



Texas Department of State
Health Services

Hansen's Disease Program

Service Delivery WORK PLAN

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I. Introduction

The Texas Department of State Health Services (DSHS) provides outpatient treatment for individuals with Hansen's disease (HD) throughout the state of Texas. These services are federally funded through the National Hansen's Disease Program (NHDP), an activity in the Department of Health and Human Services (DHHS), and the Bureau of Primary Health Care. It is authorized by Public Law 99-117, Section 2. (a), Section 320, and guided by DHHS regulations. Key legislation for HD services is outlined in the Public Health Service Act, 42 U.S.C. § 247e (a)(2), that:

"At or through the National Hansen's Disease Programs Center (located in the State of Louisiana), the Secretary shall without charge provide short-term care and treatment, including outpatient care, for Hansen's disease and related complications to any person determined by the Secretary to be in need of such care and treatment..."

The Texas DSHS HD Program is administered by the DSHS Tuberculosis and Hansen's Disease Unit. The primary goal of the program is to prevent deformity and disability from HD through early diagnosis and treatment.

This Hansen's Disease Service Delivery Work Plan (HD Work Plan) sets forth procedures established by the HD Program to ensure all Texas-based ambulatory care HD clinics receiving funding achieve the same performance standards.

II. Purpose

The purpose of the HD Work Plan is to describe the framework of a local HD program and outline clinical activities to meet DSHS HD Program standards. The HD Work Plan:

- serves as a prescriptive document to design and maintain a local HD clinic;
- outlines expectations and responsibilities of all funded HD clinical programs;
- assures consistent HD prevention and care practices are applied throughout Texas; and
- provides a blueprint to assess performance outcomes based on quality indicators.

III. Performance Tasks

The HD clinic will perform the following tasks:

Task 1: Federal Records Management

The clinic will:

1. Manage and maintain federal records.
 - Records management includes electronic records, in accordance with all applicable Texas and federal records management laws and regulations.
2. Follow applicable records categorization to manage retention and disposal.
 - Records retention for state and local governmental agencies is mandated by the Texas Administrative Code, Title 13, Chapter 6, and Section 6.10 for compliance and maintenance of records. All divisions and branches must comply with these rules.
3. Ensure applicable HD key personnel take the Health and Human Services (HHS) Records Management Training.
 - Training is required for all employees having access to (1) federal information or a federal information system, or (2) personally identifiable information (PII).
 - Must be completed at the start of employment or the start of the contract period (whichever is sooner), *and* annually.
 - Training link available at:
https://humancapital.learning.hhs.gov/courses/2023recordsmanagement/01_index.html
 - At the end of the Records Management training, the "Congratulations" slide is considered the certificate of completion.
 - Certificate of completion must be submitted to the DSHS HD Program at HDPCR@dshs.texas.gov within 30 days of completion, and annually.

Task 2: Kickoff Meeting

The clinic will:

1. Attend virtual meetings with DSHS HD Program staff, as arranged by the DSHS HD Program Nurse Administrator or designee, at the start of the NHDP project period.
 - The NHDP project period is September 28, 2023, until September 27, 2028.
2. Key personnel to attend must include, at minimum:
 - The HD Program Manager
 - The HD Nurse

Task 3: Patient Assessment & Management and Outreach and Education

The clinic will:

1. Validate patient eligibility for HD services:
 - Patient: Any individual residing in the United States or its territories, and those individuals protected under the Compact of Free Association (COFA) who has been diagnosed with HD or needs to have HD ruled out as a diagnosis.

- Contact: any individual who has shared the same enclosed airspace in a household or other enclosed environment for a prolonged period with a person who has an untreated case of HD.
- 2. Ensure any eligible patient receives treatment and case management as outlined in the HD Work Plan, and as per the NHDP Guide to the Management of Hansen's Disease (NHDP Manual), or as per NHDP consultation.
 - The most recent version of the NHDP Manual is found here:
<https://www.hrsa.gov/hansens-disease/diagnosis>
 - Clinical consultation from NHDP is available via phone: 800-642-2477.
- 3. Perform initial and ongoing patient assessments and diagnostic testing, to include:
 - History and physical exam.
 - Initial exam shall include a skin biopsy and screenings of the eyes, hands, and feet. Skin smears are optional but are useful as a clinical marker to measure bacterial load.
 - HD clinic nurse(s) must document the initial assessment on the HD-400. Documentation must include any identified psychosocial issues with appropriate referral for mental healthcare or social services, as needed.
 - Submit diagnostic specimen to confirm or rule out an HD diagnosis, or when determining therapy efficacy:
 - The DSHS HD Program has designated Quest Diagnostics as the commercial laboratory for submitting initial pathology, including hematoxylin and eosin (H&E) and fite stains collected on eligible patients. Follow the specimen collection procedures, as provided by the DSHS HD Program. *Refer to Appendix C. Submitting Hansen's Disease Laboratory Tests to Quest Diagnostics.*
 - Supplies for diagnostic laboratory testing cannot be requested from the NHDP; they may be ordered through Quest Diagnostics.
 - Arrange for additional diagnostic testing via the NHDP reference laboratory (i.e., polymerase chain reaction [PCR]), or when NHDP pathology consultation is needed.
 - Perform initial and ongoing screenings:
 - Hand and foot screens (NHDP-130, NHDP-133) are performed using Semmes Weinstein monofilaments, and are performed at the following intervals:
 - Initial assessment, to determine baseline condition
 - Quarterly, if active on multi-drug therapy (MDT) or on reaction medications
 - Annually, while in a one-to-three-year observation period
 - As needed, when patient has abnormal findings

- At closure
- Eye screen (NHDP-216)
 - Initial assessment, to determine baseline condition
 - Quarterly
 - If the patient is prescribed medications that cause change in visual acuity, the frequency shall be determined by the licensed healthcare provider (consider at least a quarterly visual acuity exam and intraocular pressure checks while on steroids and other medications that impact eye pressure and vision).
 - At closure
- Perform a physical exam of the hands and feet for loss of protective sensation (per screens), and visual assessment of any abnormalities (i.e., calluses, fissures, wounds, etc.).
 - Physical exam should occur during the hand and foot screenings.
 - Provide education on how to protect the skin on the hands and feet when there are, or there is the potential for, wounds due to loss of sensation as identified by the hand and foot screens.
 - Refer patient to receive specialty shoes as identified by each clinic or when needed, custom orthotics. To be eligible for specialty shoes or custom orthotics, patients need to be classified with a Grade 1 or above disability (see *Appendix D: Disability Grades*).
 - Consult with ancillary providers and/or NHDP as necessary on any current or potential hand and foot problems, to prevent deformity and disability (see *Appendix E: Triggers for Referral and Consultation*).
- Perform initial and ongoing monitoring of HD reactions:
 - Reactions or acute hypersensitivity to the *M. leprae* organism may occur in 30-50% of HD patients during treatment of the disease. There are no predictors for who will develop a reaction.
 - There are two types of reactions:
 - 1) Reversal Reaction (Type I Reaction)
 - 2) Erythema Nodosum Leprosum, (ENL or Type II Reaction)
 - Reactions are precursors to peripheral nerve damage and should be effectively managed to prevent deformity or loss of nerve function.
 - Reaction status and interventions must be documented on the HD-400 at each clinic visit.
- Use telehealth and telemedicine, as applicable, according to local HD clinic processes and approvals.
 - To improve access to care, the HD clinic may consider utilizing telehealth and telemedicine technologies to provide HD patient care, when feasible, after initial in-person patient assessment.

- The use of telehealth or telemedicine is best for patients that are stable and do not need hands-on patient services.
 - Refer to the National Institutes of Health (NIH) for more guidance on using telehealth and telemedicine:
<https://www.nia.nih.gov/health/telehealth-what-it-how-prepare-it-covered>.
4. Perform initial and ongoing laboratory monitoring:
- Routine blood testing should be collected as per *Appendix B: Laboratory Tests*, which includes at minimum:
 - Initial
 - CBC with differential, CMP, CRP, Sed rate, Vitamin D level, HBsAg, HCV Ab, IGRA.
 - Ongoing while on MDT or reaction medications
 - Every three months: CBC with differential, CMP, CRP, Sed rate, Vitamin D level.
 - If the HD patient is treated for a reaction, laboratory testing may increase in frequency and duration.
 - Additional laboratory tests may be required for patients treated with prednisone, thalidomide, or other medications used to manage reactions. This must be determined by the HD physician on a case-by-case basis.
 - Use locally determined laboratories:
 - Each funded HD clinic may designate their preferred laboratory for routine blood testing, using locally budgeted supplies, unless otherwise arranged by the DSHS HD Program.
 - IGRAs: the DSHS HD Program has designated Quest Diagnostics as the commercial laboratory that may be used for performing initial IGRAs. Follow the Quest Diagnostics shipping and processing procedures for IGRA testing, as outlined in *Appendix C. Submitting Hansen's Disease Laboratory Tests to Quest Diagnostics*.
 - Refer patients to a primary care clinic or the health department when tuberculosis (TB) or sexually transmitted infections (STIs)- including HIV testing- is needed, as indicated by the treating HD physician.
 - If the initial IGRA is positive, ensure the patient receives a TB evaluation.
 - If latent TB infection is diagnosed, ensure the HD physician coordinates an effective treatment plan to address HD and TB. Consult with the local health department TB program and/or NHDP, as needed.
5. Provide medications; store and reconcile inventory:

- Order medications for HD or reactions as listed in *Appendix F: DSHS Hansen's Disease Formulary*.
 - Active HD: Provide MDT for patients with multibacillary and paucibacillary disease, as listed on *Appendix A: Treatment for Hansen's Disease*, and per the NHDP Manual, ensuring a physician's order is in place.
 - The durations of treatment as per *Appendix A* are sufficient, even though large numbers of dead bacilli may remain in the tissues for several years before being eliminated by physiological processes. There is no evidence that additional, prolonged treatment hastens the elimination of these dead organisms.
 - For immunologically compromised patients: protocols may be modified, and consultation with the NHDP is encouraged.
 - For children: The occurrence of HD in children in the U.S. is rare. The HD clinic must consult with the NHDP for the management of HD in children. Consult recommendations must be documented in the patient's medical record.
 - HD clinics may choose to provide intermittent HD regimens via directly observed therapy (DOT) or by video-enabled DOT (VDOT). Utilize locally budgeted funds if needed. NOTE: If VDOT is pre-recorded, it should be date verified.
 - Reactions: Provide medication for reactions.
 - Seek medical consultation from the NHDP when methotrexate, thalidomide, or other medications for a reaction are used, if physician is unfamiliar with usage.
 - When ordering medications, use the Prescription Fax Form (preferred), or the DSHS Pharmacy Inventory Ordering System (PIOS), as outlined in *Appendix G: Medication Ordering and Inventory Tracking*.
 - Order non-formulary medications as needed to support care.
 - When non-formulary medications are needed, complete form HD-413 and maintain a copy in the patient's medical record. See process outlined in *Appendix G: Medication Ordering and Inventory Tracking*.
 - Ensure medication inventory is stored and reconciled, as outlined in *Appendix G: Medication Ordering and Inventory Tracking*.
6. Provide patient education and outreach:
- Patient education:
 - Perform routine patient education. Educate patients and families on: HD, treatment, stigma, deformity, disability, isolation, job loss, and being a source of infection to their families. Provide ongoing education on the importance of screening tools and the need for completing therapy.
 - Document routine patient education on form HD-400.

- Perform bi-monthly, *targeted patient education*. Targeted patient education activities are additional opportunities provided to HD patients and their families that go beyond the normal practice of informing patients about their health, wellness, treatment plans, potential outcomes, and other information during a patient/provider encounter. Targeted patient education provides additional opportunities for HD patients and their families to learn more about Hansen's disease.
 - Examples of targeted education activities may include HD patient group classes, development of brochures or other printed material that target patient needs (i.e., HD and diabetes), targeted education on foot care that emphasizes the prevention of wounds, home or clinic visits where family members are educated about HD based on a specific or targeted need (i.e., change in patient status), or display of educational posters.
 - Report targeted patient education monthly on the HD-410.
 - HD clinics will conduct, and report targeted patient education every other month, as scheduled by DSHS.
 - Patient outreach:
 - Perform activities to maintain patients in therapy.
 - Report to the DSHS HD program patients who have died or who have moved using the Change of Patient Information form (HD-406).
 - Patients moving out of state must be reported to the HD program within three (3) days of becoming aware of move, so that coordination with another HD clinic may be arranged.
 - Contact patients who are lost to follow up (LTFU). Provide three (3) attempts to have the patient return to the clinic: send a letter, make a phone call, at least one (1) attempt must be a certified letter explaining the need to get them back into clinic. When all attempts have failed, change patient status to LTFU when the following exists:
 - if on medications, close at 180 days/six months.
 - if not on medications, close if they have not come back for their annual follow-up and do not reply to attempts at communication.
7. Provide community outreach and education and request approval for outward-facing material.
- Community outreach:
 - Perform two community outreach activities *annually* such as: develop and distribute handouts; make Facebook, or similar social

- media posts (excluding patient-specific information); develop presentations for community partners.
- *Note: World Leprosy Day is the last Sunday in January. See <https://www.cdc.gov/leprosy/world-leprosy-day/index.html>.*
 - Contact the DSHS HD program for any suggestions of where to find applicable printed material and/or templates that may be available to support community education.
 - The DSHS HD program shall provide an educational toolkit to the Texas clinics to utilize. This toolkit consists of updated brochures, posters, flyers, presentation templates, guides, and other resources to aid in education and outreach for HD.
 - Report to the DSHS HD program outreach activities monthly on form HD-410.
8. Provide medical case management and record keeping for eligible patients:
- Ensure all patients who choose to receive services at the HD clinic have a medical record that includes signed copies of forms HD-405, L-36, CD-001 and other applicable consents at the start of service. All HD forms can be found at <https://www.dshs.texas.gov/idcu/disease/hansens/forms.shtm>.
 - Medical case management shall be performed in accordance with the most current version of NHDP's *HD Manual*, and upon consultation with a Hansen's disease physician and/or a medical consultant at NHDP.
 - Disposition, treat, provide, and document all appointments for patients actively needing HD services as follows:
 - **Active:** patients in the active phase of treatment (those taking multi-drug therapy [MDT] or medications for reactions after MDT) require a minimum of four (4) visits annually while on therapy to include quarterly hand/foot/eye screens and the Annual Follow-Up form (NHDP-208).
 - **Observation:** patients in the observation phase who have completed MDT and/or all medications for reaction, when all drugs are discontinued, and patient has no additional medical complications, may be seen annually for one to three years (as determined by the HD physician) and then discharged from the clinic. Observation is as follows:
 - Schedule a clinic visit - the annual visit should consist of a physical exam, hand/foot screens, and the Annual Follow-Up form (NHDP-208). If after one to three years the patient has no HD-related medical needs, they should be dispositioned as Inactive.
 - In lieu of a clinic visit - if the patient declines an in-person visit, the nurse should document on form HD-400 the education provided on signs and symptoms of neurological

impairments. Close the patient as Inactive once they complete the observation period or decline further follow-up.

- **Complication:** patients with complications requiring medical or case management interventions will be followed until intervention is no longer needed. Perform hand/foot screens annually and as needed, and the Annual Follow-Up form (NHDP-208) while receiving services. Close as Inactive when intervention is no longer needed.
- Disposition all other patients as per *Appendix H: Patient Statuses*.
- Records of all patients are to be kept permanently, according to the DSHS Records Retention Policy. Contact the DSHS HD Nurse Administrator for details as needed. DSHS staff may access the retention schedule at: <https://hhsconnection.hhs.texas.gov/rights-responsibilities/records-management/retention/dshs/tb-hansens-disease-patient-files>
- Maintain data security and confidentiality standards as outlined in *Appendix J: Confidentiality and Security Standards*.

Task 4: Identifying a Multidisciplinary Team

The clinic will identify a multidisciplinary team, including key personnel and ancillary care providers, to support and manage the comprehensive medical and psychosocial needs of HD patients.

Changes to key personnel must be reported to the DSHS HD Program Nurse Administrator on form [HD-407](#) within one business week.

1. Identify the following key personnel staffed at each HD clinic:
 - Primary HD Nurse
 - HD Physician (may be a licensed healthcare provider)
 - HD Program Manager

2. Identify ancillary care providers available to HD patients when indicated (the minimum required providers are discussed in Task 7):
 - Occupational Therapist
 - Ophthalmologist
 - Orthotics
 - Physical Therapist
 - Podiatrist
 - Pharmacist
 - Behavioral Health Provider

Task 5: Patient Travel Reimbursement

The clinic will ensure that indigent patients receive transportation assistance to a HD clinic or approved affiliated healthcare facility where HD care is being provided.

Patient travel will be handled as detailed below:

1. Verify eligibility for reimbursement:

- Patient must be approved as indigent, as determined by the clinic, and status must be re-verified annually and documented in the medical record.
2. Provide transportation assistance as either a bus ticket, or reimbursement for the cost of a bus ticket:
 - Reimbursement rate must not exceed the maximum allowable amount, in accordance with the Federal Travel Regulations for mileage: *reimbursement will be provided using the most economical method-lowest common carrier or ground transportation unless medical needs dictate other modes of travel.*
 - Clinics may provide a round-trip bus ticket in lieu of reimbursement.
 - If transportation is needed that exceeds the lowest common carrier (i.e., patient is medically unable to travel by bus), contact the DSHS HD program for approval prior to arranging transportation.
 3. Provide lodging assistance if overnight stays are needed:
 - Patients traveling from remote locations may need additional assistance with overnight stays to access their needed HD care.
 - At the HD clinic's discretion, based on patient need and financial ability, the clinic may pay for a local hotel stay within the locally budgeted amount afforded by the federal government at the federal government's rate for the designated area.
 4. Report travel when indicated:
 - Provide monthly reports to the DSHS HD program for any miles accrued and reimbursement amount that patients received for transportation assistance.
 - Send an email regarding mileage paid/month to: HDPCR@dshs.texas.gov

Task 6: Third-Party Reimbursement and Medical Co-Payments

The clinic will handle charges for services in the following way:

1. Determine patient insurability:
 - Identify any third-party payer (i.e., Medicaid, private insurance, etc.) as a covered entity.
 - Obtain payment through the covered entity first, then use HD funds for existing balances.
2. Do not charge HD patients out-of-pocket expenses:
 - The HD clinic is responsible for ensuring patients do not pay co-pays for HD services, including but not limited to: laboratory services, screenings, shoes, or services by ancillary providers.

Task 7: Consultation and Referrals

Refer patients to ancillary care for HD services that cannot be managed at the HD clinic. Ensure patients do not pay for ancillary care, as discussed in Task 6.

The clinic will:

1. Ensure a partnership with, at minimum, the following ancillary service providers exists:
 - Occupational Therapist
 - Ophthalmologist
 - Orthotics
 - Physical Therapist
 - Podiatrist
 - Pharmacist
 - Behavioral Health Provider
2. At the start of each project period and annually, provide a written plan for each ancillary care provider.
 - The plan shall include the names and addresses of each identified ancillary care provider, with a specification to the nature of the partnership (i.e., sub-contract, written agreement, etc.).
 - Ensure the ancillary services where patients are referred are staffed by clinicians trained and experienced in HD, who meet the qualifications, experience, and licensure, as stated in *Appendix K: Qualifications of HD Staff*.
 - The DSHS HD program must be notified of any ancillary care providers. Report any changes of HD staff on the Change of HD Personnel Form HD-407, including new hires.
3. Ensure referrals to ancillary care providers are made when indicated and are reported to the DSHS HD program.
 - The objective of referrals or consultative services is to ensure the patient receives a comprehensive approach to care by a multidisciplinary team to minimize gaps and improve clinical outcomes. The aim is to minimize loss of nerve function and sensory loss in the hands, eyes, and feet. The NHDP Manual shall be utilized as a resource guide to manage complications of HD.
 - Make referrals according to identified triggers as outlined in *Appendix E: Triggers for Referrals & Consultation* and when indicated by the HD nurse or HD physician.
4. Request additional services as needed.
 - When patient-specific services are recommended beyond those listed in Task 4, provide a written request to the DSHS HD program within three (3) days of the identified need. If approved, the clinic will be responsible for service costs and coordinating appointments with the ancillary care provider.

- This request should include:
 - A brief overview of patient (leaving outpatient identifiers, if via email), including patient status and current medical problems.
 - Referral type requested (i.e., "Neurology").
 - Justification for why the referral is necessary to their HD care.
 - Name of requesting provider.

Task 8: Medical Professional Training and Education

The clinic will:

1. Attend a six-hour virtual conference hosted by the NHDP annually.
 - At least two key personnel must attend: the HD clinic nurse and HD physician
 - The DSHS HD program will inform HD clinics of this conference at least 90 days prior to the event.
 - Email HDPCR@dshs.texas.gov a list of attendees to the DSHS HD program within five (5) business days post-conference.
2. Perform one educational activity to the medical community at least quarterly to raise awareness of HD diagnosis, management, and related complications.
 - Activities may include the following:
 - Presentations
 - Education to healthcare professionals, medical/nursing students
 - One-on-one training opportunities with medical staff
 - Clinical conferences or seminars
 - Refer to Task 11, #4 regarding pre-approval for publications that include HD data or photos obtained under current HD project period.

Task 9: Reporting Cases and Clinic Activities

The clinic will:

1. Submit patient information on applicable forms and ensure reporting information is current and accurate, within three days of patient visit.
 - Clinics must ensure reporting deadlines are met and uploaded to GlobalScape (email HDPCR@dshs.texas.gov when available) to include the following (see *Appendix M: Program Deliverables*):
 - Patient demographics
 - Classifications and status, see *Appendix H: Patient Statuses*
 - Type of medication protocol
 - Clinical visit
 - Services performed during visit
 - Education provided
 - Patient outreach, including: date, method of contact (i.e., text or home visit), and response to outreach (i.e., was contact made?)
 - Type and number of consult visits

- The above shall be provided to the DSHS HD Program on the following forms:
 - Surveillance Form (C-12)
 - Encounter Form (HD-400)
 - Hand, foot, and eye screens (NHDP-130, NHDP-133, and NHDP-216)
 - Change in Information Form when patients move from a Texas clinic to another clinic or out of state (HD-406)
 - Annual Follow-Up Form (NHDP-208)
- 2. Complete the Quality Assurance Activity Report (HD-410) monthly.
 - Report HD training, education, and outreach on the first Monday of each month, as per the HD-410.
 - Submit to: HDPCR@dshs.texas.gov
- 3. Attend bi-monthly roster conference calls:
 - Participate in DSHS HD program pre-arranged bi-monthly roster calls to provide verbal updates on HD cases and clinic activity.
 - DSHS will send clinics a bi-monthly roster prior to the calls. Updates needed on the rosters can be discussed on the call.
 - If unable to attend the scheduled call, provide a cancellation notice within 24 hours of the call with a new date/time proposed.
 - If cancelling due to inactivity of clinic, include reason for cancellation, i.e. "No patients seen this month."
 - At least one key personnel must attend meetings when actively managing patients.

Task 10: Meetings, Communication, and Site Visits

Key personnel and designated clinic staff will:

1. Attend in-person trainings sponsored by NHDP when offered and as locally determined budget allows.
2. Attend meetings as convened by the DSHS HD program.
 - Meetings will be scheduled periodically during the project period to discuss programmatic changes, provide updates, and discuss challenges and successes.
 - Participants may include all key personnel.
3. Participate in site visits by the DSHS HD program.
 - Any site visits will be pre-arranged by the DSHS HD program and, when necessary, via the DSHS Contracts Management Section (CMS).
 - HD clinics will be notified at least 90 days in advance of planned visit.

Task 11: Security, Confidentiality, and Required Training

The program manager or designee will ensure that key personnel and others (where specified) will complete training specific to their role in HD. Trainings are listed in *Appendix L: Required Trainings and Recommended Resources for Hansen's Disease Program Staff*. The program manager will also ensure staff are aware of patient confidentiality and compliance measures.

The clinic will:

1. Take [DSHS security training](#).
 - Required for all HD staff with access to confidential information.
 - Complete the training upon hire and annually; pass with an 85% or higher.
 - See *Appendix J: Confidentiality and Security Standards* for submitting certificates of completion.
2. Attend NHDP specialty training on comprehensive management of the neuropathic foot at least once during the project period, if have never previously attended.
 - Training titled "*Lower Extremity Amputation, Prevention, and Treatment of the Neuropathic Foot*" is required for key personnel who will be providing clinical HD services, *when offered by the NHDP*, at least once during their tenure in an HD clinic.
 - Email completion date(s) to: HDPCR@dshs.texas.gov within 30 days of the new contract period or date of hire (for new staff).
3. Complete additional trainings based on role and need.
 - For requirements of all other trainings, see *Appendix L: Required Trainings and Recommended Resources for Hansen's Disease Program Staff*.
 - Program managers or designees may determine training plans for all HD staff other than the DSHS-required training; communicate directly with the DSHS HD Nurse Administrator for coordination of training, as needed.
 - Program managers or designees must maintain records of staff training upon hire and annually.
4. Follow confidentiality and compliance measures.
 - The program manager or designee will ensure compliance with DSHS TB and HD Unit confidentiality and security policies and procedures regarding patient information. Refer to *Appendix J: Confidentiality and Security Standards*.
 - Address privacy incidents. Consult with the local Privacy Officer on suspected privacy incidents of protocol and confidentiality in compliance with the DSHS TB and HD Unit policies.
 - Maintain patient confidentiality. Notify the DSHS HD Program Nurse Administrator before presenting or releasing any public-facing HD-related educational material (photos, presentations, data, etc.). Patients must sign the HD 414/414a regarding use of photos.

- NHDP follows the federal confidential information clause with the following restrictions:
 - Restrictions on "any publication, patient education material, or research that involves Hansen's disease patient data, patient pictures, patient videos, or information collected under this contract";
 - any patient photo "must be de-identified and permission from the patient or legal guardian must be included in a release of information";
 - media articles, media requests, op eds, need to be cleared by HRSA Office of Communications; and
 - 45 days advanced written notice to the NHDP is required.

Task 12: Performance Measures

The following key outcome performance measures will be used to assess, in part, the clinic's effectiveness in providing the services to patients:

- Ensure that 100% of patients and, as necessary, their contacts are examined by a physician having medical expertise in HD;
- Ensure that 100% of patients who are actively managed receive hand, foot, and eye screens per protocol;
- Ensure that 100% of patients are referred for ancillary care when there is any documented disability or deformity that cannot be managed in the HD clinic;
- Ensure that 100% of patients are referred for specialty shoes or orthotics when Grade 1 (or greater) is documented on the foot screens;
- Ensure that 100% of patients on multi-drug therapy (MDT) complete HD therapy according to the schedule;
- If data indicates that MDT patients are completing HD therapy at a rate of less than 90%, the DSHS HD program may (at its sole discretion) require additional measures be taken by clinic to improve that percentage. In that scenario, the clinic must follow those additional measures, and do so according to the timetable mandated by the DSHS HD program;
- Ensure that 100% of newly identified persons with suspected or confirmed Hansen's disease will be reported within 3 days of notification to the DSHS HD program using form C-12;
- Ensure that 100% of reported cases of Hansen's disease will be evaluated and treated for Hansen's disease and its complications in accordance with the most recent version of the National Hansen's Disease Program's "*NHDP Guide to the Management of Hansen's Disease*"; and
- Ensure that 100% of patient encounters (including office visits, telephone calls, medication refills, and written communications) are documented on Form HD-400 and submitted to the DSHS HD program within three (3) working days of encounter date.

IV. Appendices

Appendix A: Treatment for Hansen's Disease

The following regimens may be prescribed by the licensed healthcare provider for the treatment of both paucibacillary and multibacillary HD.

Once Monthly Rifampin/Moxifloxacin/Minocycline (RMM)

ADULTS			
Tuberculoid (TT & BT) WHO Classification Paucibacillary (PB)			
Agent	Dose	Duration	Comments
Rifampin	600mg once a month	12 months, then discontinue	Seek consultation prior to using this regimen for patients with a baseline positive IGRA test. Patients should be informed of this regimen's use based on limited patient data, as noted on the CD-001 consent. Refer to: https://journals.sagepub.com/doi/pdf/10.1177/20499361221135885 . Due to the highly intermittent dosing schedule, administration should be provided by direct observation ONLY (either DOT or VDOT). Ideally the first dose should be given in clinic. Considerations for enhanced self-administration (i.e., calling patients monthly to confirm they have taken their dose) may be made by the treating physician on a case-by-case basis. After one month of therapy, patients should be examined by the treating physician to assess for any worsening neuropathy or other abnormal findings. Contact the treating physician if a patient misses ≥ 1 monthly dose.
Moxifloxacin	400mg once a month		
Minocycline	100mg once a month		
Lepromatous (LL, BL, BB) WHO Classification Multibacillary (MB)			
Agent	Dose	Duration	Comments
Rifampin	600mg once a month	24 months, then discontinue	Same as above.
Moxifloxacin	400mg once a month		
Minocycline	100mg once a month		

NHDP Multi-Drug Therapy (MDT) Protocols, Adults*

ADULTS		
Tuberculoid (TT & BT) WHO Classification Paucibacillary (PB)		
Agent	Dose	Duration
Option 1		
Dapsone	100 mg daily	12 months, then discontinue
Rifampin	600 mg daily	
Option 2		
Dapsone	100 mg daily	12 months, then discontinue
Rifampin	600 once a month**	
Lepromatous (LL, BL, BB) WHO Classification Multibacillary (MB)		
Agent	Dose	Duration
Option 1		
Dapsone	100 mg daily	24 months, then discontinue
Rifampin	600 mg daily	
Clofazimine	50 mg daily	
Option 2		
Dapsone	100 mg daily	24 months, then discontinue
Rifampin	600 once a month**	
Clofazimine	50 mg daily	

*Refer to: <https://www.hrsa.gov/sites/default/files/hrsa/hansens-disease/hansens-disease-guide-management.pdf>

**RIF may be given monthly for patients on prednisone

NHDP Multi-Drug Therapy (MDT) Protocols, Children*

CHILDREN		
Tuberculoid (TT & BT) WHO Classification Paucibacillary (PB)		
Agent	Dose	Duration
Dapsone	1 mg/Kg daily	12 months, then discontinue
Rifampin	10 - 20 mg/Kg daily (maximum dose 600mg)	
Lepromatous (LL, BL, BB) WHO Classification Multibacillary (MB)		
Agent	Dose	Duration
Dapsone	1 mg/Kg daily	24 months, then discontinue
Rifampin	10 - 20 mg/Kg daily (maximum dose 600mg)	
Clofazimine	1.0 mg/Kg daily**	

*Refer to: <https://www.hrsa.gov/sites/default/files/hrsa/hansens-disease/hansens-disease-guide-management.pdf>

**There is no formulation less than 50mg capsules and the capsule should never be cut open; therefore, an alternative daily dosing may be used at 2mg/Kg.

Appendix B: Laboratory Tests and Frequency

Test Name	Initial Visit	Every 3 Months While on MDT or Treatment for HD Reaction
Complete Blood Count (CBC) with Differential (CBC with diff)	X	X
Complete Metabolic Panel (CMP)	X	X
Creatinine Reactive Protein (CRP)	X	X
Erythrocyte sedimentation rate (ESR or sed rate)	X	X
Vitamin D Level	X	X
Glucose-6-Phosphate dehydrogenase (G6PD) – ONLY if starting Dapsone	X	
Interferon Gamma Release Assay (IGRA)	X	
Biopsy with Fite Stain*	X	As recommended by the treating physician
Polymerase chain reaction (PCR)*	X	
Acid-fast bacilli (AFB) skin smears	As recommended by the treating physician	As recommended by the treating physician
Hepatitis B surface antigen (HBsAg)	X	
Hepatitis C antibody (HCV Ab)	X	

**perform at baseline if the patient is referred to the HD clinic without test results*

Appendix C: Submitting Hansen's Disease Laboratory Tests to Quest Diagnostics

HD Clinics will submit the below diagnostic testing to Quest Diagnostics laboratory located in Dallas, Texas. Additional testing will be forwarded to the National Hansen's Disease Program (NHDP) Laboratory (lab) in Baton Rouge, Louisiana (LA) *by Quest* when indicated in the table below. DSHS HD clinics *will not* submit any testing directly to the NHDP without prior authorization from the DSHS HD Program.

I. Quest Diagnostics Contact Information

Each HD Clinic has a unique Quest Account Number. Contact hdpcr@dshs.texas.gov.

My HD Clinic's Quest Account Number is: _____

Quest Diagnostics Contacts	Contact Information
Quest Account Manager Name	Joan Hale
Quest Account Manager Email	Joan.y.hale@questdiagnostics.com
Quest Account Manager Phone	214-697-8636
Quest Customer Solutions Service Representative (CSS) Name	Veronica Gonzalez
CSS Email	Veronica.X.Gonzalez@questdiagnostics.com
CSS Phone	512-739-9422
General Quest Diagnostics Phone	866-MYQUEST (697-8378)

II. Quest Diagnostics Submission Information

Test Name	Ordering Supplies	Laboratory Requisition	Performing Laboratory and Shipping Details
Interferon Gamma Release Assay (IGRA) – either Tspot or QFT	May order specimen tubes and mailing supplies via Quanum, Quest's online portal; contact the Quest Account Manager or CCS for Quanum support	Available via Quanum or paper requisition. If using Quanum, select client billing (DSHS account will be billed).	<ul style="list-style-type: none"> • Ship to Quest Diagnostics. • Arrange for either daily pick up, or to schedule a pick-up call 866-MYQUEST (697-8378).
Acid-fast bacilli (AFB) skin smears	Call MYQUEST (697-8378) for slides and shipping mailers.	Use the Paper Requisition (see page 2 of the Job Aid), noting this is a skin smear for Hansen's Disease.	<ul style="list-style-type: none"> • Ship to Quest Diagnostics; Quest will forward to the NHDP lab. • Refer to the Job Aid for packaging and shipping details.

Test Name	Ordering Supplies	Laboratory Requisition	Performing Laboratory and Shipping Details
Biopsies for fite stain	Biopsies are submitted in formalin, supplied by the Quest Account Manager.	Use the Paper Requisition (see page 2 of the Job Aid), noting this is a biopsy for Hansen's Disease.	<ul style="list-style-type: none"> • Ship to Quest Diagnostics. Quest's dermatopathologist will provide the result and impression. • For shipping details, refer to Job Aid.
Polymerase Chain Reaction (PCR)	N/A	<p>If positive, Quest will reflectively send to NHDP for PCR and results will be returned to submitter – no additional requisition is needed.</p> <p>If negative and a PCR is <i>still</i> requested, complete the PCR Add On Form and fax to Quest – phone number is listed on the form.</p>	<ul style="list-style-type: none"> • Ship to Quest Diagnostics; Quest will forward to the NHDP lab in LA any positive fite stain (see above).

III. Quest Diagnostics Forms

The next three pages of this process contain the following documents that HD Clinics may print as stand-alone references.

1. Quest Diagnostics Job Aid

- a. The Job Aid contacts details about how to collect and ship testing to Quest Diagnostics for initial biopsies and skin smears

2. Instructions for Completing Paper Requisitions

- a. HD Clinics may request paper requisitions for ordering any Quest testing. Paper requisitions are required for biopsies and skin smears.

3. Referral Testing: PCR-Hansen's Disease Additional Test Request Form

- a. Complete this form ONLY if the initial biopsy submitted to Quest is negative on fite stain, but the treating physician still requests a PCR. NOTE: Quest will automatically submit positive fite stains to the NHPD lab for PCR testing.

Appendix D: Disability Grades

Disability Grades

Disability Grades for Hands and Feet	
Grade 0	No loss of protective sensation and no visible deformity
Grade 1*	Loss of protective sensation and no visible HD deformity
Grade 2	Loss of protective sensation <i>and</i> visible HD deformity

Footwear Based on Disability Grade		
Grade	Description of Findings	Footwear Recommendations
Grade 0	Has protective sensation and has NOT had a plantar ulcer	<ul style="list-style-type: none"> Well-fitting shoes
Grade 1*	Loss of protective sensation and has NOT had an ulcer	<ul style="list-style-type: none"> X-depth (a shoe with extra depth), SAS "Free Time" shoe, or running shoes (they tend to have more depth); and/or Non-molded soft inserts, as determined by the clinician Also look for: callus build up; if <u>any</u> are present, consider recommending a molded insert with the X-depth shoe
Grade 2	Loss of protective sensation and deformity but has NOT had an ulcer; may or may not have callus build up	<ul style="list-style-type: none"> X-depth or running shoe Rigid Rocker Soles (custom sole that helps off-load to prevent callus build-up), and/or Custom molded orthoses (contact NHDP for recommendations)
	Loss of protective sensation, deformity and history of an ulcer	<ul style="list-style-type: none"> X-depth or custom molded shoes Custom molded orthoses Rigid Rocker or ankle-foot orthoses (AFO) with Rigid Rocker Consult with NHDP for recommendations and consider referral to orthosis

* To qualify for specialty shoes or orthotics, patients need Grade 1 or above

Appendix E: Triggers for Referral and Consultation

HAND		
Assessment	Finding	Action
Sensory	Loss of sensation	The clinic shall provide ongoing education/safety equipment. Refer to occupational therapist for treatment and evaluation. Generally seen in Grade 1 and 2 scores for hand screens.
Skin Inspection	Dry Skin	Ensure appropriate moisturizers are obtained for the patient.
	Fissure	The clinic shall provide medical oversight. Consider a referral to occupational therapist.
	Heavy Callus/Thick nails	The clinic shall provide medical oversight. Consider a referral to occupational therapist. Generally noted with HD patients with a Grade 1 or 2 disability.
	Wound	The clinic shall provide oversight and make appropriate referrals to wound care clinic or specialist, occupational therapist, or a healthcare professional who has the appropriate skills to manage and treat. Consult NHDP for reoccurring or non-healing wounds.
Muscle Testing	Muscle Weakness	The clinic shall monitor for decrease in function and refer (consider referral to occupational therapist). Contact NHDP for recommendations.
Nerve Palpation	Enlarged/painful ulnar, median, radial cutaneous nerve	The clinic shall provide medical management. Consider a referral to an occupational therapist for a splinting. Consider elbow pads and activity modification. Consult NHDP physicians.
Deformity or Disability	Clawing, wrist drop, contracted digits	The clinic shall provide medical management and may consult with NHDP physicians and occupational therapist for conservative treatment options. Consider a consultation or referral with the orthopedic hand surgeon at NHDP for more aggressive treatment options such as reconstructive therapy.
	Osteomyelitis	The clinic shall provide medical oversight and management. Consulting with NHDP physicians or orthopedists for provisions of care is an option.
	Problems with ADLs	The clinic shall provide medical oversight. Referral to occupational therapist for adaptive equipment and ADL training should be considered. Consultations with NHDP physicians and occupational therapist for treatment approaches are available resources.

FEET		
Assessment	Finding	Action
Sensory	Loss of sensation	Provide ongoing education regarding self-care, elimination of barefoot walking. Referral to a healthcare professional who can evaluate for protective footwear and molded orthotics. Consult with NHDP physicians and physical therapist for more definitive treatment approaches if needed.
Skin Inspection	Dry Skin	The clinic shall provide appropriate moisturizers for the patient.
	Fissure	The clinic shall provide medical oversight. Consider a referral to podiatry, physical therapy, or a healthcare professional who has the appropriate skills to manage and treat.
	Heavy Callus/Thick nails	Consider a referral to podiatry, physical therapy, or a healthcare professional who has appropriate skills to manage and treat a neuropathic foot. Changes in footwear should be considered. Generally noted in HD patients with a Grade 1 or 2 disability.
	Wounds	Refer to wound care specialist, podiatry, physical therapist, or healthcare professional who has the appropriate skills to effectively manage and treat wounds. Consider immobilization, offloading, and Ankle-Foot Orthoses (AFO). Consult NHDP for reoccurring or non-healing.
Muscle Testing	Muscle Weakness	The clinic shall monitor for decrease in function and contact NHDP for recommendation on management and treatment.
Nerve Palpation	Enlarged/painful peroneal, tibia, or sural nerve	Consider anti-inflammatory measures and consult NHDP physician for treatment modalities if needed.
Deformity or disability	Clawing, foot drop, contracted digits	The clinic shall provide medical management and may consult with NHDP physicians and therapists. Consider a consultation or referral with the orthopedist at NHDP for aggressive treatment options.
	Osteomyelitis	The clinic shall consult with NHDP physicians, podiatrist, or orthopedist for provisions of care as an option.
	Abnormal shape of foot/Charcot foot	Protective footwear is recommended. Consult with NHDP physical therapists and orthopedists to develop a comprehensive treatment plan such as reconstructive therapy. Evaluation by a healthcare provider who is knowledgeable about neuropathic foot is recommended.

EYE		
Assessment	Finding	Action
Blink	Infrequent or asymmetrical blink	The clinic shall provide medical oversight and should refer to ophthalmology for a comprehensive evaluation and treatment plan. Consult NHDP physicians if needed.
Lid Closure	Lagophthalmos or weakness	The clinic shall provide medical oversight and should refer to ophthalmology for a comprehensive evaluation and treatment plan. Consult NHDP physicians if needed.
Acuity	20/200 or less, or any change in vision from baseline, as determined by the licensed healthcare provider	The clinic shall provide medical oversight and may consider referral to ophthalmology. Consult NHDP physicians if needed.
Appearance	Red Eye	The clinic shall provide medical oversight and should consider referral to ophthalmology for comprehensive treatment plan. Consult NHDP physicians if needed for provisions of care.
	Irregular shaped pupil	The clinic shall provide medical oversight and should consider referral to ophthalmology for a comprehensive evaluation and treatment plan. Consult NHDP physicians if needed.

Appendix F: DSHS Hansen's Disease Formulary

Anti-Infectives			
Drug Name Generic (Brand)	Strength	Route	Comments
Clarithromycin ER 500mg (Biaxin XL 500)	500 mg E xtended R elease	PO	Clarithromycin 500 mg tablets are available as either E xtended R elease or I mmEDIATE R elease. The Extended Release is formulated to prevent GI upset.
Clarithromycin (Biaxin)	250mg, 500 mg (regular release aka immediate release)	PO	Clarithromycin 500 mg tablets are available as either E xtended R elease or I mmEDIATE R elease. Clarithromycin 250mg is only available as regular release (no ER is manufactured).
Clofazimine*	50mg	PO	Physician must be enrolled in investigational study via NHDP; contact Catherine Crnko at 1-800-642-2477. Contact DSHS HD Program for <i>initial</i> enrollment.
Dapsone	25mg, 100mg	PO	
Levofloxacin (Levaquin)	250mg, 500 mg, 750mg	PO	
Minocycline 50mg (Minocin)	50mg, 100mg	PO	
Moxifloxacin (Avelox)	400mg	PO	
Mycobutin (Rifabutin)	150mg	PO	
Rifampin (Rifadin)	150mg, 300mg	PO	
Reaction Medications			
Drug Name Generic (Brand)	Strength	Route	Comments
Clofazimine*	50mg	PO	Physician must be enrolled in investigational study via NHDP; contact Catherine Crnko at 1-800-642-2477. Contact DSHS HD Program for <i>initial</i> enrollment.
Methotrexate	PO: 2.5mg	PO	Must be given with Folic Acid
Pentoxifylline ER (Trental)	400mg	PO	
Prednisone	2.5mg, 5mg, 10mg, 20mg	PO	
Thalidomide*	50mg	PO	Patients enroll via Celgene. Online enrollment available at www.celegenpatientsupport.com or call 1-800-931-8691. Contact DSHS HD Program for <i>initial</i> enrollment.

Other Medications			
Drug Name Generic (Brand):	Strength	Route	Comments
Alendronate (Fosamax)	35mg, 70mg	PO	
Ammonium Lactate Lotion	12%	External	
Aspirin	81mg	PO	May be used for patients on thalidomide
Ferrous Sulfate	325mg	PO	
Folic Acid	1mg		To be given with Methotrexate
FreshKote Eye Drops		Ophth.	
Gabapentin (Neurontin)	100mg, 300mg, 400mg, 600mg	PO	
Lubriderm Advanced Lotion		External	
Lubriderm SPF 15	Sun Protection Factor 15	External	Lotion contains SPF 15 sunscreen component
Petroleum Jelly (Vaseline)			
Sunscreen SPF 50	Sun Protection Factor 50	External	
Triple Antibiotic Ointment (Neosporin)		External	
Vitamin D	50,000 Units	PO	To be used with methotrexate

**Not available via DSHS Pharmacy; contact the DSHS Hansen's Disease Program for ordering information.*

Appendix G: Medication Ordering and Inventory Tracking

Ordering Medications for Patients in the HD Program

- The DSHS Pharmacy Unit is a **Class A Pharmacy** which allows for the following:
 1. **Compounding:** select *non-sterile* solutions may be compounded for pediatric or adult HD patients.
 2. **Direct-to-patient mailing:** HD clinics may choose to have medications sent directly to the patient's home.
- When either compounding or direct-to-patient mailing is needed, the following must occur:
 1. The prescribing physician must complete the **Prescription Fax Form***.
 - Ensure all patient information is current and up to date.
 - Check that the medication is to be mailed to the patient or clinic.
 - Prescriptions should align with the HD Formulary, or, for non-formulary medications, complete form HD-413 (see below).
 - The Prescription Fax Form must be physically signed by the treating physician.
 - Fax the form to the Pharmacy Unit at: **512-776-7489**.
 2. Medications should not be entered or ordered through PIOS if using this prescription form.
 3. Nurse Case Managers or designees should contact the patient to ensure medication is received and to ensure patient understands how to take the medication; document this education on form HD-400.

**The Prescription Fax Form is available from the DSHS HD Program Nurse Administrator or Pharmacy Unit by calling their main number: 512-776-7500.*

Ordering Non-Formulary Medications

- When medications are needed other than what is listed on the HD Formulary, provide the DSHS HD program with the following on the Non-Formulary Order Form HD-413:
 1. Name, dosage, and duration of requested medication
 2. Justification of the need for the non-formulary medication
 3. Name of requesting physician
- Once reviewed and if approved:
 - The DSHS HD program will inform the clinic and will contact the DSHS pharmacy to obtain.
 - The clinic is then responsible for coordinating with pharmacy and must order the drug from PIOS, or pharmacy designated ordering system.

- Ensure the completed and approved HD-413 is kept in the patient medical record.

Medication storage and reconciliation using the DSHS Pharmacy Inventory Ordering System (PIOS)

- 1) Order medications through a DSHS-enabled pharmacy ordering system, either the Prescription Fax Form provided by DSHS Pharmacy Unit, or through PIOS;
- 2) Assure that medications are stored properly and securely;
- 3) Monitor and manage program usage of HD medications and testing supplies furnished by DSHS in accordance with first expire first out (FEFO) principles of inventory control;
- 4) Count DSHS-purchased medications and supplies and reconcile inventory according to the product and lot number listed in PIOS; no later than the seventh working day of the month. Coordinate with PIOS inventory staff to ensure HD orders comply with best practices;
- 5) Products that have not been used in six months or will not be used in six months shall be returned to DSHS Pharmacy or transferred to another HD program where the demand may be greater, and recorded in PIOS, if applicable; and
- 6) All DSHS-purchased medications shall be stored properly and securely, in accordance with manufacturer's instruction.

For questions on HD medication ordering, contact DSHS Pharmacists Lester Mattson (lester.mattson@dshs.texas.gov) or Tracey Bronnenberg (Tracey.Bronnenberg@dshs.texas.gov).

For questions about how to access PIOS, contact 340b@dshs.texas.gov

Appendix H: Patient Statuses

The following terms and abbreviations shall be used to identify the status of patients receiving care in the Hansen's disease program.

- A. **Active (A)** is a person who is actively taking antimicrobial or reaction medications.
- *A: This status is for patients on multi-drug therapy (MDT) even if it is temporarily on hold due to an adverse reaction; they may or may not also be on medications for reaction.*
 - *A RX: This status is for patients who have completed MDT and are actively being treated for reaction (reversal or ENL) and are receiving steroids, methotrexate, clofazimine, thalidomide, or a medication that is used directly to treat a reaction.*
- B. **Contact (C)** is a person who has shared the same enclosed air space in a household or other enclosed environment for a prolonged period with a person with an untreated case of HD.
- *Contacts to known HD cases may be evaluated by the HD program for symptoms of HD.*
 - *Prophylaxis therapy may be considered by the treating physician.*
- C. **Complication (Comp)** is a person who has completed MDT and is being treated for a complication related to HD. Complications may include inflammation of the skin or nerves that can cause lagophthalmos, blindness, kidney failure, muscle weakness, clawed hand, foot drop, etc.
- *Include patients on supportive medications used to treat lingering sequelae of HD (i.e., patients who need Neurontin for nerve pain).*
 - *Include patients who are actively needing services in the clinic such as ancillary care (referrals to specialists), specialty shoes after the 3-year observation period, or who are receiving other supportive medications not directly related to reversal or ENL reactions.*
- D. **Deceased (D)** is a person who has died.
- E. **Inactive (IA)** is a person who has completed a full cycle of MDT or reaction therapy with a minimum of one (1) and maximum of three (3) years of observation. A person in observation is considered stable in their disease process.
- *Include patients who are in observation or complication and need annual follow-up visits, but do not return phone calls or letters. After at least 1 year in observation, if no response to clinic contact, categorize them as inactive so they may be 'closed' from the clinic roster.*
- F. **Lost to Follow-Up (LTFU)** is a person on MDT treatment who has failed to receive medications for six (6) months or 180 days.

- G. **New Case (NC)** is a person who has been previously treated outside the United States and enters this country, has been diagnosed while living in the United States, or has been referred from a provider with a confirmed HD Diagnosis.
- *Upon initial visit at the HD clinic, if the patient meets the above criteria, they are a NC- report that on the encounter form (HD-400). At the next scheduled visit, change their status to "Active" or as applicable.*
- H. **Observation (OBS)** refers to the one to three-year period immediately following completion of MDT or reaction medications. During this period – the patient is observed for adverse signs or symptoms post treatment.
- I. **Suspect (S)** is a person with clinical signs and symptoms consistent with HD. Report confirmed diagnosis as a new case.
- *Include when a patient has an initial visit to the clinic and HD is suspected but further diagnostics are pending, and no medication is started; fill out the HD-400 only and report as a suspect. Once diagnosis is made, complete the C-12 and change status to "Active" if HD is determined. If the person suspected does not end up having HD, keep status of "suspect" and on the HD-400 add a note about case closure due to non-HD.*

Appendix I: Hansen's Disease Program Forms

Forms can be downloaded at: <https://www.dshs.texas.gov/hansens-disease-leprosy/hansens-disease-leprosy-forms>

Form Number	Form Name	Frequency of Completion	Deadline for Submitting to DSHS
C 12	Texas Hansen's Disease Surveillance Form	Once	Within 3 days of report
HD 400	Texas Hansen's Disease Encounter Form	At every clinic encounter (exclude routine phone calls)	Within 3 days of encounter
HD 405/HD 405a	Patient Agreement for Hansen's Disease	Initial visit; when needed	N/A
HD 406	Change of Patient Information	When applicable	Within 3 days of notification
HD 407	Change in Personnel Form	As applicable	5 th of each month
HD 408	Skin Smear & Biopsy Chart	Reference only	
HD 409	Patient Statuses	Reference only	
HD 410	Hansen's Disease Clinic Quality Assurance Reporting Form	Monthly	First Monday of each month
HD 411	Reporting and Clinical Care Forms Deadlines	Reference only	
HD 412	Hansen's Disease Medication Formulary	Reference only	
HD 413	Order Non-Formulary Hanse's Disease Medications	As applicable	Submit to DSHS HD Program Nurse Administrator, Pharmacy
HD 414/HD 414a	Photo Consent	Initial visit	N/A
NHDP 130	Hand Evaluation Screen	Baseline, at least quarterly while on MDT; annually while in observation	Within 3 days of screen
NHDP 133	Food Evaluation Screen		
NHDP 216	Eye Evaluation Screen		
NHDP 208	NHDP Annual Follow Up Form	Annually, on the anniversary of diagnosis	Within 3 days of assessment
L 36/L 36a	General Consent and Disclosure	Initial visit	N/A
L 30/L 30a	Consent to Release Confidential Medical Information	As applicable	N/A
CD001/CD001a	Disclosure and Consent Drug Therapy for Treatment of Hansen's Disease	Medication initiation, any medication changes	N/A
CD-010	Disclosure and Consent for Skin Biopsy (English/Spanish)	When biopsy is performed	N/A
CD-011	Disclosure and Consent Skin Scrapings (English/Spanish)	When skin scraping is performed	N/A

*Forms with "a" indicate Spanish versions

Appendix J: Confidentiality and Security Standards

General Requirement

HD programs will perform activities outlined in this *HD Work Plan* in accordance with applicable state and federal security and confidentiality standards, policies, procedures and guidelines, including but not limited to:

- DSHS Policy 302.001, *Release of TB/HIV/AIDS and STD Data*, dshs.texas.gov/hivstd/policy/policies/302-001.shtm
- DSHS Procedure 2016.01, *TB/HIV/STD Section Confidential Information Security*, dshs.texas.gov/hivstd/policy/procedures/2016-01.shtm
- DSHS Policy 2011.01, *Confidential Information Security*, dshs.texas.gov/hivstd/policy/policies/2011-01.shtm
- DSHS Policy 2011.04, *Breach of Confidentiality Response*, dshs.texas.gov/hivstd/policy/policies/2011-04.shtm

Activities

- A. Submit documentation to the DSHS TB/HIV/STD (THS) Section Security Officer to confirm that all staff and subcontractors working on activities outlined in this HD Work Plan receive yearly training on the [DSHS Security and Confidentiality Training](#) with a passing score of 85% or above.
- B. Submit inquiries related to database access and security training to TBHIVSTD.AccountRequest@dshs.texas.gov.
- C. Ensure that newly hired staff successfully complete the [DSHS Security and Confidentiality Training](#) within 30 days of hire.
- D. Ensure that all staff successfully complete the [DSHS Security and Confidentiality Training](#) annually, within one year of having taken the previous training.
- E. Submit appropriate documentation of the DSHS Security and Confidentiality Training to TBHIVSTD.AccountRequest@dshs.texas.gov within ten (10) days of completing course.
- F. Designate and identify a HIPAA Privacy Officer authorized to act on behalf of the TB program in developing and implementing requirements outlined in federal and state privacy laws.
- G. Designate a program staff (e.g., Program Manager) to serve as the Local Responsible Party (LRP). The LRP will:
 1. Ensure appropriate protocols and procedures are in place for handling confidential information, releasing confidential HD data, and for rapid response to suspected privacy incidents of protocol and/or confidentiality.

- a) Local protocols and procedures must comply with DSHS policies and procedures.
 - b) HD Programs may choose to adopt DSHS policies and procedures as their own.
2. Approve and validate (provide signature) any program staff requiring access to HD confidential information.
 - a) The LRP will grant authorization to program staff who have a work-related need to view confidential information.
 - (1) Complete the LRP fields on the Account Request form.
 - (2) Contact TBHIVSTD.AccountRequests@dshs.texas.gov and copy the person requesting access. The email should include:
 - (a) a statement verifying this person is under your authority;
 - (b) person's security training certificate;
 - (c) access request form;
 - (d) confidentiality agreement; and
 - (e) acceptable use agreement form.DSHS will return access requests that do not include the required documents. The email should only request access for one person at a time. Requests for multiple employees in one email will not be accepted. Maintain email correspondence as part of your records. All current forms and instructions are at dshs.texas.gov/thsvh/account.shtm.
 3. Maintain a current list of authorized staff with permission to view and work with confidential information in accordance with the DSHS TB/HIV/STD Local Responsible Party Handbook Required Documentation Section. Refer to: [LRP Handbook \(texas.gov\)](#).
 4. Maintain copies of current confidentiality forms and training certifications (e.g., personnel files, staff training records).
 5. Ensure staff members including IT personnel, contractors, mailroom, and custodial staff with access to identifiable public health data complete the DSHS Security and Confidentiality Training annually.
 6. Consult with the THS Section Security Officer on suspected privacy incidents of protocol and confidentiality in compliance with the DSHS [TB/HIV/STD Breach of Confidentiality Response Policy](#).
 - a) Investigate and complete privacy incident reports.
 - b) Limit or restrict access to confidential information for an involved user until the privacy incident investigation is complete.
 - c) Establish and/or enforce corrective and/or disciplinary actions when needed.
 7. Submit required quarterly reports on time. See *Local Responsible Party*

Checklist at dshs.texas.gov/hivstd/policy/security.shtm.

- a) Ensure computers and networks meet DSHS security standards.
- b) Submit requests for TB/HIV/STD systems user account terminations to TBHIVSTD.AccountRequest@dshs.texas.gov within one business day of identifying the need for account termination.
- c) Identify local point of contact for changes in user access to secure data, secure network, secure reason, and for receipt of notifications once a user account is terminated.
- d) Transfer secure data electronically via GlobalScape.
- e) Maintain a visitor's log for people entering secured areas. The LRP must conduct quarterly reviews of this log.
- f) Verify user password changes occur at least every 90 days.
- g) Ensure that portable devices used to store confidential data are encrypted and approved by the LRP.

H. Ensure confidential data are:

1. maintained in a secure area when not in use;
2. not left in plain sight; and
3. shredded with a cross-cut feature before disposal.

I. See [LRP Handbook \(texas.gov\)](#) for other roles and responsibilities.

Appendix K: Qualifications of HD Staff

Program Manager or Business Manager

Education and Experience:

The program manager shall have a minimum of three (3) years of specialized experience preparing reports and other written correspondence; diagnosing and resolving administrative problems; and devising new processes for managing the work of an office.

Duties:

The program manager shall assist with planning, coordinating, and implementing activities associated with administrative management, operations, equipment, space management, logistics, budget, travel, and other areas for the performance accountability and management of the HD clinic.

The program manager shall work collaboratively with the DSHS Contract Management Services (CMS), the DSHS HD program manager, and nurse administrator to ensure that contractual and work requirements are fulfilled.

Physician

Education and Experience:

The physician shall have a degree in medicine or an equivalent degree resulting from a course of education in medicine with a permanent, full, and unrestricted license to practice medicine in a State, District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States.

The physician shall have a minimum of three (3) years of independent practicing experience as a physician.

Duties:

- Shall perform medical screenings, evaluations, and treatment of HD and reactions.
- Shall provide medical oversight and coordinate overall care for the HD patients.
- Shall document care provided in the medical records.
- Shall collaborate with NHDP physicians as needed relating planning and managing medical care for patients.
- Shall refer patients to appropriate health care professionals as clinic judgement dictates and as outlined in the NHDP Manual and HD Work Plan.
- Shall make a reasonable effort to treat HD patients prior to referring to NHDP.

Registered Nurse

Education and Experience:

The registered nurse assigned to the clinic shall be a graduate of a school of professional nursing approved by the appropriate State-accrediting agency and accredited by one of the following accrediting bodies at the time the program was completed: The Accreditation Commission for Education in Nursing (ACEN) or The Commission on Collegiate Nursing Education (CCNE).

The nurse shall have a minimum of three (3) years of experience as a full-time nurse.

Licensure:

The registered nurse shall have a current, full, active, and unrestricted license as a graduate professional nurse in a State, Territory, or Commonwealth (i.e., Puerto Rico) of the United States, or the District of Columbia.

Duties:

- The nurse shall plan and deliver comprehensive healthcare services to individuals, families, and communities with HD.
- The nurse shall conduct patient outreach for patients who have not kept clinic appointments or have a lapse in their medication regimen.
- The nurse shall provide patient teaching regarding medication side effects, disabilities, stigma, reactions, treatment, and communicability of HD.
- The nurse shall be proactive in coordinating healthcare service with other healthcare professionals, as the patient's condition requires.
- The nurse shall participate in videoconferencing with the DSHS HD program twice per year to present cases seen in their clinics.

Physical Therapist

Education and Experience:

The physical therapist shall be a graduate from a degree program in physical therapy from an approved college or university approved by the Commission and Accreditation in Physical Therapy Education (CAPTE). The CAPTE is the only accreditation agency recognized by the United States Department of Education (USDE) and Council for Higher Education Accreditation (CHEA) to accredit entry-level physical therapy programs.

The physical therapist shall have a minimum of three (3) years of full-time experience in the field of physical therapy.

Licensure:

Current, full, active, and unrestricted license to practice physical therapy in State, Territory, or Commonwealth (i.e., Puerto Rico) of the United States, or District of Columbia.

Duties:

- Screen, assess, and evaluate the functional, physical, and psychological capabilities while considering capabilities, environment, disease, and treatment.
- Coordinate and collaborate with interdisciplinary team members regarding the plan of care.
- Manage, monitor, and determine the best course for insensitive neuropathic feet.
- Educate patients on disease process and course of treatment.
- Collaborate and coordinate HD care with other interdisciplinary team members.
- Use orthotics devices as a treatment approach to address insensitive limbs.
- Perform callus and nail trim.
- Perform offloading procedures.

Podiatrist**Education and Experience:**

Successful completion of at least a Doctor of Podiatric Medicine (D.P.M.) from a school of podiatric medicine accredited by the Council of Podiatric Medical Evaluation in the year in which the degree was granted.

The podiatrist shall have a minimum of three (3) years of experience in the field of podiatry.

Licensure:

Current, full, active, and unrestricted license to practice podiatric medicine in a State, Territory, or Commonwealth (i.e., Puerto Rico) of the United States, or District of Columbia.

Duties:

- Diagnose foot disorders and determine the best course of treatment for care of insensitive neuropathic feet.
- Perform podiatric procedures as the patient's condition warrants.
- Educate patients on disease process and course of treatment.
- Collaborate and coordinate HD care with other interdisciplinary team members.
- Order orthotics as a treatment approach to address insensitive limbs.
- Perform callus and nail trim.
- Perform offloading procedures.

Ophthalmologist**Education and Experience:**

The ophthalmologist shall have a degree in medicine or an equivalent degree resulting from a course of education in medicine.

The ophthalmologist shall have a minimum three (3) years of experience in the field of ophthalmology.

Licensure:

Shall possess a current, full and unrestricted license to practice medicine or surgery in a State, Territory, or Commonwealth of the United States, or in the District of Columbia.

Duties:

- The ophthalmologist shall perform eye exams, diagnose and treat disease of the eye, prescribe medications, provide medical management of eye conditions, and perform eye surgery.

Occupational Therapist

Education and Experience:

The occupational therapist shall possess have a degree program in occupational therapy approved by the Accreditation Council for Occupational Therapy Education (ACOTE) or predecessor organizations to include interns (supervised fieldwork experience required by the educational institution). The ACOTE is the only accreditation agency recognized by the United States Department of Education (USDE) and the Council for Higher Education Accreditation (CHEA).

The occupational therapist shall have a minimum of three (3) years of time experience in an acute, chronic, rehabilitative, or outpatient facility.

Licensure:

The occupational therapist shall hold a full and current unrestricted state Occupational Therapist License and possess written documentation that the individual has passed the entry-level certification examination for OTs, which is administered by the National Board of Certified Occupational Therapy (NBCOT).

Duties:

- Screen, assess, and evaluate the functional, physical, and psychological capabilities while considering capabilities, environment, disease, and treatment.
- Coordinate and collaborate with interdisciplinary team members regarding the plan of care.

Appendix L: Required Trainings and Recommended Resources for Hansen's Disease Program Staff

	TRAINING	REFERENCE	Date	Staff initials	Supervisor initials
Required Training					
1	DSHS Data and Security Training , online course, upon hire	https://www.dshs.texas.gov/thsvh/account.shtm#existing			
2	HHS Records Management Training , online course, upon hire and annually	https://humancapital.learning.hhs.gov/courses/2023recordsmanagement/01_index.html			
3	National Hansen's Disease Program (NHDP) Guide to the Management of Hansen's Disease , Reference Manual, upon hire	https://www.hrsa.gov/sites/default/files/hrsa/hansens-disease/pdfs/hd-guide-management.pdf			
4	DSHS Hansen's Disease Service Delivery Work Plan , Reference Manual, upon hire	https://www.dshs.texas.gov/hansens-disease-leprosy/hansens-disease-leprosy-standards-care			
5	DSHS Orientation to HD Program , for new HD nurses upon hire, 1.5 hrs	Will be arranged by DSHS Central Office for new HD nurses once Change of Personnel Form is completed.			
6	NHDP Specialty Training: Lower Extremity Amputation, Prevention, and Treatment of the Neuropathic Foot , online and in person course for clinical staff when offered by the NHDP once during project period	http://www.hrsa.gov/hansensdisease/onlinecourseleap.html			
7	Hansen's Disease (Leprosy): Old World Disease, New World Resources. Grand Rounds, Texas Department of State Health Services (DSHS), May 8, 2019. Online webinar, upon hire	https://register.gotowebinar.com/recording/recordingView?webinarKey=7867210603518497283&registrantEmail=elizabeth.foy%40dshs.texas.gov			
8	NHDP: Diagnosis & Treatment of Hansen's Disease in the United States Seminar , NHDP 6-hour virtual webinar, for HD nurse and HD physician annually	Date and registration links be announced by the DSHS HD Program.			
Recommended Training					
9	DSHS-Coordinated Observational Clinic – in person training, 16-24 hours with a Hansen's Disease Clinic in TX: <ul style="list-style-type: none"> • Hand, Foot, and Eye screens • Biopsy information, education, shipping • Skin smears-procedure, preparation for reading and shipping • Visual Acuity-f/u while on steroids • Medication education • Clinic forms, reporting to DSHS 	May be arranged by DSHS Hansen's Disease Program, upon request. <ul style="list-style-type: none"> • DSHS HD Program Website: http://www.dshs.texas.gov/idcu/disease/hansens/forms/ 			

	TRAINING	REFERENCE	Date	Staff initials	Supervi sor initials
10	Annual CEs, skills training for nurses, 20 hours every 2 years	Skills training, as determined by Nurse Supervisor			
11	Health and Human Services (HHS) Security Awareness and Training, online courses <ul style="list-style-type: none"> • Cybersecurity Awareness Training • Cybersecurity Essentials Training • Phishing Training 	https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html			
12	HHS Role Based Training, online courses for IT staff in HD clinics managing data or for Managerial staff only <ul style="list-style-type: none"> • Information Security for IT Administrators • Role Based Training for Executives and Managers 	https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html			
13	When to Suspect Leprosy: Clinical Aspects and Treatment of Uncomplicated Hansen's Disease. Grand Rounds, Orange Park Medical Center, June 25, 2021. Online webinar	https://www.youtube.com/watch?v=LqM7PwMztQ8&t=2168s			
14	Vision Certification or Skills Check-Off	Local/Regional Trainings offered; contact local or region office to arrange			

Suggested Readings and Website References

- [Hansen Disease among Micronesian and Marshallese Persons Living in the United States](#), Woodall, P., Scollard, D., & Rajan, L.
- [Leprosy as Immune Reconstitution Inflammatory Syndrome in HIV-positive Persons](#), Martiniuk, F., et al.
- [Primary Multidrug-Resistant Leprosy, United States](#), Williams DL, Hagino T, Sharma R, Scollard D.
- World Health Organization: <https://www.who.int/news-room/fact-sheets/detail/leprosy>
- National Hansen' Disease Program: <https://www.hrsa.gov/hansens-disease/index.html>
- Texas Department of State Health Services Hansen's Disease Program: <https://www.dshs.texas.gov/hansens-disease-leprosy>

SIGNATURES

Program Staff Name (Print) _____ Signature _____ Date _____

Clinic Supervisor Name (Print) _____ Signature _____ Date _____

DSHS Hansen's Disease Nurse Consultant Name- if coordinated trainings (Print) _____

DSHS HD Nurse Consultant Signature: _____ Date Skills Observed (if applicable) _____

Appendix M: Project Deliverables

Deliverable Item	Due Date/How to Report Deliverable
<p>Completion of Required Trainings</p>	<p>Within 30 days of hire for staff responsible for reporting or sharing PHI with DSHS:</p> <p>1) <u>Obtain GlobalScape access:</u></p> <ul style="list-style-type: none"> ○ Access information is located on: https://www.dshs.state.tx.us/thsvh/account.shtm <p>Within 30 days of hire and annually for all staff:</p> <p>1) <u>Data and Security training:</u></p> <ul style="list-style-type: none"> ○ Submit documentation to the DSHS TB/HIV/STD (THS) Section Security Officer to confirm that all HD staff and subcontractors receive yearly training on the DSHS Security and Confidentiality Training with a passing score of 85% or above. ○ Must submit within 10 days of training. <p>2) <u>HHS Records Management Training</u></p> <ul style="list-style-type: none"> ○ HHS Annual Records Management Training is required for all employees having access to (1) Federal information or a federal information system, or (2) personally identifiable information (PII). ○ Must be completed at the start of employment or the start of the contract period (whichever is sooner), <i>and</i> annually. ○ Email completed certificates to: HDPCR@dshs.texas.gov within 30 days of new contract period or date of hire (for new staff). <p>Once during tenure during in HD Clinic:</p> <p>1) <u>NHDP Specialty Training on Management of the Neuropathic Foot</u></p> <ul style="list-style-type: none"> ○ Training titled "<i>Lower Extremity Amputation, Prevention, and Treatment of the Neuropathic Foot</i>" is required for key personnel who will be providing clinical HD services, <i>when available from the NHDP.</i> ○ Email completion dates to: HDPCR@dshs.texas.gov.
<p>Obtain ancillary care services available to the HD clinic.</p>	<ul style="list-style-type: none"> ○ Submit a written plan for provision of ancillary services within 30 days of each contract period. Identify if a contract or other formal agreement exists with each provider. For Orthotics (specialty shoes) the plan must include name and address of provider. Submit to HDCPR@dshs.texas.gov.

Deliverable Item	Due Date/How to Report Deliverable
Provide monthly reports of miles accrued and reimbursement amount for patient travel.	<ul style="list-style-type: none"> ○ Send an email regarding mileage paid/month to: HDPCR@dshs.texas.gov.
C-12 Texas Hansen's Disease Surveillance Form	<ul style="list-style-type: none"> ○ Submit via GlobalScape within three business days of visit. Email HDPCR@dshs.texas.gov when available.
HD-400 Hansen's Disease Encounter Form	
NHDP-130 Hand Screen, NHDP-133 Foot Screen, NHDP-216 Eye Screen	
NHDP-208 NHDP Annual Follow-up Form	
HD-410 Quality Assurance Activity Report (Monthly Report)	<ul style="list-style-type: none"> ○ Submit on the first Monday of each month to: HDPCR@dshs.texas.gov ○ <u>Targeted Patient Education</u>: 1 activity every other month [see <i>Task 3 subsection 6 for the reporting guidelines for each clinic</i>]. Examples: HD patient group classes; distribution of brochures or other printed materials; display of educational posters ○ <u>Community Outreach and Education</u>: 2 activities per year Examples: Develop and distribute handouts; make Facebook posts (excluding patient-specific information); develop presentations for community partners. ○ <u>Medical Community Education</u>: 1 activity per quarter Examples: Presentations; education to healthcare professionals; medical/nursing students; one-on-one trainings with medical staff; clinical conferences or seminars
Participate in DSHS HD program pre-arranged bi-monthly roster calls	<ul style="list-style-type: none"> ○ At least one key staff member must attend meetings when actively managing patents. ○ Notify the HD program within 24 hours of call with the reason for cancellation and a new date/time proposed, if actively managing patients.