they do not want to return to the STI clinic.
- 11. The clinic does not deny confidential counseling and testing for STIs, including HIV, because a client refuses other STI services.
- 12. The clinic has written policies and procedures for the referral of clients with positive HIV results for early intervention services (e.g., continuing medical evaluation, tuberculosis and immune system testing, treatment, case management, and support group counseling).
- 13. The clinic has written policies and procedures for PrEP eligibility screening and referral of clients for PrEP clinical services.
- 14. When the clinic refers clients to other health services, clinic staff confirm appointments for high-priority referrals. High priority referrals include: 1) HIV Medical Care/Early Intervention services, 2) desensitization services for people who are pregnant, require treatment for syphilis, and give a history of a penicillin allergy, 3) congenital syphilis (790) treatment, and 4) prenatal care.

12.3 Client Considerations

1. The clinic maintains client confidentiality in accordance with the Health Information Portability and Accountability Act (HIPAA) Privacy Rule. -The clinic honors the client's preference to use their preferred name or a system other than names when calling clients from waiting areas. Clinic personnel are courteous, non-judgmental, and respectful of clients. Staff maintain cross-cultural awareness and display cultural humility. Clinic personnel are sensitive to the needs of people who are transgender and gender non-conforming. This includes providing an option for clients to list preferred names and pronouns on intake documentation, consistent reference to the client by preferred names and pronouns even when the client is not present, access to gender-segregated areas such as restrooms in accordance with the client's gender identity, and access to gender-

specific dressing gowns and other items as appropriate to the client's gender identity. Staff understand that there may be a need to use the client's legal name or gender, rather than their preferred name or gender, for third-party billing, prescriptions, and/or referrals.

- 2. The clinic provides client services and education in the client's primary or preferred language, whenever possible, using competent bilingual staff and professional medical translation as needed.
- 3. The clinic has security protocols and reviews them with staff upon hire and yearly. Security protocols cover workplace violence, terrorism, fire, disaster response, bomb threats, violent and abusive people, etc.
- 4. The clinic offers medications, prescriptions and client education materials to clients with a positive gonorrhea result, a positive chlamydia result, or both to deliver to their partner(s). The clinic bases EPT for MSM on shared clinical decision-making with consideration for increased risk for bacterial STIs and HIV (EPT, <u>DSHS POPS, Chapter 12, STI Clinical Standards, Section 12.8.2-2, Medical Protocols, Management of Sex Partners</u>).
- 5. Telephone reports of STI test results follow written clinic procedures to ensure confidentiality. Test results are available any day the clinic is open. Automated electronic systems are an acceptable method to notify clients of negative test results.
- 6. The clinic does not give positive HIV test results over the telephone or with an automated results system.

12.4 Registration Process

- 1. The clinic gets registration information in a confidential manner.
- 2. The clinic checks the "expected-in" file for every person at every visit as part of the registration process. "Expected-in" is a record file of people referred to the clinic by a DIS or being sought by a DIS.
- 3. The clinic triages clients at check-in and offers "Express" services, if appropriate (<u>DSHS POPS, Chapter 12, STI Clinical Standards, Section 12.5.2, Clinic Flow Appointment and Walk-in Systems</u>).
- 4. The clinic sees DIS referrals and follow-up visits (as defined in clinic protocols) before walk-in clients.

12.5 Clinic Flow — Appointment and Walk-In Systems

 Appointment systems should not create barriers to clinic access. The clinic uses a hybrid appointment system of scheduled appointments and walk-in appointments. The clinic has systems to assess and modify client visits to assure staff see clients in one hour or less. Clients receive the appropriate level of care.

- 2. Approved staff functioning under an authorizing physician's standing delegation orders provide "Express" STI services. Such services include a sexual history and risk assessment, laboratory testing for STIs (gonorrhea [GC], chlamydia [CT], syphilis) and HIV, GC/CT treatment and instructions (except men who have sex with men [MSM] contacts to GC/CT), and risk reduction counseling.
- 3. Triage staff will determine if the client is pregnant, symptomatic for an STI, a contact to HIV, syphilis or GC/CT, or is otherwise at increased risk for STIs, as defined by STI trends in the jurisdiction. Staff will triage clients as follows:
 - Clients who are pregnant, symptomatic for an STI, a contact to HIV or syphilis, and MSM contacts to GC/CT should receive a comprehensive STI evaluation (including exam) from a licensed clinician.
 - Clients at increased risk for STIs, as defined by the jurisdiction, should receive a comprehensive STI evaluation, if available. They may receive "Express" services.
 - The clinic may offer other clients the option of "Express" services. Clients may opt for comprehensive services.
- 4. High priority clients who should receive a comprehensive STI evaluation (including exam) the same day include:
 - DIS referrals
 - Pregnant People
 - Contacts to syphilis and HIV
 - Clients reporting signs or symptoms of an STI (e.g. genital ulcer, discharge) or possible STI-related complications (e.g. epididymitis, pelvic inflammatory disease, disseminated gonorrhea infection, neurosyphilis)
- 5. The clinic gives next-day appointments to walk-in clients they cannot accommodate the same day because of time constraints. Such clients also receive a list of STI medical resources, including eligibility requirements (e.g., urgent care clinics, family planning clinics and private physicians), which they may call for a same-day appointment.
- 6. The clinic keeps client stops to a minimum (i.e., the client visits no more than three stations registration, lab and clinical care). Clinicians provide oral medications, injectable medications or both to clients to minimize the number of stops.
- 7. The clinic conducts a client flow analysis at least every other year to provide a systematic understanding of bottlenecks in clinic flow and ensure staff make corrections to minimize them.

12.6 Health Records

- 1. Health records contain enough demographic and clinical evaluation information to enable DIS to identify the client and readily interpret the examining clinician's clinical findings, assessment and management.
- 2. Administrative and clinic forms allow clients to list preferred names, pronouns, sex at birth and gender identity (e.g., male, female, trans, transgender). Clinic staff refer to clients according to client preferences. Staff also document client preferences in the health record, while recognizing the potential need to use legal name or gender for third-party billing and prescriptions.
- 3. The clinic has written procedures for the management of health records that include forms management, organization of the health record, records security, record retention, and proper disposal. Policies comply with the Health Information Portability and Accountability Act (HIPAA) and state and national rules and regulations that pertain to HIV/STI information. (See DSHS records management policies at dshs.texas.gov/retention).
- The clinic has established work settings and procedures to prevent unauthorized persons from seeing records and overhearing conversations about protected health information and clients.
- 5. The clinic assigns responsibility to manage the release of health records due to subpoena, court order or other such means to a trained person knowledgeable on state and national STI rules, HIV rules and HIPAA regulations. This person tracks all matters relating to requests to view health records.
- 6. When the clinic provides EPT to a client, staff document the number of doses in the index client's health record. Staff do not write names of partners receiving medication in the index client's health record. A health record is not required for sexual partners who receive EPT.
- 7. The clinic records EPT /FDT services provided in a log that includes index client's name, date of birth, date given, number of doses given, name of medication and strength, lot number, NDC, and expiration date.

12.7 Clinic Management Structure — Clinic Manager and Medical Director

- 1. The clinic manager has adequate training and experience in health care management, clinic management, personnel management, and public health to develop and implement clinic goals, policies, and procedures; manage personnel; orchestrate all clinic functions; and ensure quality of care.
- 2. The medical director has specialized training in STI care, is available for consultation during clinic hours, and ensures the overall quality of clinical services.

3. The clinic provides training to managers and medical directors to strengthen their STI knowledge, if needed.

12.8 Clinic Manuals

12.8.1 Staff Policies

- 1. The clinic provides job descriptions and performance standards to staff members. Descriptions and standards include:
 - qualifications and training requirements for each position;
 - a description of the role each position plays in clinic operation;
 - a description of the essential tasks required for each position;
 - the mechanism for performance evaluation; and
 - a description of the respect, consideration, and attitudes the clinic expects staff to convey to clinic clients.
- 2. Non-licensed staff who provide "Express" STI services are appropriately trained and approved to collect specimens.
- 3. The clinic enforces clearly written policies consistent with state and local employee health regulations regarding employee health (e.g., injury surveillance, blood-borne pathogen exposure, tuberculosis screening, and hepatitis B vaccination).
- 4. The clinic has written policies and procedures to conduct quality assurance, including health record reviews, client satisfaction surveys, staff development, and related training activities.
- 5. The clinic has written policies and procedures to describe disciplinary actions management will take if an employee violates a policy or procedure.
- 6. The clinic has written policies and procedures to require and document training of all staff regarding suspected sexual child abuse screening and reporting.
- 7. The clinic has written policies and procedures to ensure staff route reportable conditions to the proper surveillance staff in accordance with <u>DSHS HIV and STI Program Operating Procedures and Standards, Chapter 8, HIV/STI Surveillance</u>.

12.8.2 Medical Protocols

- 1. The supervising physician updates, approves and co-signs standing delegation orders (SDOs) and other protocols for client care every year.
- 2. Clinicians, registered nurses, licensed vocational nurses, and other staff who function under SDOs sign and date the SDOs and other protocols every year.
- 3. Protocols include, but are not limited to:

- Client evaluation
- Medical management of STIs based on current CDC STI Treatment Guidelines
- Medical consultation and referral
- Required follow-up after therapy
- Counseling and education
- Management of sex partners The clinic offers expedited partner services to clients diagnosed with gonorrhea, chlamydia or both. This includes on-site treatment of partners, EPT and FDT as needed. "Express" clinic visits are available to asymptomatic partners for gonorrhea treatment, chlamydia treatment or both (except MSM because DSHS recommends a complete clinical evaluation due to increased risk of bacterial STI and HIV co-infection).
- Expanded treatment of contacts and suspects, including self-reported exposures, during local syphilis outbreaks
- 4. Emergency medical protocols are current. Clinic staff:
 - keep one copy of an emergency protocol in the clinic manual and one copy with emergency supplies;
 - are certified to provide Basic Cardiac Life Support (BCLS) and use an automated external defibrillator (AED);
 - check emergency equipment, supplies, and medications monthly to ensure they are not depleted or expired;
 - seal emergency supplies when not in use; and
 - regularly perform and document mock emergency drills.
- 5. The clinic has current protocols for occupational exposure of healthcare workers, which the supervising physician signs and updates yearly.
- 6. The clinic has current protocols for the safe handling of blood and body fluids (standard precautions) according to Clinical Laboratory Improvement Amendments (CLIA) and Occupational Safety and Health Administration (OSHA).
- 7. Clinic management updates and approves clinic policies, procedures and protocols yearly.
- 8. Clinic policies, procedures, protocols and SDOs adhere to all applicable Texas laws, rules and regulations, including those of the Texas Medical Board and Texas Board of Nursing.

12.9 Clinician Roles and Performance Standards

1. Nurses (LVNs and RNs), advanced practice nurses (APNs), and physician assistants (PAs) work in full compliance with established clinic procedures, protocols and SDOs. The

examining and treating clinician is responsible for the entire clinical care process for the client(s) they are treating. This includes history taking, physical exam, laboratory specimen collection, diagnosis, treatment, plan for follow-up, counseling and education.

- 2. Non-physician clinicians have adequate physician backup and operate under procedures, protocols and SDOs signed by a physician.
- 3. Minimum background and training include:
 - Licensure (e.g., LVN, RN, APN, PA, or physician) or credentials required by the state or locality to perform the functions of an STI clinician. The clinic has a written procedure to verify current licensure.
 - A veteran clinician trains and observes clinicians new to STI/HIV and/or the clinic before caring for clients.
 - Within one year of hire, clinicians complete the following training:
 - A comprehensive STI clinician course through an STI/HIV Prevention Training Center or similar provider *
 - An HIV/AIDS update that includes clinical and epidemiologic information about HIV infection *
 - Gender identity training, including how to appropriately respond to sexual assault of people who are gender non-conforming
 - Human trafficking and intimate partner violence training

Clinicians receive updates on STI and HIV topics at least every two years.

- *On-line trainings such as std.uw.edu for STIs and aidsetc.org/training for HIV/AIDS are acceptable alternatives to classroom training.
- 4. The clinic provides STI clinical services in as follows:
 - Clinicians are sensitive and competent.
 - Clinicians get the medical history and risk assessment by asking open-ended questions, (e.g., how long, when, how many, what, describe, etc.).
 - Clinicians examine appropriate anatomy with professional thoroughness.
 - Clinic staff collect and correctly label laboratory specimens.
 - The chief complaint, history of present illness, medical and sexual history, physical exam, laboratory results, diagnosis, treatment plan and treatment provided, counseling/education, follow-up plan, and referrals are accurate and documented in the health record.
 - Counseling messages are specific, clear, brief and allow time for client questions.

- When clinic staff offer EPT to a client, they document client acceptance or refusal in the health record. If clinic staff provide EPT to a client, they counsel the client, give written information (in the partner's language whenever possible) and document the medication and number of prescriptions provided in the index client health record.
- Clinicians strictly adhere to standard precautions (previously referred to as universal blood and body fluid precautions).
- Clinicians inform and facilitate a seamless transfer of a client to other team members as appropriate (e.g., DIS, case manager, immunization staff member).

12.10 Laboratory Services

- 1. All clinics that provide STI services and have an on-site stat laboratory or capacity to perform stat tests must have a current CLIA certificate and comply with CLIA-88.
- 2. Stat laboratories perform the following tests, all classified as moderately complex under CLIA, except for urine pregnancy tests, which are CLIA-waived:
 - Gram stain to detect intracellular gram-negative diplococci and presence of white blood cells to detect urethritis
 - Non-treponemal antibody tests for syphilis (e.g., RPR)
 - Darkfield exam for Treponema pallidum, if available
 - Saline wet mount for Trichomonas vaginalis and detection of clue cells of bacterial vaginosis
 - KOH wet mount for the identification of yeast and for amine odor (Whiff) test
 - Pregnancy test
 - Rapid HIV test*
 - Rapid treponemal test for syphilis (e.g., Syphilis Health Check) *
 - *Some rapid HIV and syphilis tests are CLIA-waived. Consult manufacturer instructions for each.
- 3. Preparing for multi-drug resistant gonorrhea:
 - The clinic has a relationship with a reference laboratory and a well-defined procedure for culture and antibiotic susceptibility testing when the clinician suspects resistant gonorrhea.
 - The clinic has a procedure to report suspected or confirmed antibiotic resistance to the proper health authorities.

12.11 Quality Assurance Procedures

- 1. A quality assurance committee meets regularly and follows an approved protocol to conduct audits, analyze findings, and develop recommendations.
- 2. The clinic regularly audits health records (checked against clinic protocols) to determine the appropriateness of diagnoses and treatment and the completeness of documentation.
- 3. The clinic regularly monitors quality of stat laboratory procedures.
- 4. Appropriate clinical managers regularly observe staff interactions with clients.
- 5. The clinic has an established written procedure for receiving, reviewing, and responding to client complaints.
- 6. The clinic has a written procedure to ensure staff properly label and pack specimens for shipping in accordance with the receiving laboratory specifications.
- 7. The clinic performs semi-annual safety audits to determine appropriate use of electrical equipment, storage of chemical, and first-aid stations.

12.12 Sexual Assault and Abuse

- The clinic has written policies and procedures to describe how the agency determines, documents, and reports instances of suspected child abuse in accordance with <u>Chapter</u> <u>261 of the Texas Family Code</u>.
- 2. The clinic maintains records relating to services to minors age 13 and younger.
- 3. Clinic staff receive annual training on the provisions of the state child abuse and neglect statute and their obligations with regard to Chapter 261 of the Texas Family Code.
- 4. Clinic staff receive annual training on applicable STI and HIV confidentiality statutes. Staff are sensitive to limitations on reporting supplementary information related to suspected abuse cases.
- 5. The clinic has written procedures that outline the referral of clients who are victims of alleged child sexual abuse or adult sexual assault who need or request a forensic exam.
- 6. Clinic staff document a completed checklist for screening for suspected sexual child abuse and reporting in health records when appropriate and contractually required, in accordance with Chapter 261 of the Texas Family Code.
- 7. The clinic has access to a client advocate who maintains links with victim assistance programs.
- 8. The clinic has a written procedure for assisting and referring victims of human trafficking and intimate partner violence to the appropriate community resources.

12.13 References

The Texas Department of State Health Services (DSHS) bases these standards on the following references:

- 1. Centers for Disease Control and Prevention (CDC). <u>Program Operations Guidelines for STD Prevention, Medical and Laboratory Services</u>, (2001) (or latest version).
- 2. Centers for Disease Control and Prevention (CDC). <u>CDC Division of STD Prevention Funding</u>
 Announcement (STD-PCHD for 2019-2023) (or latest version).
- 3. Centers for Disease Control and Prevention (CDC). <u>CDC Sexually Transmitted Infections Treatment Guidelines</u>, 2021 (or latest version).
- 4. Centers for Disease Control and Prevention (CDC). <u>CDC Recommendations for Providing Quality STD Clinical Services</u>, 2020 (or latest version).
- 5. Texas Department of State Health Services (DSHS). <u>DSHS Client Services Standards for Public Health and Community Clinics</u>, 2004 (or latest version).
- 6. Centers for Disease Control and Prevention (CDC). <u>CDC Expedited Partner Therapy (EPT) in the Management of Sexually Transmitted Diseases</u>, 2006 (or latest version).
- 7. Texas Department of State Health Services (DSHS). <u>DSHS Expedited STI Management Implementation Guide 2021</u> (or latest version).
- 8. Texas Department of State Health Services (DSHS). <u>Management of Gonorrhea Treatment Failure.</u>
- 9. 106th U.S. Congress. <u>Trafficking Victims Protection Act of 2000</u> (Public Law No. 106-386), as amended, and 19 U.S.C. 1591.
- 10. Texas Medical Board
- 11. Texas Board of Nursing