

MEMORANDUM OF UNDERSTANDING

**DEPARTMENT OF STATE HEALTH SERVICES
AND**

<INSERT CLINIC'S NAME >

FOR

CENTRAL DISTRIBUTION MODEL PARTICIPANTS

DSHS CONTRACT NO. <INSERT CONTRACT NO. >

This Memorandum of Understanding (“MOU”) is entered into between **Department of State Health Services** (“DSHS”) and **<Insert Clinic’s Full Legal Name including any dba>** (“Clinic”), each referred to in this MOU as a “Party” and collectively as the “Parties,” to treat and control the spread of infectious disease across Texas through the U.S. Federal Government’s 340B Drug Pricing Program (the “Program”).

I. Purpose

This MOU serves to establish roles and responsibilities concerning the Parties’ compliance with Program guidelines related to providing medication to patients via DSHS’s Pharmacy Unit ordering platform.

II. DSHS Requirements

Under this MOU, DSHS will:

- A. Create, review, and update policies and procedures to ensure compliance with the Program guidelines;
- B. Purchase medications for the treatment of sexually transmitted diseases (“STDs”) and tuberculosis (“TB”) with state and federal funds allocated for specific public health purposes. The medications will be administered and dispensed in compliance with the Program’s regulations, as authorized by the Texas Health and Safety Code, Chapters 81, 85, and 1001;
- C. Monitor Clinic’s registration in the Office of Pharmacy Affairs Information System (“OPAIS”) to confirm that such registration remains current by conducting regular online searches of the OPAIS website;
- D. Provide education concerning compliance with the Program’s guidelines to Clinic through initial and ongoing trainings and by providing information on how to sign-up for

the Apexus PVP Program, a Health Resources and Services Administration (“HRSA”) contractor, for further education;

- E. Monitor and support Clinic as it relates to all compliance elements of the Program addressed in the policies outlined by the DSHS HIV/STD Program, which can be accessed at <https://www.dshs.texas.gov/hivstd/policy/>; and
- F. Monitor and support Clinic as it relates to all compliance elements of the Program addressed in the policies outlined by the DSHS Tuberculosis and Hansen’s Disease Branch in the Texas Tuberculosis Work Plan, which can be accessed at <https://www.dshs.texas.gov/idcu/disease/tb/policies/>.

III. Clinic Requirements

Under this MOU, Clinic will:

- A. Establish policies and procedures that align with DSHS’s Program policies and procedures;
- B. Obtain medications from the DSHS Pharmacy Unit for outpatient treatment of STDs or for TB services and medications;
- C. Distribute medications at no charge to qualified uninsured patients;
- D. Ensure that medications are used only for the treatment of STDs and TB;
- E. Ensure that medications from the Program are not sold or exchanged to any unqualified or insured individual or entity;
- F. Ensure that TB medications are provided through local, pre-authorized health departments and entities;
- G. Maintain a Class D pharmacy license;
- H. Designate a staff member who will oversee the ordering, provision, reconciliation, and reporting of medications from the DSHS Pharmacy Unit. Clinic’s designated staff member will reconcile medications prior to the last day of each month;
- I. Maintain a tangible or electronic tracking-log that documents the following information for each medication distributed:
 - 1. Record of the patient’s information to ensure that the medication is administered or dispensed to a qualified patient of clinical services in an outpatient setting;

2. The National Drug Code (NDC);
 3. Total quantity of the medication dispensed or administered; and
 4. Reconciled medication inventory.
- J. Maintain records that establish appropriate use of each Program medication, as records may be requested and audited by DSHS or for an internal review at any time to ensure compliance. Records include, but are not limited to, billing records, medication tracking logs, and relevant patient records;
- K. Ensure that all Program medications for treatment of STDs comply with current policies and procedures outlined by the DSHS HIV/STD Program, which can be accessed at <https://www.dshs.texas.gov/hivstd/policy/>;
- L. Ensure all Program medications for TB services comply with current policies and procedures outlined by the DSHS Tuberculosis and Hansen's Disease Branch in the Texas Tuberculosis Work Plan, which can be accessed at <https://www.dshs.texas.gov/idcu/disease/tb/policies/>;
- M. Develop and implement policies and procedures for Program medication tracking and distribution that are accessible to DSHS. Clinic may adopt guidance from DSHS or create its own policies and procedures provided it follows the Program's guidelines and does not contradict DSHS's Program policies and procedures;
- N. Register with OPAIS and obtain its approval as a covered entity in the OPAIS database using the DSHS Program grant number, maintain such registration during the entire term of this MOU (See SECTION 5, herein), and identify the program area that Clinic receives funding or in-kind contributions from DSHS. The OPAIS database can be accessed at <https://340bopais.hrsa.gov/>; and
- O. Complete **ATTACHMENT A, LOCATION LIST OF CLINIC'S PARTICIPATING CLINICS**, prior to or upon MOU's execution, by identifying the name, location, and phone number of each participating clinic.

IV. Term of MOU

This MOU will commence on the last date of signature of both parties, and terminates on August 31, 2028, unless sooner terminated pursuant to the terms and conditions of the MOU. This MOU does not include any renewal options.

V. Termination

Either Party may terminate this MOU without cause upon providing thirty (30) calendar days' advance written notice of its intent to terminate to the non-terminating Party's MOU Representative(s).

VI. Additional Terms and Conditions

A. DSHS Data

1. As between the Parties, all data and information acquired, accessed, or made available to Clinic by, through, or on behalf of DSHS or DSHS contractors, including all electronic data generated, processed, transmitted, or stored by Clinic in the course of providing data processing services in connection with Clinic's performance hereunder (the "DSHS Data"), is owned solely by DSHS.
2. Clinic has no right or license to use, analyze, aggregate, transmit, create derivatives of, copy, disclose, or process the DSHS Data except as required for Clinic to fulfill its obligations under the MOU or as authorized in advance in writing by DSHS.
3. Clinic is expressly prohibited from using, and from permitting any third party to use, DSHS Data for marketing, research, or other non-governmental or commercial purposes, without the prior written consent of DSHS.
4. Clinic shall make DSHS Data available to DSHS, including to DSHS's designated vendors, as directed in writing by DSHS. The foregoing shall be at no cost to DSHS.
5. The proprietary nature of Clinic's systems that process, store, collect, and/or transmit the DSHS Data shall not excuse Clinic's performance of its obligations hereunder.

B. Confidentiality

1. Clinic will comply with **ATTACHMENT B, PRIVACY, SECURITY AND BREACH NOTIFICATION**, which is incorporated by reference and made a part of this MOU for all purposes.
2. Clinic will maintain confidentiality and not disclose any DSHS information to third parties without DSHS's prior written consent, including but not limited to, DSHS Data, business activities, practices, systems, conditions, and services. This section will survive termination or expiration of this MOU. The obligations of Clinic under this section will survive termination or expiration of this MOU.
3. All confidential information requirements must be included in all subcontracts awarded by Clinic.

C. No Cost

This is a "no cost" agreement. DSHS shall not be obligated to make any payments of any amounts to Clinic as a result of this MOU. Any costs and expenses incurred under

the terms of this MOU will be paid by the Party incurring the cost or expense. No funds appropriated to either Party will be exchanged under this MOU.

D. Assignment

Clinic will not assign all or any portion of its rights under or interests in this MOU or delegate any of its duties without prior written consent of DSHS. Any written request for assignment or delegation must be accompanied by written acceptance of the assignment or delegation by the assignee or delegation by the delegate. Except where otherwise agreed in writing by DSHS, any assignment or delegation will not release Clinic from its obligations under this MOU.

E. No Implied Waiver of Provisions

The failure of the DSHS to object to or to take affirmative action with respect to any conduct of Clinic that is in violation or breach of the terms of the MOU shall not be construed as a waiver of the violation or breach, or of any future violation or breach.

F. Public Information Act

Clinic understands that DSHS will comply with the Texas Public Information Act (Chapter 552 of the Texas Government Code) as interpreted by judicial rulings and opinions of the Attorney General of the State of Texas.

G. Record Maintenance and Retention

1. Clinic shall keep and maintain under Generally Accepted Accounting Principles (“GAAP”) or Governmental Accounting Standards Board (“GASB”), as applicable, full, true, and complete records necessary to fully disclose to DSHS, the Texas State Auditor’s Office, the United States Government, and their authorized representatives’ sufficient information to determine compliance with the terms and conditions of this MOU and all state and federal rules, regulations, and statutes.
2. Clinic shall maintain and retain legible copies of this MOU and all records relating to the performance of the MOU. These records shall be maintained and retained by Clinic for a minimum of seven (7) years after the MOU’s expiration date or seven (7) years after the completion of all audits, claim, litigation, or dispute matters involving the MOU are resolved, whichever is later.

H. DSHS’s Right to Audit

1. Clinic shall make available at reasonable times, upon reasonable notice, and for reasonable periods, work papers, reports, books, records, and supporting documents kept current by Clinic pertaining to the MOU for purposes of inspecting, monitoring, auditing, or evaluating by DSHS and the State of Texas.
2. In addition to any right of access arising by operation of law, Clinic, any of Clinic’s affiliate or subsidiary organizations, or subcontractors, shall permit DSHS or any

of its duly authorized representatives, as well as duly authorized federal, state, or local authorities, unrestricted access to and the right to examine any site where business is conducted or services are performed, and all records (including but not limited to financial, client and patient records, books, papers or documents) related to this MOU. In addition, agencies of the State of Texas that shall have a right of access to records as described in this section include: DSHS, HHSC, HHSC's contracted examiners, the State Auditor's Office, the Texas Attorney General's Office, and any successor agencies. Each of these entities may be a duly authorized authority.

3. If deemed necessary by DSHS or any duly authorized authority, for the purpose of investigation or hearing, Clinic shall produce original documents related to this MOU.
4. DSHS and any duly authorized authority shall have the right to audit billings, both before and after payment, and all documentation that substantiates the billings.
5. Clinic shall include this **SUBSECTION VI.H**, herein, concerning the right of access to, and examination of, sites and information related to this MOU in any subcontract it awards.

I. Compliance with Audit or Inspection Findings

1. Clinic must act to ensure its compliance and its subcontractors' compliance with all corrections necessary to address any finding of noncompliance with any law, regulation, audit requirement, or generally accepted accounting principle, or any other deficiency identified in any audit, review, or inspection of the MOU and the services provided. Any such correction will be at Clinic's sole expense or its subcontractor's sole expense. Whether Clinic's action corrects the noncompliance shall be solely DSHS's decision.
2. Upon DSHS's request, Clinic must provide DSHS a copy of those portions of Clinic's internal audit reports and its subcontractors' internal audit reports relating to the services provided to the State of Texas under this MOU.

J. State Auditor's Right to Audit

1. The state auditor may conduct an audit or investigation of any entity receiving funds from the state directly under the MOU or indirectly through a subcontract under the MOU. The acceptance of funds directly under the MOU or indirectly through a subcontract under the MOU acts as acceptance of the authority of the state auditor, under the direction of the legislative audit committee, to conduct an audit or investigation in connection with those funds. Under the direction of the legislative audit committee, an entity that is the subject of an audit or investigation by the state auditor must provide the state auditor with access to any information the state auditor considers relevant to the investigation or audit.

2. The Clinic shall comply with any rules and procedures of the state auditor in the implementation and enforcement of Section 2262.154 of the Texas Government Code.

K. Amendment

This MOU may only be modified by written amendment signed by the Parties.

L. Change in Law and Compliance with Laws

Clinic shall comply with all laws, regulations, requirements, and guidelines applicable to a vendor providing services required by this MOU to an agency of the State of Texas, as these laws, regulations, requirements, and guidelines currently exist and as amended throughout the term of the MOU. DSHS reserves the right, in its sole discretion, to unilaterally amend the MOU to incorporate any modifications necessary for DSHS's compliance, as an agency of the State of Texas, with all applicable state and federal laws, regulations, requirements, and guidelines.

M. Governing Law and Venue

This MOU shall be governed by and construed in accordance with the laws of the State of Texas, without regard to the conflicts of law provisions. The venue of any suit arising under this MOU is fixed in any court of competent jurisdiction of Travis County, Texas, unless the specific venue is otherwise identified in a statute which directly names or otherwise identifies its applicability to DSHS.

N. Dispute Resolution

1. The dispute resolution process provided for in Chapter 2260 of the Texas Government Code must be used to attempt to resolve any dispute arising under the MOU. If the Clinic's claim for breach of contract cannot be resolved informally with DSHS, the claim shall be submitted to the negotiation process provided in Chapter 2260. To initiate the process, the Clinic shall submit written notice, as required by Chapter 2260, to the individual identified in the MOU for receipt of notices. Any informal resolution efforts shall in no way modify the requirements or toll the timing of the formal written notice of a claim for breach of contract required under Section 2260.051 of the Texas Government Code. Compliance by the Clinic with Chapter 2260 is a condition precedent to the filing of a contested case proceeding under Chapter 2260.
2. The contested case process provided in Chapter 2260 is the Clinic's sole and exclusive process for seeking a remedy for an alleged breach of contract by DSHS if the Parties are unable to resolve their disputes as described above.
3. Notwithstanding any other provision of the MOU to the contrary, unless otherwise requested or approved in writing by the DSHS, the Clinic shall continue

performance and shall not be excused from performance during the period of any breach of contract claim or while the dispute is pending.

O. Limitation on Authority

1. Any authority granted to Clinic by DSHS is limited to the terms of this MOU.
2. Clinic shall not have any authority to act for or on behalf of the DSHS or the State of Texas except as expressly provided for in the MOU; no other authority, power, or use is granted or implied. Clinic may not incur any debt, obligation, expense, or liability of any kind on behalf of DSHS or the State of Texas.
3. Clinic may not rely on implied authority and is not granted authority under the MOU to:
 - a. Make public policy on behalf of DSHS.
 - b. Promulgate, amend, or disregard administrative regulations of program policy decisions made by state and federal agencies responsible for administration of a DSHS program; or
 - c. Unilaterally communicate or negotiate with any federal or state agency or Texas Legislature on behalf of DSHS regarding DSHS programs or this MOU.

P. Severability

If any provision of the MOU is held to be illegal, invalid, or unenforceable by a court of law or equity, such construction will not affect the legality, validity, or enforceability of any other provision or provisions of this MOU. It is the intent and agreement of the Parties that this MOU shall be deemed amended by modifying such provision to the extent necessary to render it valid, legal, and enforceable while preserving its intent or, if such modification is not possible, by substituting another provision that is valid, legal, and enforceable and that achieves the same objective. All other provisions of this MOU will continue in full force and effect.

Q. Force Majeure

Neither Party shall be liable to the other for any delay in, or failure of performance of, any requirement included in the MOU caused by force majeure. The existence of such causes of delay or failure shall extend the period of performance until after the causes of delay or failure have been removed provided the non-performing party exercises all reasonable due diligence to perform. Force majeure is defined as acts of God, war, fires, explosions, hurricanes, floods, failure of transportation, or other causes that are beyond the reasonable control of either Party and that by exercise of due foresight such Party could not reasonably have been expected to avoid, and which, by the exercise of all reasonable due diligence, such Party is unable to overcome.

- R. Sovereign Immunity
 Nothing in the MOU shall be construed as a waiver of the DSHS’s or the State of Texas’s sovereign immunity. This MOU shall not constitute or be construed as a waiver of any of the privileges, rights, defenses, remedies, or immunities available to DSHS or the State of Texas. The failure to enforce, or any delay in the enforcement of, any privileges, rights, defenses, remedies, or immunities available to DSHS or the State of Texas under the MOU or under applicable law shall not constitute a waiver of such privileges, rights, defenses, remedies, or immunities or be considered as a basis for estoppel. DSHS does not waive any privileges, rights, defenses, or immunities available to DSHS by entering into the MOU or by its conduct prior to or subsequent to entering into the MOU.
- S. Entire MOU and Modification
 This MOU constitutes the entire agreement of the Parties and is intended as a complete and exclusive statement of the promises, representations, negotiations, discussions, and other agreements that may have been made in connection with the subject matter hereof. Any additional or conflicting terms in any future document incorporated into the MOU will be harmonized with this MOU to the extent possible.

VII. Authorized Representatives

The following will act as the designated representative (“MOU Representative”) authorized to administer activities including, but not limited to, notices, consents, approvals, or other general communications to the maximum extent possible. The designated Party MOU Representatives are as follows:

DSHS

<Full Name>
 DSHS Medications, Pharmacy Branch
 <Address and Mail Code>
 <City, State, and Zip Code>
 <Phone Number>
 <Email>

Clinic

<Full Name>
 <Clinic’s Name>
 <Address and Mail Code>
 <City, State, and Zip Code>
 <Phone Number>
 <Email>

VIII. Notice Requirements

- A. All notices given by Clinic shall be in writing, include the DSHS contract number, comply with all terms and conditions of the MOU, and be delivered to DSHS’s MOU Representative identified above.
- B. Clinic shall send legal notices to DSHS at the address below and provide a copy to DSHS’s MOU Representative:

Health and Human Services Commission
Attn: Office of Chief Counsel
4601 W. Guadalupe, Mail Code 1100
Austin, Texas 78751

With copy to:
Department of State Health Services
Attn: Office of General Counsel
1100 W. 49th Street, Mail Code 1919
Austin, Texas 78756

- C. Notices given by DSHS to Clinic may be emailed, mailed, or sent by common carrier. Email notices shall be deemed delivered when sent by DSHS. Notices sent by mail shall be deemed delivered when deposited by DSHS in the United States mail, postage paid, certified, return receipt requested. Notices sent by common carrier shall be deemed delivered when deposited by DSHS with a common carrier, overnight, signature required.
- D. Notices given by Clinic to DSHS shall be deemed delivered when received by DSHS.
- E. Either Party may change its MOU Representative or Legal Notice contact by providing written notice to the other Party at least ten (10) calendar days prior to the change.

IX. Legal Authority

DSHS enters into this MOU under the authority of Texas Health and Safety Code Chapters 12, 81, 85, and 1001.

X. Contract Documents

The following documents are incorporated by reference and made a part of this MOU for all purposes.

ATTACHMENT A - LOCATION LIST OF CLINIC'S PARTICIPATING CLINICS
ATTACHMENT B - PRIVACY, SECURITY, AND BREACH NOTIFICATION

XI. Authorized Signatures

By signing, Parties acknowledge that they have read the MOU in its entirety and agree to its terms. The individuals whose signatures appear below have the requisite authority to execute this MOU on behalf of the named Party.

**SIGNATURE PAGE FOR
MEMORANDUM OF UNDERSTANDING
DSHS CONTRACT NO. <INSERT CONTRACT NO.>**

DEPARTMENT OF STATE HEALTH SERVICES

**<INSERT CLINIC'S FULL LEGAL NAME
INCLUDING ANY DBA>**

By: _____

By: _____

Printed Name: _____

Printed Name: _____

Title: _____

Title: _____

Date of Signature: _____

Date of Signature: _____

ATTACHMENT A
LOCATION LIST OF CLINIC’S PARTICIPATING CLINICS
DSHS CONTRACT NO. <INSERT CONTRACT NO.>

Clinic Name	Address	City	Zip	Phone Number

ATTACHMENT B
PRIVACY, SECURITY, AND BREACH NOTIFICATION
DSHS CONTRACT NO. <INSERT CONTRACT NO.>

1.0 Definitions

“Breach” means the acquisition, access, use, or disclosure of Confidential Information in an unauthorized manner which compromises the security or privacy of the Confidential Information.

“DSHS Confidential Information” means any communication or record (whether oral, written, electronically stored or transmitted, or in any other form) provided to or made available to Clinic electronically or through any other means that consists of or includes any or all of the following:

- (a) Protected Health Information in any form including without limitation, Electronic Protected Health Information or Unsecured Protected Health Information (as these terms are defined in 45 C.F.R. §160.103);
- (b) Sensitive Personal Information defined by Texas Business and Commerce Code Chapter 521;
- (c) Federal Tax Information (as defined in Internal Revenue Service Publication 1075);
- (d) Personal Identifying Information (as defined in Texas Business and Commerce Code Chapter 521);
- (e) Social Security Administration Data (defined as information received from a Social Security Administration federal agency system of records), including, without limitation, Medicare or Medicaid information (defined as information relating to an applicant or recipient of Medicare or Medicaid benefits); and
- (f) All information designated as confidential under the constitution and laws of the State of Texas and of the United States, including the Texas Health & Safety Code and the Texas Public Information Act, Texas Government Code, Chapter 552.

1.1 DSHS Confidential Information

Any DSHS Confidential Information received by Clinic under this MOU may be disclosed only in accordance with applicable law. By signing this MOU, Clinic certifies that Clinic is, and intends to remain for the term of this MOU, in compliance with all applicable state and federal laws and regulations with respect to privacy, security, and breach notification, including without limitation the following:

- (a) Title 5 United States Code (USC) Part I, Chapter 5, Subchapter II, Section 552a, Records Maintained on Individuals, The Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988.
- (b) Title 26 USC, Internal Revenue Code.

- (c) Title 42 USC Chapter 7, Subchapter XI, Part C, Administrative Simplification, the relevant portions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA);
- (d) Title 42 USC Chapter 7, the relevant portions of the Social Security Act;
- (e) Title 42 USC Chapter I, Subchapter A, Part 2, Confidentiality of Substance Use Disorder Patient Records;
- (f) Title 45 Code of Federal Regulations (CFR) Chapter A, Subchapter C, Part 160, General Administrative Requirements;
- (g) Title 45 CFR Chapter A Subchapter C, Part 164, Security and Privacy;
- (h) Internal Revenue Service Publication 1075, Tax Information Security Guidelines for Federal, State and Local Agencies, Safeguards for Protecting Federal Tax Returns and Return Information;
- (i) Office of Management and Budget Memorandum 17-12, Preparing for and Responding to a Breach of Personally Identifiable Information;
- (j) Texas Business and Commerce Code Title 11, Subtitle B, Chapter 521 Unauthorized Use of Identifying Information;
- (k) Texas Government Code, Title, 5, Subtitle A, Chapter 552, Public Information, as applicable;
- (l) Texas Health and Safety Code, Title 2, Subtitle D, Chapter 81, Section 81.006, Funds;
- (m) Texas Health and Safety Code Title 2, Subtitle I, Chapter 181, Medical Records Privacy;
- (n) Texas Health and Safety Code Title 7, Subtitle E, Chapter 611, Mental Health Records;
- (o) Texas Human Resources Code, Title 2, Subtitle A, Chapter 12, Section 12.003, Disclosure of Information Prohibited;
- (p) Texas Occupations Code, Title 3, Health Professions, as applicable;
- (q) Constitutional and common law privacy; and
- (r) Any other applicable law controlling the release of information created or obtained in the course of providing the services described in this MOU.

Clinic further certifies that Clinic will comply with all amendments, regulations, and guidance relating to those laws, to the extent applicable.

1.2 Cybersecurity Training

All of Clinic’s authorized users, workforce and subcontractors with access to a state computer system or database will complete a cybersecurity training program certified under Texas Government Code, Title 10, Subtitle B, Chapter 2054, Section 2054.5192, Cybersecurity Training Required: Certain State Contractors, by the Texas Department of Information Resources.

1.3 Business Associate Agreement

Clinic will ensure that any subcontractor of Clinic who has access to DSHS Confidential Information will sign a HIPAA-compliant Business Associate Agreement with Clinic, and Clinic will submit a copy of that Business Associate Agreement to DSHS upon request.

1.4 Clinic's Incident Notice, Reporting and Mitigation

Clinic's obligation begins at discovery of any unauthorized disclosure of Confidential Information or any privacy or security incident that may compromise Confidential Information. "Incident" is defined as an attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system. Clinic's obligation continues until all effects of the Incident are resolved to DSHS's satisfaction, hereafter referred to as the "Incident Response Period."

1.5 Notification to DSHS.

- (a) Clinic must notify DSHS within the timeframes set forth in Section (c) below.
- (b) Clinic must require that its subcontractors and contractors take the necessary steps to assure that Clinic can comply with all of the following Incident notice requirements.
- (c) Incident Notice:

1. Initial Notice.

Within twenty-four (24) hours of discovery, or in a timeframe otherwise approved by DSHS in writing, Clinic must preliminarily report on the occurrence of an Incident to the DSHS Privacy and Security Officers via email at: privacy@HHSC.state.tx.us.

This initial notice must, at a minimum, contain:

- (i) all information reasonably available to Clinic about the Incident, (ii) confirmation that the Clinic has met any applicable federal Breach notification requirements, and
- (iii) a single point of contact for the Clinic for DSHS communications both during and outside of business hours during the Incident Response Period.

2. Formal Notice.

No later than three (3) Business Days after discovery of an Incident, or when Clinic should have reasonably discovered the Incident, Clinic must provide written formal notification to DSHS using the Potential Privacy/Security Incident Form which is available on the HHSC website at <https://hhsconnection.hhs.texas.gov/rights-responsibilities/office-chief-counsel/privacy>. The formal notification must include all available information about the Incident, and Clinic's investigation of the Incident.

1.6 Clinic Investigation, Response, and Mitigation.

Clinic must fully investigate and mitigate, to the extent practicable and as soon as possible or as indicated below, any Incident. At a minimum, Clinic will:

- (a) Immediately commence a full and complete investigation.
- (b) Cooperate fully with DSHS in its response to the Incident.
- (c) Complete or participate in an initial risk assessment.

- (d) Provide a final risk assessment.
- (e) Submit proposed corrective actions to DSHS for review and approval.
- (f) Commit necessary and appropriate staff and resources to expeditiously respond.
- (g) Report to DSHS as required by DSHS and all applicable federal and state laws for Incident response purposes and for purposes of DSHS's compliance with report and notification requirements, to the satisfaction of DSHS.
- (h) Fully cooperate with DSHS to respond to inquiries and/or proceedings by federal and state authorities about the Incident.
- (i) Fully cooperate with DSHS's efforts to seek appropriate injunctive relief or to otherwise prevent or curtail such Incidents.
- (j) Recover, or assure destruction of, any Confidential Information impermissibly disclosed during or as a result of the Incident; and
- (k) Provide DSHS with a final report on the Incident explaining the Incident's resolution.

1.7 Breach Notification to Individuals and Reporting to Authorities.

- (a) In addition to the notices required in this section, Clinic must comply with all applicable legal and regulatory requirements in the time, manner, and content of any notification to individuals, regulators, or third-parties, or any notice required by other state or federal authorities, including without limitation, notifications required in Title 45 CFR Chapter A, Subchapter C Part 164, Subpart D Notification in the Case of Breach of Unsecured Protected Health Information and Texas Business and Commerce Code, Title 11, Subtitle B, Chapter 521, Section 521.053(b), Notification Required Following Breach of Security of Computerized Data, or as specified by DSHS following an Incident.
- (b) The Clinic must assure that the time, manner, and content of any Breach notification required by this section meets all federal and state regulatory requirements.
- (c) Breach notice letters must be in Clinic's name and on Clinic's letterhead and must contain contact information to obtain additional information, including the name and title of Clinic's representative, an email address, and a toll-free telephone number.
- (d) Clinic must provide DSHS with copies of all distributed communications related to the Breach notification at the same time Clinic distributes the communications.
- (e) Clinic must demonstrate to the satisfaction of DSHS that any Breach notification required by applicable law was timely made. If there are delays outside of Clinic's control, Clinic must provide written documentation to DSHS of the reasons for the delay.