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Texas Department of State  
Health Services

*Hansen's Disease Program*

# **Service Delivery WORK PLAN**

## 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 Bureau of Primary Health Care. It is authorized by Public Law 99-117, Section 2. (a), Section 320 and guided by DHHS regulations.

The Texas DSHS Hansen's Disease Program (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 Service Delivery Work Plan (HD Work Plan) sets forth procedures established by the HD Program to ensure all HD clinics receiving state 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 and DSHS-supported 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: Client Assessment and Management**

The clinic will:

#### **1. Validate client eligibility for HD services:**

- **Patient:** any individual in the continental US and territories 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 untreated HD.

## 2. Provide medical case management and record keeping for eligible clients:

- Ensure all clients who choose to receive services at the HD clinic have a medical record that includes signed copies of forms HD-405, L36, CD-001 and other applicable consents at the start of service. All HD forms can be found at [dshs.texas.gov/idcu/disease/hansens/forms.shtm](https://dshs.texas.gov/idcu/disease/hansens/forms.shtm).
- Medical case management shall be performed in accordance with the most current version of NHDP's *Guide to the Management of Hansen's Disease (HD Manual)*, and upon consultation with a Hansen's Disease physician and/or a medical consultant at NHDP. The *HD Manual* can be found at: [hrsa.gov/sites/default/files/hrsa/hansens-disease/pdfs/hd-guide-management.pdf](https://hrsa.gov/sites/default/files/hrsa/hansens-disease/pdfs/hd-guide-management.pdf).
- Disposition, treat, provide, and document all appointments for clients actively needing HD services as follows:
  - **Active:** Clients in the active phase of treatment (those taking multi-drug therapy [MDT] **or** medications for reactions after MDT) require a minimum of four visits annually while on therapy to include quarterly hand/foot/eye screens and the Annual Follow-Up form (NHDP 208).
  - **Observation:** Clients in the observation phase who have completed MDT and/or all medications for reaction, when all drugs are discontinued, and client 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. Timeframe of follow-up should be documented on the HD-400. 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:** clients 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 clients as per *Appendix G: Client Statuses*.
- Records of all clients are to be kept permanently, according to the DSHS Records Retention Policy, available at: [hhsconnection.hhs.texas.gov/rights-responsibilities/records-management/retention/dshs/tb-hansens-disease-patient-files](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 H: Confidentiality and Security Standards*.

### **3. Perform client assessments to include:**

- History and Physical
- Skin biopsy and skin smears, if needed for diagnosis or assessment as determined by the HD physician (refer to NHDP 199, HD-408 as applicable).
- Screenings:
  - Hand and foot screens (NHDP 130, NHDP 133)
    - Baseline
    - Quarterly in active MDT or on reaction medications
    - As needed, when client has abnormal findings
    - At closure
  - Eye screen (NHDP 216)
    - Baseline
    - Quarterly
    - If client 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
- 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.).
  - Provide education on how to protect the skin on the hands and feet when there are current, or there is the potential for, wounds due to loss of sensation as identified by the hand and foot screens.
  - Refer client to receive specialty shoes as identified by each clinic or when needed, custom orthotics. To be eligible for specialty shoes or custom orthotics, clients need to be classified with a Grade 1 or above disability (see *Appendix C: 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 D: Triggers for Referral and Consultation*).

### **4. Perform diagnostic tests including biopsies and skin smears, and perform routine laboratory blood draws at designated intervals:**

- Submit specimen for biopsy testing and/or skin smear testing when indicated to confirm a HD diagnosis or when determining therapy efficacy:
  - HD clinics must send specimen for biopsies and/or skin smears to the laboratory designated by the HD program.

- Supplies for laboratory testing cannot be requested from the NHDP and must be purchased using the clinic's HD supply budget.
- When HD physicians request special testing at the NHDP laboratory for either confirmatory tests or polymerase chain reaction (PCR) testing, or when NHDP pathology consultation is needed, the program must submit a written request to the NHDP for permission prior to specimen submission; cc the DSHS Nurse Administrator.
- Routine blood testing should be collected as per *Appendix B: Laboratory Tests*, which include:
  - Baseline
    - CBC, AST/ALT, CRP, creatinine, BMP, bilirubin, G6PD
    - HBV, HCV if on prednisone
  - Periodically
    - 2<sup>nd</sup> visit: CBC, CRP
    - 3 months: CBC, AST/ALT, CRP
    - 6 months: CBC, AST/ALT, CRP
    - Every 12 months: CBC, AST/ALT, CRP
  - Annually or as needed
    - CBC, AST/ALT, CRP, BMP
- Refer clients to a primary care clinic or health department when tuberculosis (TB) or sexually transmitted infections (STIs) including HIV testing is needed, as indicated by the treating HD physician.

#### **5. Provide medications; store and reconcile inventory:**

- Order medications for HD or reactions as listed in *Appendix E: DSHS Hansen's Disease Formulary*.
  - **Active HD:** Provide MDT for clients with multibacillary and paucibacillary disease, as listed on *Appendix A: Treatment for Hansen's Disease*, and per *HD Manual*, ensuring a provider order is in place.
  - **Reactions:** Provide medication for reactions as per *HD Manual* (clofazimine, thalidomide, prednisone, methotrexate).
    - Seek medical consultation when needed (methotrexate, other medications for reaction if provider is unfamiliar with usage).
  - When ordering medications, use the Prescription Fax Form (preferred), or ITEAMS, as outlined in *Appendix F: 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 F: Medication Ordering and Inventory Tracking*.
- Ensure medication inventory is stored and reconciled, as outlined in *Appendix F: Medication Ordering and Inventory Tracking*.

## 6. Provide client education and outreach:

- Client education:
  - Educate clients 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 all client education on form HD-400.
- Client outreach:
  - Perform activities to maintain clients in therapy.
  - Report to the DSHS HD program outreach activities; report on the Quality Improvement Activity Report (HD-410).
  - Report to the DSHS HD program clients who have died or who have moved using the Change of Client Information form (HD-406).
  - Contact clients who are lost to follow up (LTFU). Provide three attempts to have the client return to the clinic: send a letter, make a phone call, at least one attempt must be a certified letter explaining the need to get them back into clinic. When all attempts have failed, change client 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.
- Community outreach:
  - Perform two community outreach activities annually such as: develop and distribute handouts; make Facebook posts excluding client-specific information; develop presentations for community partners.
    - *Note: World Leprosy Day is the last Sunday in January. See [cdc.gov/leprosy/world-leprosy-day/](http://cdc.gov/leprosy/world-leprosy-day/).*
  - Report to the DSHS HD program outreach activities on bi-monthly roster calls, and by reporting on form HD-410.

## Task 2: Multidisciplinary and Consultative Services

The clinic will provide medical case management and referral services. The services where clients are referred shall be staffed by clinicians trained and experienced in Hansen's disease, who meet the qualifications, experience and licensure as stated in *Appendix I: Qualifications of HD Staff*.

The following key personnel and providers should be available to the clinic:

### 1. Key Personnel:

- Primary Nurse
- Physician
- Project Director/Business Manager

**2. Ancillary providers:**

- Occupational therapist
- Ophthalmologist
- Orthotics (specialty shoes). *Must be in place within 30 days of contract period.*
- Physical therapist
- Podiatrist

All client visits to ancillary providers must be documented as a referral on form HD-400.

The DSHS HD program must be notified of any ancillary providers. Report any changes of HD staff on the Change of HD Personnel Form HD-407, including new hires.

**Task 3: Client Travel Reimbursement**

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

Client travel will be handled as detailed below:

**1. Verify eligibility for reimbursement:**

- Client must be approved as indigent, as determined by the clinic, and that must be re-verified annually and documented in the medical record.

**2. Provide transportation assistance as either a bus ticket, or reimburse the cost of the 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 the reimbursement.
- If transportation is needed that exceeds the lowest common carrier (i.e. client is medically unable to travel by bus), contact the DSHS HD program for approval prior to arranging transportation.

**3. Report travel when indicated:**

- Provide monthly reports to the DSHS HD program any miles accrued and reimbursement amount that clients received for transportation assistance.
- Send an email regarding mileage paid/month to: [HDPCR@dshs.texas.gov](mailto:HDPCR@dshs.texas.gov)

**Task 4: Third Party Reimbursement and Medical Co-Payments**

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

**1. Determine client 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 clients out of pocket expenses:**

- The HD clinic is responsible for ensuring clients do not pay co-pays for HD services, including but not limited to: laboratory services, screenings, shoes, or services by ancillary providers.

**Task 5: Consultation and Referrals**

Refer clients to ancillary care for HD services that cannot be managed at the HD clinic.

The clinic will:

**1. Provide ancillary services as medically necessary, as stated in Task 2.** Refer according to *Appendix D: Triggers for Referral and Consultation*, to the following:

- Occupational therapy
- Physical therapy
- Ophthalmology
- Orthotics (specialty shoes)
- Podiatry

**2. Request additional services as needed.** When client-specific services are requested by the HD physician beyond those listed above, provide a written request to the DSHS HD program within three days of the identified need. If approved, the clinic will be responsible for service costs and coordinating appointments with the ancillary provider.

This request should include:

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

**Task 6: Reporting Requirements**

The clinic will:

**1. Document patient information on applicable forms and ensure reporting information is current and accurate:**

- Clinics must ensure reporting deadlines are met and uploaded to GlobalScape to include the following (see *Appendix L: Program Deliverables*):
  - Client demographics
  - Classifications and status, see *Appendix G: Client Statuses*
  - Type of medication protocol



- Clinical visit
- Services performed during visit
- Education provided
- 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 clients move from a Texas clinic to another clinic or out of state (HD-406)
  - Annual Follow-Up Form (NHDP 208)

**2. Complete the Quality Improvement Activity Report (HD-410) on a bi-monthly basis.**

- Submit to the HD program via [GlobalScope](#) by close of business on the following dates per reporting period:

Reporting Periods	Due to DSHS HD Program
December and January	February 3
February and March	April 1
April and May	June 3
June and July	August 3
August and September	October 3
October and November	December 2

**3. Attend Bi-monthly Roster Conference Calls:**

- Participate in DSHS HD program pre-arranged bi-monthly roster calls.
  - 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 reporting period."
  - At least one key personnel must attend meetings annually when actively managing patients.

**Task 7: Out of State Travel**

Key personnel and designated clinic staff will:

**1. Attend trainings sponsored by NHDP upon approval by the DSHS HD program**

- Send to the DSHS HD Program dates, staff, and name of training.

## Task 8: Video Conference

The project director or designee will ensure that:

### 1. Key Personnel attend a twice-yearly video conference, as convened by the DSHS HD program

- Conference will provide updates and discuss challenges and successes.
- Participants may include all key personnel.

## Task 9: Required Training

The project director 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 K: Required Trainings and Recommended Resources for Hansen's Disease Program Staff*.

Required training includes but is not limited to:

### 1. DSHS Data and Security Training

- Required for all HD staff with access to confidential information.
- Complete the training and pass with an 85% or higher upon hire and annually.
- See *Appendix H: Confidentiality and Security Standards* for submitting certificates of completion.

### 2. Health and Human Services (HHS) Security Awareness and Training

- Cybersecurity awareness training, cybersecurity essentials training, and phishing training for all HD staff upon hire and annually.
- Email completion dates for each to [HDPCR@dshs.texas.gov](mailto:HDPCR@dshs.texas.gov) within 30 days of the new contract period or date of hire (for new staff).

### 3. HHS Role-Based Training

- Information security for IT administrators and role-based training for executives and managers training is required upon hire and annually for staff with significant security responsibilities, as determined by the Project Director.
- Email completion dates to [HDPCR@dshs.texas.gov](mailto:HDPCR@dshs.texas.gov) within 30 days of the new contract period or date of hire (for new staff).

### 4. 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.
  - At the end of the Records Management training, the "Congratulations" slide is considered the certificate of completion.

- Email completed certificates to [HDPCR@dshs.texas.gov](mailto:HDPCR@dshs.texas.gov) within 30 days of new contract period or date of hire (for new staff).

### **5. NHDP Specialty Training on Management of the Neuropathic Foot**

- Training titled "Lower Extremity Amputation, Prevention, and Treatment of the Neuropathic Foot" is required for key personnel who will be providing clinical HD services.
- Email completion dates to [HDPCR@dshs.texas.gov](mailto:HDPCR@dshs.texas.gov) within 30 days of the new contract period or date of hire (for new staff).

### **6. Other trainings based on role and need**

- For requirements of all other trainings, see *Appendix K: Required Trainings and Recommended Resources for Hansen's Disease Program Staff*.
- Project directors 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.
- Project directors or designees must maintain records of staff training upon hire and annually.

## **Task 10: Performance Measures**

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

- Ensure that 100% of clients and, as necessary, their contacts are examined by a physician having medical expertise in HD;
- Ensure that 100% of clients who are actively managed receive hand, foot, and eye screens per protocol;
- Ensure that 100% of clients 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 clients are referred for specialty shoes or orthotics when Grade 1 is documented on the foot screens;
- Ensure that 100% of clients on multi-drug therapy (MDT) complete HD therapy according to the schedule;
- If data indicates that MDT clients 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 5 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 "*NHDP Guide to the Management of Hansen's Disease*," National Hansen's Disease Program; and

- Ensure that 100% of client encounters (including office visits, telephone calls, medication refills, or written communications) are documented on Form HD-400 and submitted to the DSHS HD program within five (5) working days of encounter date.

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## Appendix A

**Treatment for Hansen's Disease**

<b>ADULTS</b>		
<b>Tuberculoid (TT &amp; BT) WHO Classification Paucibacillary (PB)</b>		
Agent	Dose	Duration
Dapsone	100 mg daily	12 months, then discontinue
Rifampin	600 mg daily	
<b>Lepromatous (LL, BL, BB) WHO Classification Multibacillary (MB)</b>		
Agent	Dose	Duration
Dapsone	100 mg daily	24 months, then discontinue
Rifampin	600 mg daily	
Clofazimine	50 mg daily	

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

\*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**

	Initial Visit	2 <sup>nd</sup> Visit (1-2 Months)	3 Months	6 Months	12 Months or every 3 months until active treatment completed	Annually or as needed after active treatment completed
Complete Blood Count (CBC) + platelets	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Aspartate Aminotransferase (AST)	<b>X</b>		<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Alanine Aminotransferase (ALT)	<b>X</b>		<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Creatinine Reactive Protein (CRP)	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Basic Metabolic Panel (BMP)	<b>X</b>					<b>X</b>
Creatinine	<b>X</b>					
Bilirubin	<b>X</b>					
Glucose-6-Phosphate dehydrogenase (G6PD)	<b>X</b>					
Hepatitis B* (HBV)	<b>X</b>					
Hepatitis C* (HCV)	<b>X</b>					
*Screen if client requires prednisone						

## Appendix C

### Disability Grades

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

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

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



Appendix D

**Triggers for Referral and Consultation**

<b>HAND</b>		
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 client.
	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 clients 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 consult 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 orthopedist 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. Consults with NHDP physicians and occupational therapist for treatment approaches are available resources.

<b>FEET</b>		
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 client.
	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 a consideration. Generally noted in HD clients 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 therapist. Consider a consult 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 orthopedist to develop a comprehensive treatment plan such as reconstructive therapy. Evaluation by a healthcare provider who is knowledgeable about neuropathic foot is recommended.

<b>EYE</b>		
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 may consider referral to ophthalmology for a comprehensive evaluation and treatment plan. Consult NHDP physicians if needed.

## Appendix E

**DSHS Hansen's Disease Formulary**

Anti-Infectives			
Drug Name Generic (Brand):	Strength	Route	Comments
<b>Clarithromycin ER 500mg (Biaxin XL 500)</b>	500 mg <b>E</b> xtended <b>R</b> elease	PO	Clarithromycin 500 mg tablets are available as either <b>E</b> xtended <b>R</b> elease or <b>I</b> mmEDIATE <b>R</b> elease. The Extended Release is formulated to prevent GI upset.
<b>Clarithromycin (Biaxin)</b>	250mg, 500 mg (regular release aka immediate release)	PO	Clarithromycin 500 mg tablets are available as either <b>E</b> xtended <b>R</b> elease or <b>I</b> mmEDIATE <b>R</b> elease. Clarithromycin 250mg is only available as regular release (no ER is manufactured).
<b>Clofazimine*</b>	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.
<b>Dapsone</b>	25mg, 100mg		
<b>Levofloxacin (Levaquin)</b>	250mg, 500 mg, 750mg	PO, IV	
<b>Minocycline 50mg (Minocin)</b>	50mg, 100mg	PO, IV	
<b>Rifampin (Rifadin)</b>	150mg, 300mg	PO, IV	
Reaction Medications			
Drug Name Generic (Brand):	Strength	Route	Comments
<b>Clofazimine*</b>	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.
<b>Methotrexate</b>	PO: 2.5mg, 5mg, 7.5mg, 10mg, 15mg IV: 25mg/ml	PO, IV	Must be given with Folic Acid
<b>Prednisone</b>	2.5mg, 5mg, 10mg, 20mg	PO	
<b>Thalidomide*</b>	50mg	PO	Patients enroll via Celgene. Online enrollment available at <a href="http://celegenpatientsupport.com">celegenpatientsupport.com</a> or call 1-800-931-8691. Contact DSHS HD Program for <i>initial</i> enrollment.

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

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

## Appendix F

### Medication Ordering and Inventory Tracking

#### Ordering Medications for Clients 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 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 or electronically 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 ITEAMs 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 ITEAMS, or pharmacy designated ordering system.
- Ensure the completed and approved HD-413 is kept in the client medical record.

**Medication storage and reconciliation using the DSHS Inventory Tracking Electronic and Asset Management System (ITEAMS):**

- 1) Order medications through a DSHS-enabled pharmacy ordering system, either the Prescription Fax Form provided by DSHS Pharmacy Unit, or the DSHS Inventory Tracking Electronic and Asset Management System (ITEAMS);
- 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-expiring-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 the ITEAMS; no later than the seventh working day of the month. Coordinate with ITEAMS 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 ITEAMS, 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 or ITEAMS, contact DSHS Pharmacists Lester Mattson ([Lester.Mattson@dshs.texas.gov](mailto:Lester.Mattson@dshs.texas.gov)) or Tracey Bronnenberg ([Tracey.Bronnenberg@dshs.texas.gov](mailto:Tracey.Bronnenberg@dshs.texas.gov)).

## Appendix G

**Client Statuses**

The following terms and abbreviations shall be used to identify the status of clients 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 untreated case HD.
- *Contacts to known HD cases may be evaluated by the HD program for symptoms of HD.*
  - *Prophylaxis therapy may be considered by the treatment 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 and maximum of three 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 H

### Confidentiality and Security Standards

#### General Requirement

HD programs will perform activities outlined in this *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](https://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](https://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](https://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](https://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 *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](mailto: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 security and confidentiality training to [TBHIVSTD.AccountRequest@dshs.texas.gov](mailto: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., Project Director) 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](mailto: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. Email should only request access for one person. Requests for multiple employees 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](https://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.
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](https://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](mailto: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 [DSHS TB/HIV/STD Local Responsible Party \(LRP\) Handbook](#) for other roles and responsibilities.

## Appendix I

### **Qualifications of HD Staff**

#### **Project Director or Business Manager**

##### Education and Experience:

The project director shall have a minimum of three year 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 project director shall assist with planning, coordinating, and implementing activities associated with administrative management, operations, equipment, space management, logistics, budget, travel, and other area for the performance accountability and management.

The project director shall work collaboratively with the DSHS Contracting Management Services (CMS) and 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 years of independent practicing experience.

##### Duties:

- Shall perform medical screenings, evaluations, and treatment of HD and reactions.

- Shall provide medical oversight and coordinate overall care for the HD clients.
- Shall document care provided in the medical records.
- Shall collaborate with NHDP physicians as needed relating planning and managing medical care for clients.
- Shall refer clients to appropriate health care professionals as clinic judgement dictates and as outlined in the *HD Manual* and the DSHS Service Delivery Work Plan.
- Shall make a reasonable effort to treat HD clients 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 by The Accreditation Commission for Education in Nursing (ACEN) or The Commission on Collegiate Nursing Education (CCNE).

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

### Licensure:

The registered nurse shall have a current, full, active, and unrestricted 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 client outreach for clients who have not kept clinic appointments or have lapse in their medication regimen.
- The nurse shall provide client 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 client'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 years of full-time experience.

### 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 clients 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.

Shall have a minimum of three years of experience working in the field of podiatry.

### Licensure:

Applicants shall be currently licensed to practice podiatric medicine in one of the States, District of Columbia, or Puerto Rico.

### Duties:

- Diagnose foot disorders and determine the best course of treatment for care of insensitve neuropathic feet.
- Perform podiatric procedures as the client's condition warrants.
- Educate clients 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 insensitve 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 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 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 J

Completing the HD 400 Encounter Form



TEXAS DEPARTMENT OF STATE HEALTH SERVICES  
HANSEN'S DISEASE ENCOUNTER FORM

Encounter Date: \_\_\_\_\_

Patient Name: _____		Clinic: _____	
DOB: _____	SSN: _____	Gender: _____	MD: _____
Address: _____		Contact: _____	
Phone: _____			
Insurance: _____	HD Type: _____	Year Dx: _____	Type of Visit: _____
Other Insurance: _____	Last Skin Smear: _____	Service Provided: <input type="checkbox"/> Rx (medication) refill <input type="checkbox"/> Screens	
Allergies: _____	Results: _____	<input type="checkbox"/> Labs <input type="checkbox"/> Education <input type="checkbox"/> Callous trim <input type="checkbox"/> Wound care	
	Last Biopsy: _____	<input type="checkbox"/> Other: _____	
	Results: _____	Status: _____	

**HD Type:** Mark which type of disease corresponds with the biopsy. If patient is suspected of HD but no medications are started pending further testing, select in the drop-down "Unspecified, Leprosy" until confirmed.

- LL
- BL
- TT
- BT
- IN Indeterminate
- BB
- Unspecified, Leprosy

**Type of Visit:** Indicate main reason for encounter. If just a phone call or letter, mark "Other" and describe, but only send these to DSHS if a status has changed or service was provided such as medication refill, or **after** 3 attempts of contacting a patient before calling him/her LTFU (compile all attempts in 1 encounter).

- Consult- refer to ancillary or NHDP
- Initial - newly reported, first visit
- Episodic- unplanned due to patient issue
- Routine- scheduled visit
- Annual- yearly visit
- Other- describe in notes

**Service Provided:** Select all that apply to services performed at the encounter.

**Status:** Ensure status is updated and applicable at **each** encounter. Statuses are defined on the HD-409. Note: if a patient is suspected of disease but no medications are started, they are "S" suspect. Update their status once known.

- Active - A
- Contact - C
- Complication - Comp
- Deceased - D
- Inactive - IA
- Lost to Follow Up - LTFU
- New Case - NC
- Observation - OBS
- Suspect - S

Drug	Dosage	Frequency	Start Date	Stop Date	Reason Discontinued	Re-Start Date	Re-Stop Date	Refill Needed Yes/No	Refill Duration
Dapsone									
Rifampin									
Clofazamine									
Clarithromycin									
Minocycline									
Levofloxacin									

  

Reaction Medications:	Start Date	Start mg	End Date
Clofazamine			
Methotrexate			
Prednisone			
Thalidomide			

  

Other Prescribed Medications:	Start Date	Stop Date

**Re-start/Re-stop date:** added to show medication regimen

**Reaction Medications:** if on a medication with a taper, only provide start date, start mg, and end date.

**Other Prescribed Medications:** only medications listed on the HD

**Type of Consult:** Select when patient is referred to ancillary care, needs shoes, or to NHDP for in-patient care. NOTE: When referring for specialty shoes (SAS or other company), select "Orthotist- Specialty Shoes" in the drop-down.

- Ears/Nose/Throat (ENT)
- Ophthalmology (Eyes)
- Occupational Therapy (OT)
- Physical Therapy (PT)
- Orthopedist
- Orthotist- Specialty Shoes
- Podiatrist
- Wound Care
- NHDP Referral

**Reactional State:** Select when patient is actively in reaction. De-select when resolved.

<b>Client Education:</b> <input type="checkbox"/> Compliance to Chemotherapy <input type="checkbox"/> Cause/Transmission <input type="checkbox"/> Drug Regimen/Toxicity <input type="checkbox"/> Reaction(s) <input type="checkbox"/> Care of Hands/Feet/Eyes <input type="checkbox"/> Acceptance	<b>Screens (Baseline, Quarterly, as needed):</b> <input type="checkbox"/> Hands <input type="checkbox"/> Feet <input type="checkbox"/> Eyes <b>Medical Compliance/Tolerance:</b> _____ <input type="checkbox"/> Annual Follow-up Form Date last completed: _____	<b>Reactional State:</b> <input type="checkbox"/> Type I - Reversal <input type="checkbox"/> Type II - Erythema Nodosum Leprosum (ENL) <input type="checkbox"/> Both <input type="checkbox"/> Lucio <input type="checkbox"/> Uncertain	<b>Consult/Referral date:</b> _____ <b>Type of consult:</b> _____ <b>Other referral:</b> _____ <b>Name of referral site:</b> _____ <b>Reason for referral:</b> _____
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Laboratory Tests:			
Initial visit:	Follow-up visits:	Other labs as needed:	Other tests as needed:
<input type="checkbox"/> CBC + platelets <input type="checkbox"/> CMP (Includes AST/ALT/BUN/Creatine/Bilirubin) <input type="checkbox"/> CRP <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> G6PD <input type="checkbox"/> Hepatitis B* <input type="checkbox"/> Hepatitis C* <small>Screen if patient has risk factors and may need prednisone</small>	<input type="checkbox"/> CBC + platelets <input type="checkbox"/> CRP <input type="checkbox"/> AST <input type="checkbox"/> ALT <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> CMP <input type="checkbox"/> BMP <input type="checkbox"/> Bilirubin <input type="checkbox"/> Alkaline Phos <input type="checkbox"/> Eosinophil count <input type="checkbox"/> Other, specify: _____
			<input type="checkbox"/> UA <input type="checkbox"/> Occult Blood <input type="checkbox"/> Ova Parasites <input type="checkbox"/> PCR <input type="checkbox"/> Other, specify: _____

**Annual Follow-up Form:** Mark if the Annual Follow up form was completed at in-person visit. If only phone call, note on the top "Type of Visit" that it was an Annual-yearly visit and note phone call in "Other". The Form should be completed on or near the anniversary of diagnosis for any client still on roster.

## Appendix K

**Required Trainings and Recommended Resources for Hansen's Disease Program Staff**

	TRAINING	REFERENCE	Date	Staff initials	Supervisor initials
1+	<b>DSHS Data and Security Training</b> (and any applicable locally required training)	<a href="https://dshs.texas.gov/thsvh/account.shtm#existing">dshs.texas.gov/thsvh/account.shtm#existing</a>			
2+	<b>Health and Human Services (HHS) Security Awareness and Training, online courses</b> <ul style="list-style-type: none"> <li>• Cybersecurity Awareness Training</li> <li>• Cybersecurity Essentials Training</li> <li>• Phishing Training</li> </ul>	<a href="https://hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/">hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/</a>			
3	<b>HHS Role Based Training, online courses for IT staff in HD clinics managing data or for Managerial staff only</b> <ul style="list-style-type: none"> <li>• Information Security for IT Administrators</li> <li>• Role Based Training for Executives and Managers</li> </ul>	<a href="https://hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/">hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/</a>			
4+	<b>HHS Records Management Training, Online course</b>	<a href="https://humancapital.learning.hhs.gov/courses/2020recordsmanagement/01_index.html">humancapital.learning.hhs.gov/courses/2020recordsmanagement/01_index.html</a>			
5*	<b>National Hansen's Disease Program (NHDP) Guide to the Management of Hansen's Disease, Reference Manual</b>	<a href="https://hrsa.gov/sites/default/files/hrsa/hansens-disease/pdfs/hd-guide-management.pdf">hrsa.gov/sites/default/files/hrsa/hansens-disease/pdfs/hd-guide-management.pdf</a>			
6*	<b>DSHS Orientation to HD Program, for new HD nurses, 1.5 hrs</b>	Will be arranged by DSHS Central Office for new HD nurses once <a href="#">Change of Personnel Form</a> is completed			
7*	<b>NHDP Specialty Training: Lower Extremity Amputation, Prevention, and Treatment of the Neuropathic Foot, Online course for clinical staff</b>	<a href="https://hrsa.gov/hansensdisease/onlinecourseleap.html">hrsa.gov/hansensdisease/onlinecourseleap.html</a>			
8*	<b>DSHS Grant Rounds: Hansen's Disease (Leprosy): Old World Disease, New World Resources, Online webinar</b>	<a href="https://register.gotowebinar.com/recording/recordingView?webinarKey=7867210603518497283&amp;registrantEmail=elizabeth.foy%40dshs.texas.gov">register.gotowebinar.com/recording/recordingView?webinarKey=7867210603518497283&amp;registrantEmail=elizabeth.foy%40dshs.texas.gov</a>			
9	<b>DSHS-Coordinated Observational Clinic – in person training, 16-24 hours with a Hansen's Disease Clinic in TX:</b> <ul style="list-style-type: none"> <li>• Hand, Foot, and Eye screens</li> <li>• Biopsy information, education, shipping</li> <li>• Skin smears-procedure, preparation for reading and shipping</li> <li>• Visual Acuity-f/u while on steroids</li> <li>• Medication Education</li> <li>• Clinic forms, reporting to DSHS</li> </ul>	May be arranged by DSHS Hansen's Disease Program, upon request.  <u>Review the following:</u> <ul style="list-style-type: none"> <li>• Hansen's Disease Service Delivery Work Plan – required activities and reporting deadlines</li> <li>• DSHS HD Program Website: <a href="https://dshs.texas.gov/idcu/disease/hansens/forms/">dshs.texas.gov/idcu/disease/hansens/forms/</a></li> </ul>			

10*	<b>NHDP: Diagnosis &amp; Treatment of Hansen's Disease in the United States Seminar</b> , <i>In-person training at NHDP in Louisiana, 16hr</i>	Held annually at the NHDP in Baton Rouge, Louisiana. Contact NHDP for registration: <a href="http://hrsa.gov/hansensdisease/training.html">hrsa.gov/hansensdisease/training.html</a>			
11*	<b>When to Suspect Leprosy: Clinical Aspects and Treatment of Uncomplicated Hansen's Disease. Grand Rounds, Orange Park Medical Center, June 25, 2021.</b> <i>Online webinar (in lieu of #10, above, if travel restrictions occur)</i>	<a href="https://youtube.com/watch?v=LqM7PwMztQ8">youtube.com/watch?v=LqM7PwMztQ8</a>			
12*	<b>Vision Certification or Skills Check-Off</b>	Local/Regional Trainings offered; contact local or region office to arrange			
13	<b>Annual CEs, skills training for nurses, 20 hours every 2 years</b>	Skills training, as determined by HD Clinic Manager/Director			

+Required for all program staff funded by the HD program within 30 days of hire and annually

\*Required for nurses within the first 3 months of hire. For trainings that include travel, requirements may be waived if travel restrictions occur. Managers may determine required courses for all other HD staff.

### Suggested Readings

- [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.

### Reference Websites

- World Health Organization: [who.int/news-room/fact-sheets/detail/leprosy](http://who.int/news-room/fact-sheets/detail/leprosy)
- National Hansen's Disease Program: [hrsa.gov/hansens-disease/](http://hrsa.gov/hansens-disease/)
- Texas Department of State Health Services Hansen's Disease Program: [dshs.texas.gov/idcu/disease/hansens/](http://dshs.texas.gov/idcu/disease/hansens/)

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### 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 L

**Project Deliverables**

Deliverable Item	Due Date/How to Report Deliverable
Completion of Required Trainings	<p><b>Within 30 days of hire for staff responsible for reporting or sharing PHI with DSHS:</b></p> <p>1) Obtain GlobalScape access:</p> <ul style="list-style-type: none"> <li>○ Access information is located on: <a href="https://dshs.texas.gov/thsvh/account.shtm">dshs.texas.gov/thsvh/account.shtm</a></li> </ul> <p><b>Within 30 days of hire and annually for all staff:</b></p> <p>1) <i>Data and Security training:</i></p> <ul style="list-style-type: none"> <li>○ 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 <a href="#">DSHS Security and Confidentiality Training</a> with a passing score of 85% or above. Must submit within 10 days of training. For new staff, complete within 30 days of hire.</li> </ul> <p>2) <i>Health and Human Services (HHS) Security Awareness and Training</i></p> <ul style="list-style-type: none"> <li>○ Cybersecurity awareness training, cybersecurity essentials training and phishing training for all HD staff upon hire and annually.</li> <li>○ Email completion dates for each to <a href="mailto:HDPCR@dshs.texas.gov">HDPCR@dshs.texas.gov</a> within 30 days of the new contract period or date of hire (for new staff).</li> </ul> <p>3) <i>HHS Records Management Training</i></p> <ul style="list-style-type: none"> <li>○ Training is required for all employees having access to (1) Federal information or a Federal information system, or (2) personally identifiable information (PII).</li> <li>○ Must be completed at the start of employment or the start of the contract period (whichever is sooner), <b>and</b> annually.</li> <li>○ At the end of the Records Management training, the "Congratulations" slide is considered the certificate of completion.</li> <li>○ Email completed certificates to <a href="mailto:HDPCR@dshs.texas.gov">HDPCR@dshs.texas.gov</a> within 30 days of new contract period or date of hire (for new staff).</li> </ul>

	<p><b>Upon hire (within 30 days) and annually for key personnel based on role:</b></p> <p><i>1) HHS Role-Based Training</i></p> <ul style="list-style-type: none"> <li>○ Information security for IT administrators and role-based training for executives and managers required upon hire and annually for staff with significant security responsibilities, <i>as determined by the Project Director.</i></li> <li>○ Must be completed at the start of employment or the start of the contract period (whichever is sooner), <b>and</b> annually.</li> <li>○ At the end of the Records Management training, the "Congratulations" slide is considered the certificate of completion.</li> <li>○ Email completed certificates to <a href="mailto:HDPCR@dshs.texas.gov">HDPCR@dshs.texas.gov</a> within 30 days of new contract period or date of hire (for new staff).</li> </ul> <p><b>Upon hire (within first 3 months) for clinical staff:</b></p> <p><i>2) NHDP Specialty Training on Management of the Neuropathic Foot</i></p> <ul style="list-style-type: none"> <li>○ Training titled "Lower Extremity Amputation, Prevention, and Treatment of the Neuropathic Foot" is required for key personnel who will be providing clinical HD services.</li> <li>○ Email completion dates to <a href="mailto:HDPCR@dshs.texas.gov">HDPCR@dshs.texas.gov</a> within 90 days of hire.</li> </ul>
<p>Obtain ancillary care services available to the HD clinic.</p>	<p>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 the Nurse Administrator and cc <a href="mailto:HDCPR@dshs.texas.gov">HDCPR@dshs.texas.gov</a>.</p>
<p>Provide monthly reports of any miles accrued and reimbursement amount that clients received for transportation assistance.</p>	<p>Send an email regarding mileage paid/month to: <a href="mailto:HDPCR@dshs.texas.gov">HDPCR@dshs.texas.gov</a>.</p>

C-12 Texas Hansen's Disease Surveillance Form and Case Report	Submit via GlobalScape within five business days of first visit.														
HD-400 Hansen's Disease Encounter Form	Submit via GlobalScape within five business days of encounter.														
NHDP-130 Hand Screen, NHDP-133 Foot Screen, NHDP-216 Eye Screen	Submit via GlobalScape within five business days of screening.														
NHDP-208 NHDP Annual Follow-up Form	Submit via GlobalScape within five business days of visit.														
HD-410 Quality Improvement Activity Report (Bi-monthly Report)	Submit via GlobalScape by close of business on the following dates: <table border="1" data-bbox="743 632 1438 890"> <thead> <tr> <th>Reporting Periods</th> <th>Due</th> </tr> </thead> <tbody> <tr> <td>December and January</td> <td>February 3</td> </tr> <tr> <td>February and March</td> <td>April 1</td> </tr> <tr> <td>April and May</td> <td>June 3</td> </tr> <tr> <td>June and July</td> <td>August 3</td> </tr> <tr> <td>August and September</td> <td>October 3</td> </tr> <tr> <td>October and November</td> <td>December 2</td> </tr> </tbody> </table>	Reporting Periods	Due	December and January	February 3	February and March	April 1	April and May	June 3	June and July	August 3	August and September	October 3	October and November	December 2
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February and March	April 1														
April and May	June 3														
June and July	August 3														
August and September	October 3														
October and November	December 2														
Participate in DSHS HD program pre-arranged bi-monthly roster calls or notify the HD program within 24 hours of call reason for cancellation with new date/time proposed, if actively managing patients.	At least one key staff must attend meetings when actively managing patents.														
Perform two community outreach activities annually such as: develop and distribute handouts; make Facebook posts excluding client-specific information; develop presentations for community partners.	Report to the DSHS HD program on bi-monthly roster calls and include on the HD-410.														
HD-406 Change of Patient Information	Submit via GlobalScape within five business days of notification.														
HD-407 Change in HD Personnel	Submit to the HD Nurse Administrator the 5 <sup>th</sup> of each month, when changes occur.														