

# Telepharmacy Pilot Project Proposal

1. **Scope** - Mission of pilot
2. **Proposed Locations** - Locations to be included in the Pilot project
3. **Background** - *A brief description, narrative, or summary of the new process or procedure for which approval is being sought.*
4. **Waivers** - A listing of the laws or regulations for which waivers are being requested through approval of this pilot program.
5. **Objectives** - An explanation as to the rationale and objectives for the program
6. **Outcomes** - A summary of outcomes which will be measured, method for measuring, and timelines for measurements and reporting to the Board
7. **Security** - Any measures which will be taken to ensure security of drug product and Confidential/HIPAA information in the execution of the pilot program.
8. **Disclosure** - Disclosure of any financial interests, if applicable.
9. **Appendix** - Any additional supporting information, such as technical or other descriptive literature describing equipment or a process, or information from another state where this process or procedure has been tested.
  - a. See policies & procedures in Exhibit A
  - b. See supporting studies & resources in Exhibit B
  - c. See telepharmacy application information in Exhibit C
  - d. See letters of support in Exhibit D
  - e. See description of Prescription Shop in Exhibit E
  - f. See description of Self Inspection Report in Exhibit F
  - g. See proposed Telepharmacy Rules in Exhibit G
  - h. See proposed pharmacy layout in Exhibit H

# Texas Administrative Code

[Next  
Rule>>](#)

[TITLE 22](#)  
[PART 15](#)  
[CHAPTER 291](#)  
[SUBCHAPTER](#)  
[A](#)

EXAMINING BOARDS  
TEXAS STATE BOARD OF PHARMACY  
PHARMACIES  
ALL CLASSES OF PHARMACIES

RULE §291.23 Pilot or Demonstration Research Projects for Innovative  
Applications in the Practice of Pharmacy

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(a) Purpose. The purpose of this section is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy as authorized by §554.011 of the Texas Pharmacy Act (Chapters 551- 566 and 568 - 569, Texas Occupations Code). In reviewing projects, the board will only consider projects that expand pharmaceutical care services which contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage.

(b) Scope of pilot or demonstration research projects and the board's approval of such projects.

(1) Pilot or demonstration research projects may not:

(A) expand the definition of the practice of pharmacy as provided in the Act; or  
(B) include therapeutic substitution or substitution of medical devices used in patient care.

(2) The board's approval of pilot or demonstration research projects may include the granting of an exception to the rules adopted under the Texas Pharmacy Act, but may not include an exception from any law relating to the practice of pharmacy. Such exception to the rules shall be for a specified period of time and such period may not exceed 18 months.

(3) The board may extend the time an exception to a rule is granted as necessary for the board to adopt an amendment or modification of the rule.

(c) Procedures for applying for approval of pilot or demonstration research projects. A person who wishes the board to consider approval of a pilot or demonstration research project shall submit to the board a petition for approval which contains at least the following information:

(1) name, address, telephone number, and pharmacist's license number of the pharmacist responsible for overseeing the project;

(2) specific location and, if a pharmacy, the pharmacy license number where the proposed pilot or demonstration project will be conducted;

(3) a detailed summary of the proposed pilot or demonstration project which includes:

(A) the goals, hypothesis, and/or objectives of the proposed project;

(B) a full explanation of the project and how it will be conducted;

(C) the time frame for the project including the proposed start date and length of study. Such time frame may not exceed 18 months;

(D) background information and/or literature review to support the proposal;

(E) the rule(s) that will have to be waived in order to complete the project and a request to waive the rule(s);

(F) procedures to be used during the project to ensure that the public's health and safety are not compromised as a result of the rule waiver.

(d) Review and approval or denial of the proposed projects.

(1) On receipt of a petition for approval of a pilot or demonstration research project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration for any reason, staff shall return the petition with a letter of explanation. Such review shall be completed within 30 working days of receipt of the petition.

(2) Once board staff has determined that the petition is complete and appropriate, a task force composed of board staff, at least one board member and, if deemed necessary, resource personnel appointed by the board president, shall review the petition and make a written recommendation to the board regarding approval. Such recommendation shall be presented to the board at the next regularly scheduled meeting of the board that occurs at least three weeks after completion of the review and written recommendation.

(3) A copy of the recommendation shall be provided to the petitioner and the board at least two weeks prior to the board meeting.

(4) Both the petitioner and a representative of the task force shall be given equal

time for presentations to the board.

(5) Upon hearing the presentations, the board shall either approve or deny the petition. If the board approves the petition, the approval:

(A) shall be specific for that project and for a specific time period; and

(B) may include conditions or qualifications, if deemed appropriate by the board.

(6) The board or its representatives shall be allowed to inspect and review the project documentation and site at any time during the review process and after the project is approved.

(e) Presentation of results to the board.

(1) The pharmacist responsible for overseeing the project shall forward to the board a summary of the results of the project and conclusions drawn from the results within three months after completion of the project.

(2) A task force composed of board staff, at least one board member and, if deemed necessary, resource personnel appointed by the board president, shall review the results and make written recommendations to the board regarding the results of the project.

(3) The board will receive the report of the task force at the next regularly scheduled meeting of the board that occurs at least three weeks after the task force has completed its review and issued written recommendations.

(4) A copy of the task force recommendation shall be provided to the petitioner and the board at least two weeks prior to the board meeting.

(5) Both the petitioner and a representative of the task force shall be given equal time for presentations to the board.

**Scope** - Modify current regulation 291.121(c) to eliminate some of the barriers to allow the provision of pharmacy services through the use of a telepharmacy system. This will allow our pharmacy to expand pharmaceutical care services which contribute to positive patient outcomes.

**Proposed Location -**

**Telepharmacy #1**

**Pharmacist in-charge:** Micah Pratt

**Pharmacy Address:** 524 8th St, Olton, TX 79064

**Telephone Number:** TBD

**Pharmacy License Number:** TBD

**Description of location:** Olton Clinic is a rural health clinic who recently was purchased by Lamb Healthcare Center (county own hospital - Lamb County)

**Closest Pharmacy** - Prescription shop 30 miles, or pharmacies in Plainview,tx 30 miles

**Telepharmacy #2**

**Pharmacist in-charge:** Micah Pratt

**Proposed Pharmacy Address:** 201 E Grant Ave, Morton, TX 79346 (Cochran Memorial Hospital or Morton rural health clinic)

**Telephone Number:** TBD

**Pharmacy License Number:** TBD

**Description of location:** This location use to have a pharmacy but no more. They do have a hospital and clinic. They are considered a rural indigent county like Lamb County

**Closest Pharmacy** - 37 miles from Prescription Shop and 28 miles from Levelland, Tx

**Host Pharmacy -**

**Pharmacist in-charge:** Micah Pratt

**Pharmacy Address:** 1506 A South Sunset, Littlefield, Tx 79339

**Telephone Number:** 806-385-4491

**Pharmacy License Number:** 27958

## **Background**

In Texas, there are 149 communities (177,598 residents) that have to travel 10 miles or more to the nearest pharmacy, and according to the US Department of Health and Human Services, 1,146 areas that have a shortage of health care professionals.. Access to a pharmacist has been shown to be highly effective in improving outcomes<sup>1</sup>, and the closing of rural pharmacies is having a devastating effect on these critical services for Texas residents living in rural areas.

Seventy-seven percent of rural counties in the United States are designated as primary care health professional shortage areas. Residents in these areas, typically elderly, have to travel long distances to pick up their prescription medications and see their pharmacist. These patients already face a number of challenges related to healthcare services close to home, including weather, geography, and social barriers. Patients see their pharmacist more often than any other healthcare professional<sup>2</sup>, so making them more readily available should be a top priority.

Studies have been done to evaluate factors that contribute to decreased medication adherence; lack of access to healthcare services and prescribers has been listed as a top cause. Additionally, patients have described difficulties in receiving medication refills often leading to gaps in therapy when access to a healthcare provider is limited.<sup>3</sup> Medication nonadherence contributes to increased costs to taxpayers and health systems due to poor outcomes, hospital readmissions, and unnecessary doctor visits. By eliminating the barrier to accessible pharmacy services and increasing rural access to a pharmacist, there is an opportunity to decrease state healthcare costs, while improving patient outcomes. Additionally, keeping funds from health care spending in a community increases the feasibility of local health clinic services and allows the local economy to flourish. When a community loses their pharmacy, these funds disperse (some of which leaves the state) and there is increased risk of losing local health provider(s). Local pharmacies and clinics are crucial in maintaining the health of citizens in smaller communities.

In response to established rules by the Texas Board of Pharmacy for pharmacy pilot or demonstration research projects (291.23), the **purpose of this application is to study the effects of a telepharmacy on patient/community satisfaction and pharmacist services. Telepharmacy is using technology to enable community pharmacists to deliver patient care services across the state of Texas.** The telepharmacy model has allowed for patient access to a pharmacist services in areas not able to support a pharmacy under the traditional model. This project proposes to set a future potential study of the impact which an easily accessible pharmacy has on patient levels of adherence, and in turn its potential to increase outcomes from therapy.

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<sup>1</sup> Improving Patient and Health System Outcomes through Advanced Pharmacy Practice; A Report to the U.S. Surgeon General 2011. Rev: 5/2011, 8/2011, 12/2011. US Public Health Service.

[http://www.accp.com/docs/positions/misc/improving\\_patient\\_and\\_health\\_system\\_outcomes.pdf](http://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf)

<sup>2</sup> George E. MacKinnon III, PhD, RPh, FASHP. *Recognizing pharmacists as healthcare providers—a solution for the Patient Protection and Affordable Care Act roll-out.* August 13, 2013.

<sup>3</sup> Kelly M, McCarthy S, Sahn LJ. *Knowledge, attitudes and beliefs of patients and carers regarding medication adherence: a review of qualitative literature.* Eur J Clin Pharmacol. 2014 Dec;70(12):1423-31. doi: 10.1007/s00228-014-1761-3. Epub 2014 Oct 4. Review. PubMed PMID: 25277162.

## Waivers Required

Although Texas has had rules allowing the practice of remote pharmacy services using a telepharmacy system since 2007, very few locations are utilizing the rule to provide these services. Since 2007, advancements in technology and decreased cost in technology. This should allow for more access to these services, however some of the provisions of the current rule do create some barriers to initiating this type of service.

Regulation	Purpose	Passage
291.121(c)(4)(C)(vi)	The provider pharmacy shall have procedures that specify drugs may only be delivered to the remote site by the provider pharmacy.	As described below, the telepharmacy model we plan to implement uses a pharmacy technician at the telepharmacy facility to fill the prescriptions. The technician is supervised remotely by a pharmacist who verifies the dispensing process and provides patient counseling. This model requires the ordering and storage of bulk pharmaceuticals purchased from a wholesaler at the telepharmacy site.
291.121(D)(i)	Drugs shall only be dispensed at the remote site through a telepharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in the manner authorized by 291.34(b).	This proposed project would rely on a scanned copy of the original prescription. Waiting for the provider pharmacy to obtain an original prescription would not allow patients to pick up their prescriptions while they are at the facility
291.121(D)(ii)	Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use containers that are: (l) Prepackaged in suitable containers at the provider pharmacy and appropriately labeled as specified in 291.33(c)(6); or In original manufacturer's containers.	As described below, the telepharmacy model we plan to implement uses a pharmacy technician at the telepharmacy facility to fill the prescriptions. The technician is supervised remotely by a pharmacist who verifies the dispensing process and provides patient counseling. Under this model, restricting the products to unit-of-use containers does not work as the pharmacy technician fills the prescriptions from bulk containers just as they would at the provider pharmacy

## Objectives

In response to the escalation of rural pharmacy closures across the United States, North Dakota State University conducted a federally-funded study from 2002-2008 to look at the safety of telepharmacy in providing pharmacy services to areas where it was no longer economically feasible to have a pharmacy. They found that telepharmacy is a safe and effective solution to this problem. In fact, the rate of dispensing errors was less than 1 percent, compared to the national average of ~2 percent.<sup>4</sup>

It is widely accepted that telepharmacy has a place in the future of pharmacy. The goal of this pilot project is to collect and analyze data to help determine what role it should play in Texas. This information will enable with additional research and knowledge to guide their decision-making process on telepharmacy while also providing access to pharmacy services in the selected sites.

Telepharmacy is defined by NABP as “The provision of pharmacy care through the use of telecommunications to patients at a distance.” The practice that will be used in this pilot is the remote dispensing model, which follows these steps:

1. The prescription arrives at the pharmacy through normal channels
2. Data entry by the pharmacy technician takes place in the pharmacy management system installed on site.
3. Once the prescription is ready to be filled, a label will be printed and the pharmacy technician will begin the filling process.
4. The technician will utilize store-and-forward technology to capture images of the hardcopy prescription, stock bottle (including lot and expiration), prescription label, and physical drug.
5. All this information, including the prescription information from the PMS, is forwarded to the Verification Site for the pharmacist to approve.
6. Once approved, the prescription will be prepared and placed in will-call to await the patient.
7. When the patient arrives to pick up their prescription, they will be counseled by a pharmacist through a live interactive HD video connection.

The study will take place over a 18-month period. Following is a brief description of what the practice will look like:

- The pharmacist will be physically located at the Verification Site and will be readily available to the technicians and patients at the Telepharmacy Sites at all times.

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<sup>4</sup> The North Dakota Experience: Achieving High-Performance Health Care Through Rural Innovation And Cooperation. May 2008

Pharmacists will continue to have ultimate authority over the dispensing process in this model.

- The prescription department is staffed by certified pharmacy technicians. The pharmacist-technician relationship will remain important as the pharmacist will utilize new technologies and the leadership of head technicians to maintain safety protocols for patients.
- All pharmacy technicians working at the telepharmacy site will be required to obtain and maintain current Pharmacy Technician certification. They will also be required to have the following:
  - Must adhere to all rules and regulations set forth by the Texas Board of Pharmacy
- Technicians will not perform any roles requiring the professional judgment of the pharmacist as described in Texas Board of Pharmacy Rules
- Prescriptions will be filled according to all the standard operating procedures of a pharmacy. As the technician is filling the prescription, they will capture images of all steps to provide to the verifying pharmacist. These images, along with any other documentation, will be sent to the pharmacist to verify the dispensing and clinical accuracy of the prescription. The prescription must be verified by the pharmacist before it is able to be dispensed to the patient.
- All of the information about the prescriptions filled at the Telepharmacy will be recorded and maintained in secure records with redundant backups for 10 years. This audit trail is readily available for any prescription processed at the Telepharmacy.
- A supervisor will travel to the Telepharmacy site at least once weekly during the first month of operation to ensure policies and procedures are being followed.
- A pharmacist will travel to the Telepharmacy at least once monthly to perform a self-inspection (form attached.) While the pharmacist is on site, (s)he will verify all policies and procedures are being properly followed. When a pharmacist is not available on site, all verification and counseling will be provided by an Texas licensed pharmacist.
- Medication counseling and responding to patient questions will be completed through a secure video connection in a private area when the medications are dispensed to the patient. Pharmacists will always be available for consultation with patients, prescribers, and other care providers through a secure video connection

Each location will utilize a Texas licensed pharmacist at the Verification Site to remotely verify prescriptions and counsel patients. This site will have a pharmacist on-site visit at least once monthly.

Trained Pharmacy Technicians will be hired to work at each telepharmacy location. Each location will have 1-2 technicians staffed daily, with an additional technician on call as needed. Every effort will be made to hire technicians who reside in or around the community for ease of commute and connection to the community.



## Outcomes

### Project Components

There is one component of our proposed project. Details are contained in the following pages.

#	Component	Description	Partners
1	Telepharmacy pilot	Infrastructure of telepharmacies representing a use case across the state	<ul style="list-style-type: none"><li>• Host Site - Prescription Shop</li><li>• Remote Site - Olton, TX, Morton, TX</li><li>• TelePharm</li></ul>

### Project Timeline

This pilot project is planned to last 24 months from the approval date:

Dates	Project Activities
Months 1-6	<ul style="list-style-type: none"><li>• Begin work on telepharmacy locations</li><li>• Collect baseline data for all sites</li></ul>
Month 6	<ul style="list-style-type: none"><li>• Open telepharmacy sites</li><li>• Begin collecting data on telepharmacy locations</li></ul>
Months 6-16	<ul style="list-style-type: none"><li>• Collect any necessary comparative data</li><li>• Quarterly data reporting to the board</li></ul>
Months 16-18	<ul style="list-style-type: none"><li>• Data analysis and report writing</li></ul>
Month 18	<ul style="list-style-type: none"><li>• Pilot project authority expires unless renewed</li></ul>

### Data Reporting

Data will be collected at each of the telepharmacy sites and reported to the Texas Board of Pharmacy throughout the duration of the pilot project:

Data to Report	Description
Prescription interpretation errors	Errors which are made during filling process but caught before being dispensed to the patient
Medication dispensing errors	Any medication errors that reach a patient

## **METHODS**

### ***Sites***

This study will use telepharmacy locations in Olton and Morton, Texas, and will utilize TelePharm's software platform for all telepharmacy activities and will commit to participating in all phases of the project, from design to final assessments. Agreements will be executed with the Telepharmacy Site and with the Verification Site providing the remote pharmacist verification, counseling, and other services for the telepharmacy.

### ***Documentation by Sites***

Each location agrees to document all required error reporting forms, counseling activities, and pharmacist daily activity logs. Pharmacies will agree to disclose all documentation on dispensing activities, error rates and Continuous Quality Improvement (CQI) data, including descriptions of any error events and how these were resolved.

### ***Research Aims***

#### **Aim 1: Document and investigate any dispensing errors in study telepharmacies.**

For each telepharmacy, a pharmacist will be on site at least once monthly and will re-verify a random sample of either 5% or 20 prescriptions, whichever is greater, waiting to be picked up. Also, remote pharmacists and local technicians will be tasked with completing error reporting forms should errors be identified.

If the error rate is substantially greater than the comparator pharmacy, a continuous quality improvement process led by the parent pharmacy will be conducted. This process may include providing additional training to technician staff or an examination of processes and communication between the pharmacist and the telepharmacy technical staff.

Each telepharmacy will be compared to a control pharmacy serving a similar community. They will also engage in re-verifying a sample of prescriptions using the same schedule as the telepharmacy. The comparator pharmacy may or may not be the same as the Verification Site pharmacy. Research consultants will compare safety of telepharmacies by assessing the nature and rate of errors uncovered and provide quarterly safety reports to the Board of Pharmacy.

# Security

## **Security of drug product**

Technology utilized to implement telepharmacy will have the following drug security features:

- Photo documentation of every step in filling process
- Bar code scans
- Hard halt checks to ensure no dispensing before approval
- Stock drug data and images, provided through Medispan
- All data, including audit logs, securely stored for seven years
- All user actions logged with timestamp

## **HIPAA Information**

Technology utilized for the pilot will enable robust HIPAA privacy and security compliance. On-site TeleHealth HIPAA training will be conducted prior to opening by telepharmacy application provider for all remote and verification site personnel. All ePHI information is encrypted in transfer and stored with AES-256-bit encryption at rest in on dedicated infrastructure. Encrypted backups are taken nightly, backups are stored in geographically redundant locations within the US. Access given and actions taken against ePHI, or in any context, are logged and monitored with identifying information relating to the authorized actor.

## Disclosure

Micah Pratt will own the telepharmacy sites, thus assuming all financial risk and reward.

## Appendix

# Exhibit A: Telepharmacy Policies & Procedures

## Prescription Shop Telepharmacy Policy & Procedures

### I. Managing Pharmacy Contract

- A. Morton/Olton Pharmacy (Telepharmacy) shall be contracted with Prescription Shop (Managing Pharmacy) to provide pharmacist verification services. A copy of said contract will be included with this document.

### II. Facility & Licensing

- A. The Telepharmacy will be located at 524 8th St, Olton, TX 79064 and 201 E Grant Ave, Morton, TX 79346 . It is designed to meet all requirements of a traditional retail pharmacy as described by the Texas Board of Pharmacy. The Managing Pharmacy will ensure that all Texas Board of Pharmacy telepharmacy rules & regulations are followed while operating as a telepharmacy.
- B. The prescription department will be secure and inaccessible from the small retail space available. The store will be monitored via video surveillance and armed with security alarms.
- C. The pharmacy will maintain the following licenses: General Pharmacy License, DEA Registration, and Controlled Substance Registration.
- D. Consultation Area/Register - there will be an area which will be partitioned such that it is confidential and private during consultations.
- E. Patient Notification: there will be a large sign on entry door to facility and on pharmacy drop-off window, informing patients that:
  1. This is a remote dispensing site supervised by a pharmacist located in the Managing Pharmacy
  2. The pharmacist is required to speak with patient over an audiovisual link for each new prescription delivered at the remote site.

### III. Personnel

- A. Technicians: There will be one Pharmacy Technicians available to work at the Telepharmacy to begin, eventually increasing to two as business grows;
- B. Pharmacists: The following pharmacists will be providing services to the Telepharmacy: Micah Pratt (pic), Kelly Pratt (staff full time), Beth West (staff part time), James Dooley (relief)
- C. A log book will be kept daily for the pharmacist who is designated to verify prescriptions and for the CPhT working that day to sign, list license number, and initial.

### IV. Duties of Pharmacist - to be performed at Managing Pharmacy

- A. Upon open every day, verify functionality of live video link to the remote telepharmacy.
- B. Receive oral prescriptions from physician or physician's agent for dispensing to a patient at the Telepharmacy. All phones will be linked with the managing pharmacy and only refills will be taken at the Telepharmacy, all new orders must be received directly by the pharmacist.

- C. Verify accuracy of prescription data entry, via digital review, in the same manner as is currently done in traditional retail settings.
- D. Ensure functionality of telepharmacy system for verification and consulting purposes.
- E. Perform final verification per digital image comparison of the product used to fill the prescription vs. a file photo of the product that was to be dispensed per the pharmacy software.
- F. Verify image of label produced via pharmacy software matches that which the technician has procured through the telepharmacy software via barcode.
- G. Counseling the patient or patient's caregiver will be done in a counseling area readily accessible to patients and be designed to maintain the confidentiality and privacy of a patient's conversation with the pharmacist.
- H. On a monthly basis inspect Telepharmacy and generate a report for reviewing areas where improvements can be made and making changes to policy to enact those improvements. Then archiving these reports for no less than a 12 month period, so as they are easily retrievable.
- I. At least monthly the pharmacist must visit site to review narcotic counts, and operational pharmacy procedures, assuring a quality level of practice
- J. Regularly review and document Quality Assurance events.
- K. Verify competency and continually train technicians to the level needed to perform duties
- L. Ensure and maintain contract between Managing Pharmacy and Telepharmacy (although the two are owned by the same entity.)

V. **Duties of the Technician**

- A. Upon open every day, verify functionality of audio/visual link with pharmacist through the telepharmacy software system.
- B. Receive telephone orders for refills only, not new prescriptions.
- C. Process both new and refill prescriptions sent electronically from patients and doctors through the pharmacy software system to produce a label.
- D. Upon procurement of label, begin filling process
- E. Via barcode verification, ensure that the label and drug description produced via the pharmacy software system match that of the stock bottle obtained from pharmacy inventory.
- F. Count the prescribed quantity of product ordered by physician and approved by pharmacist.
- G. Place the label partially on the prescription bottle, such that a full image of the label can be procured.
- H. Technician completes the filling process by taking images of the prescription in the telepharmacy software
- I. Await verification/release by pharmacist that product and label are correctly matched, and that DUR has taken place. While pending verification, the prescription is to be kept in a separate bin.
- J. Once the prescription is approved, the technician prepares the product for the patient.
  - 1. Technician notifies the patient of the requirement to speak with a pharmacist
  - 2. Technician assists patients in using software to adequately receive counselling
  - 3. Technician completes sale using the POS system
- K. Daily clean and sanitize counters, counting trays, vacuum floors, and remove trash
- L. Technician will place order from software system at days end to the wholesaler
- M. Generate daily reports necessary
- N. Receive and file daily inventory reports

VI. **Policy and Procedures of Operation of Telepharmacy**

- A. All policies and procedures shall be in writing and shall be maintained in the Telepharmacy and the Managing Pharmacy. These shall be reviewed annually and revised as necessary, and such review shall be documented. Any changes, deletions, or amendments shall be signed by the pharmacist-in-charge and dated when approved or changed. This manual shall be easily retrievable and available to the Board upon request.
- B. Policies & Procedures
  - 1. Equipment
    - a) Computer RX- pharmacy software vendor
    - b) Computer RX - NDC Verification at fill level
    - c) Computer RX - Point-of-Sale software vendor
    - d) TelePharm software and related equipment including, but not limited to: Imaging camera, consultation monitor and counselling station
  - 2. Security
    - a) The pharmacy itself will be secured via lock and key. Only registered technicians and pharmacists will be permitted to open and close the pharmacy and have a key.
    - b) Texas Homeland Security and Sound security system will be installed, requiring unique ID
    - c) The pharmacy will be securely locked when not open
    - d) The pharmacy software system will be secured via VPN and Password
    - e) The technician will set alarm, and lock door upon exit every evening
    - f) Telepharmacy software has its own built in security and meets all HIPAA requirements
  - 3. Storage of Medications
    - a) Telepharmacy will be stocked as any typical retail location with medications on shelving by alphabetical order, this area will be secure from public.
    - b) CIII-IV substances will be dispersed throughout the stock of noncontrolled substances in a manner so as to obstruct the theft or diversion of the controlled substances
    - c) CII narcotics will be kept in a securely locked, substantially constructed cabinet
    - d) Refrigerator will be kept in pharmacy department for medications only. The temperature will be logged and maintained between 36 and 42 degrees.
    - e) Outdated medications will be removed from the system and tracked until returned to manufacturer for credit.
  - 4. Operations
    - a) The Telepharmacy shall not open before the Pharmacist arrives and is on duty at Managing Pharmacy
    - b) Technician opens Telepharmacy daily and sign log book with day and time of opening
    - c) Pharmacist verifies narcotic order from previous day
    - d) Pharmacist / Technician will verify cleanliness of Telepharmacy
    - e) Technician will begin processing prescriptions
      - (1) Technician prints prescription labels for refills and new prescriptions that have been received via the automated phone system, or other refill request method.

- (2) Technician scans prescription label in the telepharmacy software, procure stock bottle and scan it. These scans must match in order to proceed. This scan also triggers the DUR review for the pharmacist.
- (3) Technician takes an image of the original hardcopy prescription. If this is a refill, the software will pull this image from its database.
- (4) Technician takes an image of the printed prescription label.
- (5) Technician takes an image of the actual drug product used to fill the prescription. To complete, they place the drug in the lid of the prescription bottle, ensuring this is the only bottle the product could have come from.
- (6) Once all images have been taken, the technician submits the prescription to pharmacist for review.
- (7) Pharmacist receives this information and verifies it matches stock photo and data previously input, which is still on the screen. All this data is on one large monitor in quadrants for easy verification.
- (8) After pharmacist approval, the software releases prescription to be sent to an Approved Queue.
- (9) Technician at Telepharmacy may now package medication to be sold.
- (10) At the point of sale, the technician informs patient of pharmacist duty to consult. The patient is then directed to the secure consultation area where they are connected through the a live audio/visual link for counselling purposes.
- (11) Pharmacist counsels patient as needed regarding medication for all new prescriptions, and possibly for refills as well.
- (12) As time permits, the technician enters received inventory from wholesaler into system and places on shelves.

5. Returns

- a) **NO** medications will be accepted as returns.

6. Labeling

- a) A custom label will be used which will include:
  - (1) Name, address, and phone of both sites
  - (2) A unique prescription number for the Telepharmacy
  - (3) Name of patient
  - (4) Name of the prescriber
  - (5) Date dispensed
  - (6) Directions for use, plus precautions
  - (7) Name/Strength/Quantity of medication dispensed
  - (8) Initials of pharmacist who verified information at Managing Pharmacy and technician at Telepharmacy who filled the prescription
  - (9) Both the brand and generic names of the medication

VII. **Quality Assurance**

- A. A log shall be kept of all errors and a report generated quarterly
  1. If no errors in a quarter, it shall be duly noted, not omitted.
  2. Errors shall be first identified by which step they occurred
    - a) Telephone incorrect transcription - pharmacist error

- b) Technician data input error
  - c) Pharmacist error in checking data input and DUR or failure to do so
  - d) Technician error in procuring product
  - e) Pharmacist error in final verification of product
  - f) Technician/Pharmacist error in failure to consult properly
  - g) Other
3. Types of Errors
- a) Data Entry Error
  - b) Incorrect Drug, Dose, Quantity, or Dosage Form
  - c) Incorrect instructions for use
  - d) Incorrect Patient Name
  - e) Other
- B. Upon finding errors, a plan of correction shall be designed and implemented, then discussed with staff, so that all understand the correction, then sign the QA correction form

VIII. **Drug Inventory**

- A. It is our intent to work closely with the clinic to develop a formulary that is limited in scope however, we do intend to fully stock the pharmacy as any other retail location.
- B. There will be no transfer of drugs to companies outside of the managing pharmacy
- C. Drugs will be delivered directly to the Telepharmacy from the courier assigned by the wholesaler
- D. These drugs will only be accepted when a technician or pharmacist is on site to receive them.

IX. **Pharmacist Inspection**

- A. General
  - 1. The pharmacy's license is current and posted.
  - 2. All required current licenses are posted in a conspicuous location of the pharmacy.
  - 3. The PIC has personally reviewed the licenses of all registrants and determined that they are current.
  - 4. Registrants wear proper clean attire and have proper name tags and designations.
  - 5. All pharmacy technicians have completed the required training set forth by the state.
  - 6. Meet all the requirements when there is a change in Pharmacist-in-Charge including but limited to proper notification to the Department.
  - 7. The schedule during which pharmacy services are provided is conspicuously displayed.
  - 8. No remote site may be open when the home pharmacy is closed, unless a pharmacist employed or contracted by the home pharmacy, or by a pharmacy contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section.
- B. Security
  - 1. Security provisions are provided for all drugs and devices within the pharmacy.
  - 2. Refrigerators for the exclusive use of medications are clean, defrosted and in working order maintaining proper temperature.
  - 3. Pharmacy is clean and sanitary.
  - 4. Food and/or beverages are kept in designated areas away from dispensing activities and stored in refrigerators not used for medications.
  - 5. The pharmacy area and all store rooms shall be well-lighted and properly ventilated.

C. Dispensing and Record Keeping

1. These sites must be staffed with a certified pharmacy technician who has the knowledge necessary to use computer audio/video link for dispensing and consultation to occur. Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.
2. Recordkeeping shall be conducted by the pharmacist (time/date) when dispensing and offer to counsel occurred.
3. The facility shall have a private or semi-private area designated for patient consultation exclusive of any waiting area.
4. Counseling for all new and refill prescriptions must be done by a pharmacist via audio and video link.
5. Controlled drug prescriptions and records must be properly filed and maintained.
6. Annual inventory of controlled substances are properly recorded, dated and signed.
7. Any theft or significant loss of controlled substances are immediately filed using the DEA form 106 with the Drug Enforcement Administration, with a copy to the Division of Professional Regulation directed to the attention of the Drug Compliance investigator.
8. All controlled substances kept in inventory by the remote telepharmacy shall be listed on a perpetual inventory log, which shall be updated upon the dispensing of each controlled substance prescription or other disposition.
9. Pharmacist's and technician's initials are recorded on each filled prescription.
10. Pharmacist can accurately compare the stock bottle, drug dispensed and drug strength, and check entire label after it has been affixed to the prescription container prior to being dispensed.

## Exhibit B: Supporting Studies & Resources

### Rural Independent Pharmacy Studies

#### One Year In: Sole Community Rural Independent Pharmacies and Medicare Part D

- Concerned about their ability to sell their stores upon retirement
- Decreasing profit margin might make the idea of owning an independent pharmacy less enticing to potential buyers
- One pharmacist stated that he believes owning a rural independent pharmacy is no longer financially viable and that “he would discourage anybody from going into the field.”
- One is considering trying to sell both his physical location and book of business to a chain, while the other is considering selling only her book of business to the nearest chain located 25 miles away (physical location would close). Both pharmacists were very concerned that these alternatives would be detrimental to their customers’ well-being.  
<http://www.shepscenter.unc.edu/rural/pubs/report/FR92.pdf>

#### The Key Role of Sole Community Pharmacists in Their Local Healthcare Delivery Systems

- Most sole community pharmacists (83%) provided important services for other health care providers and facilities in their communities.
- Almost all (92%) of the communities served by a single independent retail pharmacy are also served by at least one other type of inpatient or outpatient health care organization.
- Almost half of all pharmacists (42%) offered additional clinical and educational services to community residents including blood pressure checks, screening for cholesterol and osteoporosis, glucose screening and diabetes counseling, tobacco cessation programs, and immunizations.  
<https://www.public-health.uiowa.edu/rupri/publications/policybriefs/2009/KeyRoleofSoleCommPharms.pdf>

### North Dakota

- In 2001, North Dakota was the first U.S. state to establish Pilot Telepharmacy Rules in response to increasing rural community pharmacy closures.
- September 2002, received a federal grant from the Department of Health and Human Services to implement a statewide telepharmacy program.
- June 2003, due to enormous success of the pilot project the North Dakota State Board of Pharmacy established permanent rules allowing for the utilization of telepharmacy.
- As of 2012, 53 retail pharmacies were involved with the ND Telepharmacy Project
  - 73% of North Dakota’s counties have access to a pharmacy within county lines
  - Approximately 80,000 rural citizen have had pharmacy services restored, retained, or established
  - Added an estimated \$26.5M in economic development to the local rural economy

- 60+ new rural community jobs added

## North Dakota Articles

- <https://www.ndsu.edu/telepharmacy/history/>
- [https://www.ndsu.edu/fileadmin/telepharmacy/Rural\\_Monitor-pharmacies\\_struggle\\_-\\_Copy.pdf](https://www.ndsu.edu/fileadmin/telepharmacy/Rural_Monitor-pharmacies_struggle_-_Copy.pdf)
- [https://www.ndsu.edu/fileadmin/telepharmacy/Alumni\\_News2009Telepharmacy\\_Project\\_models\\_coop.pdf](https://www.ndsu.edu/fileadmin/telepharmacy/Alumni_News2009Telepharmacy_Project_models_coop.pdf)
- <https://www.ndsu.edu/fileadmin/telepharmacy/RuralElectricMagazineTelepharmacyFeature.pdf>

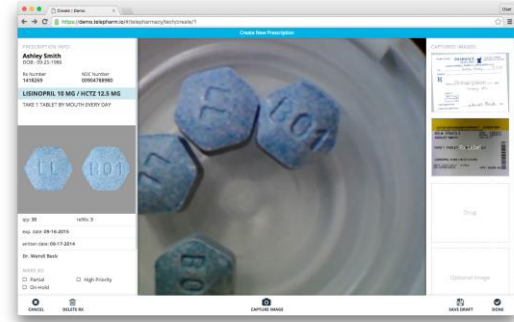
## Exhibit C: Telepharmacy application information

### TELEPHARMACY APPLICATION FEATURES

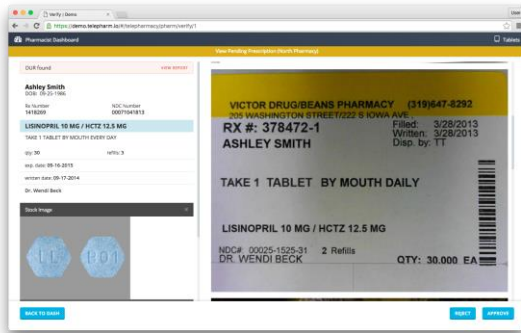
- Patented Telepharmacy multi-site prescription workflow
  - Barcode driven multi-site prescription workflow with built-in hard halts
  - Queue based prescription workflow management
- HIPAA and HI-TECH compliant data storage up to 10 years
- Readily available audit logs that includes:
  - User ID, timestamp, prescription data and user action
- Military-grade security including SSL 256-bit AES and two-step user authentication
  - User identification for each prescription submission and verification
- Two-way interfacing with 27 Pharmacy Management Systems
- Secure audio-visual link with instant connection to all stores and pharmacists
- Any-to-any architecture for multi-site pharmacist availability
- Pharmacist authorization of will-call prescriptions
- Detailed patient education prior to counseling with pharmacist
- 24-month history of 99.9% application uptime



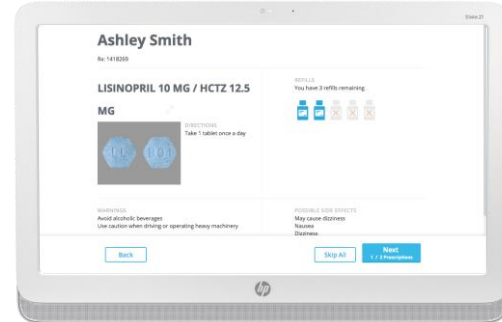
1. Technician enters the prescription into the Pharmacy Management System



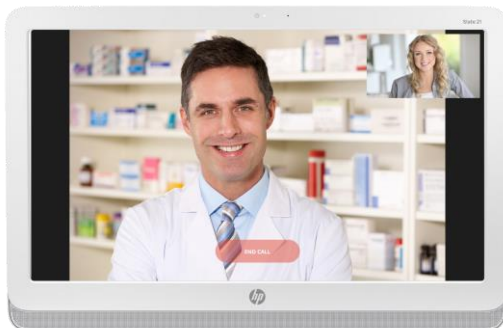
2. Technician images the prescription as it's being filled. User identification required on submittal.



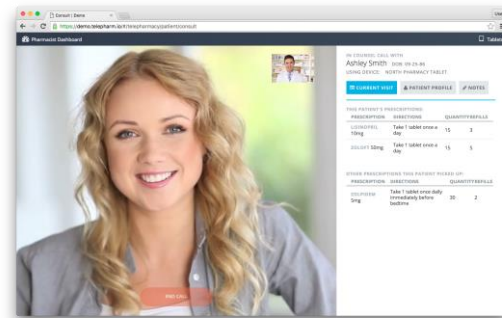
3. Pharmacist verifies the prescription through the store-and-forward images. User identification required to approve.



4. Patient arrives to pick up prescription, reviews prescription side effects and warnings



5. Patient is counseled by the pharmacist via a live and interactive HD video



6. Pharmacist counsels patient and has prescription & patient information available for review

Exhibit D:



## City of Olton

900 Main P.O. Box 1087

Olton, Texas 79064

Phone: 806-285-2611 Fax: 806-285-2139

January 16, 2016

Texas Board of Pharmacy

To whom it may concern:

This letter is from the Mayor and City Council of Olton, Texas. As a whole, we are happy to call Olton home. But, we as a community desperately need access to a local pharmacy. In fact, every single one of our 2,215 residents would benefit from local access to pharmaceutical care, including our local clinic. We are writing you to express our full support of the city of Olton obtaining pharmacy access in the form of a telepharmacy.

As a long-time residents of our secluded community, we fully understand the difficulties many of us, especially the elderly, endure to access adequate medical care. Currently we have very limited options and are required to travel at least 23 miles each way to access the nearest pharmacy. This is almost 50 miles roundtrip and can take more than an hour of driving time! The distance to get access to a pharmacy for our residents is a tremendous burden and also presents challenges to the other businesses in town. It is difficult for us to attract new employers when they know their employees will need to travel to get their prescriptions. It is also difficult for the local clinic to maintain a patient base when they have to travel almost 50 miles after seeing the doctor. Many patients choose to go to the doctor in a surrounding community where they can also pick up their prescriptions.

Unfortunately, the realities of operating a traditional retail pharmacy within a community such as ours would not generate nearly enough prescription volume to be viable as a business. That is why we need a telepharmacy. A telepharmacy in our community would have a positive impact on our people, other businesses, our county and the state of Texas. It would allow us to provide this basic medical service to our residents here locally, leading to a better standard of living. It will also keep them local so they are more likely to shop at our local stores, rather than supporting the economies of the surrounding counties and towns. Our local grocery store, banks, convenience stores, restaurants, and other small businesses which are the lifeblood of our community all stand to benefit. A telepharmacy can provide one of the fundamental building blocks we need here in our community to continue the growth and development we have already started.

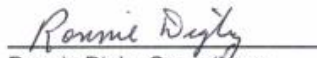
We ask that you please consider the residents of Olton and allow us to gain access to this critical resource right here in our own town. We are proud of our community, and providing a pharmacy to our residents will be a huge benefit to providing everyone here the quality of life they deserve. We chose to live in a rural community for the lifestyle, and feel that we deserve the same services available in other communities as well. The possibility is there, and you can help us realize it.

Thank you for your time and your thoughtful consideration of this issue.

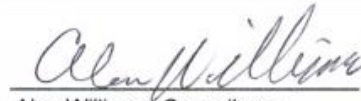
Sincerely,



Mayor, City of Olton  
PO Box 1087  
Olton, TX 79064  
806-285-2611



Ronnie Digby, Councilman



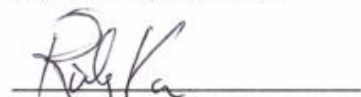
Alan Williams, Councilman



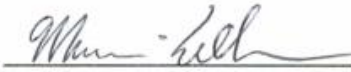
Kevin Blount, Councilman



Jay Light, Councilman



Ricky Karr, Councilman



Marvin Tillman, City Manager

## Exhibit E:

When I graduated from pharmacy school in 2006, one of my ultimate dreams was to own my own business, more specifically, a pharmacy. I have always had a passion to care for people and for my customers. My dad, Kelly Pratt, owned the pharmacy at the time I graduated from school and I ended up working for him until March of 2012 when I purchased my mother and him out. Around 3 years ago, Olton Pharmacy closed and sold to CVS, who moved all the customer records into Plainview, TX. I decided to start offering a delivery service to the Olton community free of charge to provide better access for the residents there. My goal was to capture those patients that I knew were going to have a hard time driving to and from Plainview or even Littlefield. Olton is a great community but with all rural communities, the population age is not getting any younger so offering a delivery service to Olton I felt like helps those patients healthcare needs and keeps them off the busy highways. Our delivery service has grown over the years so therefore expenses have grown especially since we have continued to offer a free delivery service. I have never wanted to charge for a delivery fee because like all of us, everyone has a budget they must follow. Being from a small, rural town I understand the benefits and/or consequences that come whenever businesses close down or open up. Olton, like any other rural community, has struggled over the past couple of years solely due to the fact they are an agriculture driven community. Their council definitely understands the impact that the community sees with the pros and cons of not having a pharmacy in their community. For example,, asking questions to a pharmacist with having a location present (even though it is via telepharmacy) creates a very positive atmosphere for patients to have the access to a pharmacist and medications. One of the star criteria for Medicare is for all their recipients to remain compliant with their medication use therefore eliminating hospital stays. Having a telepharmacy in Olton would greatly increase patient compliance to medications and ultimately keeping themselves healthy and out of the hospitals. My staff and I at the Prescription Shop have always shown the compassion to our customers and more specific to the Olton area. They understand that Olton is in a tight situation and they do their very best to get patients medications ran and processed on the same day so those patients will not be out of their medications.

Another piece to the puzzle is to open up a telepharmacy for the community of Morton, Tx. Like Olton, it is agriculture driven community. At this point they have a 13 bed hospital with a clinic but no pharmacy (which sold out a couple of years ago). It was told to me that patients will drive to the clinic from the New Mexico/Texas boarder, see the physician, and drive to either Portales, NM or Clovis, NM to get their prescriptions filled. The quality and service of healthcare in the Morton area is very poor when there is no pharmacy available. These patients live where they live and we cannot dispute that but we can offer the service that these patients need in order to better their health and livelihood.

## TELEPHARMACY- REMOTE DISPENSING SITE

### Pharmacy Self-Inspection Form

Texas Law holds the Pharmacist-in-Charge (PIC) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy.

The primary objective of this report is to provide an opportunity to identify and correct areas of non-compliance with state and federal law.

<b>TELEPHARMACY-REMOTE DISPENSING SITE</b>				<b>INSPECTION DATE</b>			
<u>HOME PHARMACY</u>				<u>REMOTE DISPENSING SITE</u>			
BUSINESS NAME				BUSINESS NAME			
ADDRESS				ADDRESS			
CITY				CITY			
ZIP CODE				ZIP CODE			
TELEPHONE				TELEPHONE			
E-MAIL				E-MAIL			
<u>OPERATING HOURS</u>				<u>OPERATING HOURS</u>			
M-F				M-F			
SAT-SUN				SAT-SUN			
<u>OWNERSHIP</u>				<u>OWNERS</u>			
Individual pharmacist Individual Non-pharmacist Partnership Corporation n LLC				NAME			
				TELEPHONE			
				E-MAIL			
				<u>PHARMACIST IN CHARGE</u>			
LICENSE NO.				EXPIRES			
DEA REG. NO.				EXPIRES			
LICENSE NO.				EXPIRES			
LICENSE NO.				EXPIRES			
LICENSE NO.				EXPIRES			

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If the Pharmacist in charge listed above is the PIC in other pharmacies, list here					
NAME		ADDRESS	PHONE NUMBER		
1.					
2.					
QUESTION		YES	NO	N/A	AUTHORITY
<b>GENERAL</b>					
The pharmacy's license is current and posted.					
All required current licenses are posted in a conspicuous location in the pharmacy (pocket license or photocopy may be used when registrants are employed at multiple sites).					
Pharmacy is compliant with applicable sections in chapters 551-569 of the Texas Pharmacy Practice Act Rules					
The PIC has personally reviewed the licenses of all registrants and determined that they are current.					
Registrants wear proper clean attire and have proper name tags and designations.					
All pharmacy technicians and certified pharmacy technicians have completed the required training.					
Meet all the requirements when there is a change in Pharmacist-in-Charge including but limited to proper notification to the Department and completing Controlled Substance Inventory.					
The schedule during which pharmacy services are provided is conspicuously displayed.					
Each site where such telepharmacy operations occur shall be a separately licensed pharmacy.					
Each site where such telepharmacy operations occur shall have a home pharmacy.					
Pharmacies shall abide by all Texas laws and rules when filling prescriptions for Texas residents, except as otherwise provided in the Rules.					
All pharmacists performing services must display a copy or electronic image of their licenses at the remote site where they provide services					

Each remote site must display a sign, easily viewable by the customer, that states: The facility is a telepharmacy supervised by a pharmacist located at Prescription Shop				
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No remote site may be open when the home pharmacy is closed, unless a pharmacist employed or contracted by the home pharmacy, or by a pharmacy contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section.				
---	--	--	--	--

<b>SECURITY, SANITATION AND STORAGE</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>AUTHORITY</b>
Security provisions are provided for all drugs and devices within the pharmacy during the absence of a pharmacist.				
Refrigerators for the exclusive use of medications are clean, defrosted and in working order maintaining proper temperature.				
Pharmacy is clean and sanitary.				
Pharmacy must have a sink with hot and cold running water.				
Food and/or beverages are kept in designated areas away from dispensing activities and stored in refrigerators not used for medications.				
Pharmacy area shall not be used for storage of merchandise that interferes with the practice of pharmacy.				
The pharmacy area and all store rooms shall be well- lighted and properly ventilated.				
All dispensing and drug storage areas of the pharmacy are contiguous.				
Expired medications are stored separately from active medication stock.				
All C-II controlled substances are stored securely within the pharmacy and a perpetual inventory is maintained.				

<b>DISPENSING AND RECORD KEEPING</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>AUTHORITY</b>
Written prescriptions presented to the remote dispensing site shall be scanned into the electronic data processing equipment to ensure initial dispensing and each refill and the original prescription may be viewed on the monitor at both the remote dispensing site and home pharmacy site				

A remote site is considered to be under the supervision of the pharmacist-in-charge of the home pharmacy.				
---	--	--	--	--

<p>The remote site shall use its home pharmacy and pharmacy management system.</p> <ul style="list-style-type: none"> <li>A) The system shall assign consecutive prescription numbers.</li> <li>B) Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy.</li> <li>C) Daily reports must be separated for the home and remote site.</li> </ul>				
<p>A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site.</p> <ul style="list-style-type: none"> <li>A) Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.</li> <li>B) A pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength and its beyond use date. The entire label must be checked for accuracy on the video link.</li> <li>C) The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed.</li> </ul>				
<p>An offer to counsel shall be made on all new prescriptions. Counseling must be done by a pharmacist via video link and audio link.</p>				
<p>A pharmacist-in-charge or his or her designated pharmacist must complete twice-yearly inspections of the remote site. Inspection criteria must be included in the policies and procedures for the site.</p>				
<p>Controlled substances shall be kept at the remote site in accordance with the Act and this Part. All records must be stored at the home pharmacy or at the remote site.</p>				
<p>There shall be a working computer link, video link and audio link to a pharmacist at a home pharmacy whenever the prescription area is open to the public.</p>				

<p>The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is physically present at the remote site.</p> <ul style="list-style-type: none"> <li>A) The pharmacy technician located at the remote dispensing site must be certified as a pharmacy technician, or be a student pharmacist.</li> <li>B) New prescriptions received at the remote dispensing site may be entered into the remote computer system with all verification, interaction, checking and profile review by the pharmacist at the home pharmacy.</li> <li>C) Each pharmacist at the home pharmacy may electronically supervise no more than 3 remote sites that are simultaneously open.</li> </ul>				
<p>The facility must have a sign clearly identifying it as a remote dispensing site.</p>				
<p>The facility shall have an area for patient consultation, exclusive of any waiting area.</p>				
<p>No prescription may be dispensed after one year from the date of the original issuance of the prescription by the prescriber.</p>				
<p>Procedure to ensure proper drug recall process</p>				
<p>Proper transferring of prescriptions and handling of transferred prescriptions.</p>				
<p>All transferred prescriptions for controlled substances in Schedule III, IV and V are transferred only once from the pharmacy which has the original prescription drug order unless the two pharmacies share a common database.</p>				
<p>All controlled substances are dispensed in Good Faith.</p>				
<p>Controlled drug prescriptions must contain the following:</p> <ul style="list-style-type: none"> <li>1. Name and address of patient</li> <li>2. Date of Issuance</li> <li>3. Practitioner's name and DEA number</li> <li>4. Dispensing pharmacist's <u>written</u> signature or initials</li> <li>5. Date of filling</li> <li>6. No Schedule III, IV, and V filled or refilled more than 5 times nor more than 6 months</li> <li>7. A prescription for a Schedule II controlled substance shall not be issued for more than a 30 day supply and shall be valid for up to 90 days after the date of issuance.</li> </ul>				
<p>Controlled drug prescriptions and records must be properly filed and maintained.</p>				

Annual inventory of controlled substances are properly recorded, dated and signed.				
Controlled substance data collection is submitted to the Prescription Monitoring program as required at least once a week if appropriate.				
Any theft or significant loss of controlled substances are immediately filed using the DEA form 106 with the Drug Enforcement Administration, with a copy to the Division of Professional Regulation directed to the attention of the Drug Compliance investigator.				
Controlled substance purchase invoices are signed and kept in a separate file.				
DEA 222 Form properly documented.				
Electronically transmitted prescriptions are only being received directly from the prescribing practitioner or agent.				
The pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in the dispensing shall sign a statement each day attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown.				
Proper transferring of prescriptions and handling of transferred prescriptions				
Records for returned drugs are properly maintained.				
All records are maintained for 5 years and are readily retrievable.				

<b>LABELING</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>AUTHORITY</b>
<b>All prescriptions are labeled with:</b> <ol style="list-style-type: none"> <li>1. Pharmacy name and address;</li> <li>2. Date and initials of person authorized to dispense;</li> <li>3. Name of patient;</li> <li>4. Prescription number;</li> <li>5. Prescriber's last name;</li> <li>6. Directions of use, quantity and dosage; and</li> <li>7. Name of the drug.</li> </ol>				

Any prepackaged drug must have a label affixed- name and strength of the drug, name of the manufacturer or distributor, beyond use date, lot number on each container.				
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I hereby certify that I have verified that this pharmacy is in compliance with all laws and rules related to the practice of pharmacy in the State of Texas and the answers marked on this report are true and correct to the best of my knowledge.

PIC NAME: \_\_\_\_\_

LICENSE NUMBER: \_\_\_\_\_

PIC SIGNATURE: \_\_\_\_\_

DATE: \_\_\_\_\_

## Exhibit G - Proposed Telepharmacy Language

### *Draft Language for Discussion*

#### **REMOTE DISPENSING SITE REGISTRATION.**

**01. Remote Dispensing Site Registration.** A limited service outlet registration must be obtained by a remote dispensing site prior to participating in the practice of telepharmacy.

**02. Supplemental Registration Application Requirements.** Prior to construction or conversion, an applicant for registration of a remote dispensing site must submit a registration application. The application must include:

- a. An attached description of the telepharmacy communication, electronic recordkeeping, and electronic verification systems;
- b. The operating specifications including, but not limited to location, ownership, current levels of pharmacist and technician staffing, and current number of supervised remote dispensing sites;
- c. An accurate scale drawing of the facility that illustrates:
  - i. The layout and location of the systems;
  - ii. The location of a patient counseling area; and
  - iii. All access points to the electronic recordkeeping system and the electronic verification system.
- iv. A description of the proposed supervising pharmacy located in Texas.

#### **03. Approval of Registration and Renewal.**

##### **OUTPATIENT TELEPHARMACY WITH REMOTE DISPENSING SITES.**

Pharmacies and pharmacists commencing retail telepharmacy operations with a remote dispensing site must comply with the following requirements:

- 1. Independent Entity Contract.** Unless jointly owned, a supervising pharmacy and a remote dispensing site must enter into a written contract that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the contract.
  - a.** The contract must be retained by the supervising pharmacy and made available to the Board upon request.
- 2. PIC Responsibility.** Unless an alternative PIC from the supervising pharmacy is specifically designated in writing, the PIC of the supervising pharmacy is also considered the responsible PIC for the remote dispensing site.
- 3. Remote Dispensing Site Staffing and Limitations.** The PIC and pharmacist-on-duty are responsible for ensuring that the supervising pharmacy and remote dispensing sites are sufficiently staffed to allow for appropriate supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare.

a. A pharmacist may neither be designated nor function as the PIC of more than three (3) total locations at one time.

b. The ratio of pharmacists to student pharmacists and technicians may not exceed one (1) pharmacist for every six (6) students and technicians in total at the supervising pharmacy and remote dispensing sites.

c. A designated pharmacist must be capable of being on site at the remote dispensing within 12 (12) hours if an emergency arises.

**4. Technician Staffing.** Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least one (1) certified technician with at least two thousand (2,000) hours pharmacy technician experience. All technicians must remain under the supervision of a pharmacist at the supervising pharmacy at all times that the remote site is operational. Supervision does not require the pharmacist to be physically present at the remote dispensing site, but the pharmacist must supervise telepharmacy operations electronically from the supervising pharmacy.

**5. Common Electronic Recordkeeping System.** The remote dispensing site and the supervising pharmacy must utilize a common electronic recordkeeping system that must be capable of the following:

a. Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site; and

b. Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed from the supervising pharmacy.

**6. Records Maintenance.** Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, federal law.

**7. Video and Audio Communication Systems.** A supervising pharmacy of a remote dispensing site must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site personnel and consumers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or delivery of drugs. The remote dispensing site must retain a recording of facility surveillance, excluding patient communications, for a minimum of ninety (90) days.

a. Adequate supervision by the pharmacist in this setting is maintaining constant visual supervision and auditory communication with the site and full supervisory control of the automated system, if applicable, and must not be delegated to another person or entity.

b. Video monitors used for the proper identification of and communication with persons receiving prescription drugs must be a minimum of twelve inches (12") wide, be of high definition, and provided at both the pharmacy and the remote location for direct visual contact between the pharmacist and the patient or the patient's agent.

c. Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed to the public if any component of the communication system is malfunctioning until system corrections or repairs are completed.

**d.** The video and audio communication system used to counsel and interact with each patient or patient's caregiver must be secure and HIPAA-compliant.

**8. Access and Operating Limitations.** Unless a pharmacist is present, a remote dispensing site must not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system must allow for tracking of entries into the remote dispensing site, and the PIC must periodically review the record of entries.

**9. Delivery and Storage of Drugs.** If controlled substances are maintained or dispensed from the remote dispensing site, transfers of controlled substances from the supervising pharmacy to the remote dispensing site must comply with applicable state and federal requirements.

**a.** Drugs must only be delivered to the remote dispensing site in a sealed container with a list identifying the drugs, drug strength, and quantities included in the container. Drugs must not be delivered to the remote dispensing site unless a technician or pharmacist is present to accept delivery and verify that the drugs sent were actually received, unless placed in a secure delivery area in accordance with state and federal law. The technician or pharmacist who receives and checks the order must verify receipt by signing and dating the list of drugs delivered.

**b.** If performed by a technician, a pharmacist at the supervising pharmacy must ensure, through use of the electronic audio and video communications systems or bar code technology, that a technician has accurately and correctly restocked drugs into the ADS system or cabinet, as applicable.

**c.** Drugs at the remote dispensing site must be stored in a manner to protect their identity, safety, security, and integrity and comply with the drug product storage requirements of these rules.

**d.** Drugs, including previously filled prescriptions, not contained within an ADS system must be stored in a secure manner and access must be limited to pharmacists from the supervising pharmacy and the technicians authorized in writing by the PIC.

**10. Security.** A remote dispensing site must be equipped with adequate security.

**a.** At least while closed, a remote dispensing site must utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. Two (2) factoring credentialing is required for entry, which must include two (2) of the following:

- i. Something known (a knowledge factor);
- ii. Something possessed (a hard token stored separately from the computer being accessed); and
- iii. Something biometric (fingerprint, retinal scan, etc.);

**11. Patient Counseling.** A remote dispensing site must include an appropriate area for patient counseling.

**a.** Unless onsite, a pharmacist must use a HIPAA-compliant video and audio communication system to counsel each patient or the patient's caregiver on new medications.

**12. Remote Dispensing Site Sign.** A remote dispensing site must display a sign, easily visible to the public, that informs patients that:

**a.** The location is a remote dispensing site providing telepharmacy services supervised by a pharmacist located in another pharmacy;

**b.** Identifies the city or township where the supervising pharmacy is located; and

**c.** Informs patients that a pharmacist is required to speak with the patient using audio and video communication systems each time a new medication is delivered and if counseling is accepted on a refill at a remote dispensing site.

**13. Pharmacist Inspection and Inventories of Remote Dispensing Site.** A pharmacist must complete and document:

**a.** A monthly in-person self-inspection using a form designated by the board, and such inspection reports must be retained.

**b.** A perpetual inventory must be kept for all schedule II controlled substances.

**c.** Three (3) controlled substances must be audited and documented quarterly by the pharmacist.

**14. Continuous Quality Improvement Program.** The PIC of the remote dispensing site must develop and implement a continuous quality improvement program. This program must be made available to the board upon request.

## **OUTPATIENT TELEPHARMACY WITH REMOTE DISPENSING SITES: PRESCRIPTION DRUG ORDERS.**

**1. Pharmacist Verification of New Prescription Drug Order Information.** If a technician at the remote dispensing site enters original or new prescription drug order information into the automated pharmacy system, the pharmacist at the supervising pharmacy must, prior to approving, verify the information entered against a faxed, electronic, or video image of the original prescription.

**a.** The technician may transmit the prescription drug order to the pharmacist by scanning it into the electronic recordkeeping system if the means of scanning, transmitting, or storing the image does not obscure the prescription information or render the prescription information illegible.

**b.** Alternatively, the technician may make the original prescription available to the pharmacist by placing the prescription in an appropriate position to facilitate viewing of the original prescription via video communication systems between the remote dispensing site and the supervising pharmacy. Using the video communication, the pharmacist must verify the accuracy of the drug dispensed and must check the prescription label for accuracy, unless checked in compliance with the accuracy checking technician procedures.

**c.** Except when prohibited by law for controlled substances, the technician may also transmit

the prescription drug order to the supervising pharmacist by fax.

**2. Pharmacist and Technician Identification.** The initials or other unique identifiers of the pharmacist and technician involved in the dispensing must appear in the prescription record.

**3. Pharmacist Verification of Drug Product and Label.** A pharmacist must compare, via video or image-based communication, the drug stock, the drug dispensed, and the label including the beyond use date.

**4. Electronic Verification System.** The remote dispensing site must use an electronic verification system that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. The technician must electronically verify each prescription prepared for dispensing.

#### **OUTPATIENT TELEPHARMACY WITH REMOTE DISPENSING SITES: POLICIES AND PROCEDURES.**

A supervising pharmacy commencing telepharmacy operations with a remote dispensing site must adopt policies and procedures that address each of the following areas prior to engaging in the practice of telepharmacy.

**1. Minimum Standards.** The establishment of minimum standards and practices necessary to ensure safety, accuracy, security, sanitation, recordkeeping, and patient confidentiality, including at least:

**a.** Identification of personnel authorized to have access to drug storage and dispensing areas at the remote dispensing site and to receive drugs delivered to the remote dispensing site;

**b.** Procedures for the procurement of drugs and devices to the remote site and into any ADS systems used, as applicable; and

**c.** The criteria for monthly in-person pharmacist inspections of the remote dispensing site and appropriate documentation.

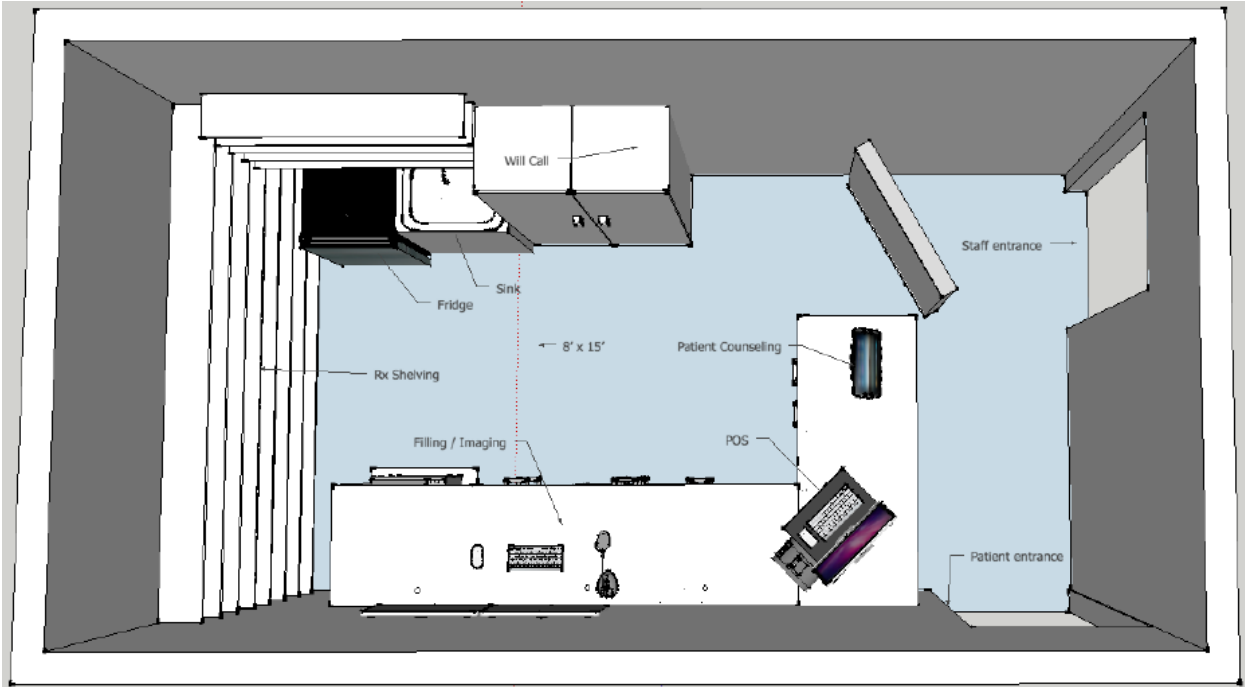
**2. Training Standards.** The adoption of standards and training required for remote dispensing site technicians and pharmacists to ensure the competence and ability of each person that operates the electronic verification system, electronic recordkeeping, and communication systems and a requirement for retention of training documentation.

**3. Written Recovery Plan.** A written plan for recovery from an event that interrupts or prevents pharmacist supervision of, or otherwise compromises, the dispensing of drugs from the remote dispensing site that includes at least the following:

**a.** Procedures for response while the communication or electronic recordkeeping systems are experiencing downtime or for an electronic verification system malfunction; and

**b.** Procedures for the maintenance and testing of the written plan for recovery.

**Exhibit H.**







By: \_\_\_\_\_ .B. No. \_\_\_\_\_

Substitute the following for \_\_\_\_B. No. \_\_\_\_\_:

By: \_\_\_\_\_ C.S.\_\_\_\_.B. No. \_\_\_\_\_

A BILL TO BE ENTITLED

1 AN ACT

2 relating to the provision of pharmacy services through a  
3 telepharmacy system; establishing a remote dispensing site  
4 license.

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

6 SECTION 1. Section 562.110, Occupations Code, is amended by  
7 amending Subsections (a), (b), (d), (e), and (f) and adding  
8 Subsections (g) and (h) to read as follows:

9 (a) In this section:

10 (1) "Provider pharmacy" means a Class A or Class C  
11 pharmacy that provides pharmacy services through a telepharmacy  
12 system at a remote dispensing site.

13 (2) "Remote dispensing site" means a location licensed  
14 as a telepharmacy that is authorized by a provider pharmacy through  
15 a telepharmacy system to store and dispense prescription drugs and  
16 devices, including dangerous drugs and controlled substances.

17 (3) "Telepharmacy [~~,"telepharmacy~~]" means a  
18 system that monitors the dispensing of prescription drugs and  
19 provides for related drug use review and patient counseling  
20 services by an electronic method, including the use of the  
21 following types of technology:

22 (A) [~~(1)~~] audio and video;

23 (B) [~~(2)~~] still image capture; and

24 (C) [~~(3)~~] store and forward.

1 (b) A Class A or Class C pharmacy located in this state may  
2 provide pharmacy services, including the dispensing of drugs,  
3 through a telepharmacy system at locations separate from [~~in a~~  
4 ~~facility that is not at the same location as~~] the Class A or Class C  
5 pharmacy.

6 (d) A telepharmacy system may be located only at:

7 (1) a health care facility in this state that is  
8 regulated by this state or the United States; or

9 (2) a remote dispensing site.

10 (e) The board shall adopt rules regarding the use of a  
11 telepharmacy system under this section, including:

12 (1) the types of health care facilities at which a  
13 telepharmacy system may be located under Subsection (d)(1), which  
14 must include the following facilities:

15 (A) a clinic designated as a rural health clinic  
16 regulated under 42 U.S.C. Section 1395x(aa) [~~as amended~~]; and

17 (B) a health center as defined by 42 U.S.C.  
18 Section 254b [~~as amended~~];

19 (2) the locations eligible to be licensed as remote  
20 dispensing sites, which must include locations in medically  
21 underserved areas, areas with a medically underserved population,  
22 and health professional shortage areas determined by the United  
23 States Department of Health and Human Services;

24 (3) licensing and operating requirements for remote  
25 dispensing sites, including:

26 (A) a requirement that a remote dispensing site  
27 license identify the provider pharmacy that will provide pharmacy

1 services at the remote dispensing site;  
2 (B) a requirement that a provider pharmacy be  
3 allowed to provide pharmacy services at not more than two remote  
4 dispensing sites;  
5 (C) a requirement that a pharmacist employed by a  
6 provider pharmacy make at least monthly on-site visits to a remote  
7 dispensing site or more frequent visits if specified by board rule;  
8 (D) a requirement that a pharmacist employed by a  
9 provider pharmacy be physically present at a remote dispensing site  
10 when the pharmacist is providing services requiring the physical  
11 presence of the pharmacist, including immunizations;  
12 (E) a requirement that a remote dispensing site  
13 be staffed by an on-site pharmacy technician who is under the  
14 continuous supervision of a pharmacist employed by the provider  
15 pharmacy;  
16 (F) a requirement that all pharmacy technicians  
17 at a remote dispensing site be counted for the purpose of  
18 establishing the pharmacist-pharmacy technician ratio of the  
19 provider pharmacy; and  
20 (G) any additional training or practice  
21 experience requirements for pharmacy technicians at a remote  
22 dispensing site;  
23 (4) the areas that qualify under Subsection (f);  
24 (5) [~~3~~] recordkeeping requirements; and  
25 (6) [~~4~~] security requirements.  
26 (f) A telepharmacy system located at a health care facility  
27 under Subsection (d)(1) may not be located in a community in which a

1 Class A or Class C pharmacy is located as determined by board rule.  
2 If a Class A or Class C pharmacy is established in a community in  
3 which a telepharmacy system has been located under this section,  
4 the telepharmacy system may continue to operate in that community.

5 (g) A telepharmacy system located at a remote dispensing  
6 site under Subsection (d)(2) may not be located in a community in  
7 which a Class A or Class C pharmacy is located. For purposes of this  
8 subsection, a community is:

9 (1) the census tract in which the remote dispensing  
10 site is located for a remote dispensing site located in a  
11 metropolitan statistical area as designated by the United States  
12 Office of Management and Budget; or

13 (2) the area within 10 miles of the remote dispensing  
14 site for a remote dispensing site not located in a metropolitan  
15 statistical area as designated by the United States Office of  
16 Management and Budget.

17 (h) The board by rule shall require and develop a process  
18 for a remote dispensing site to apply for classification as a Class  
19 A pharmacy if the average number of prescriptions dispensed per day  
20 at the remote dispensing site is more than 125, as calculated each  
21 calendar year.

22 SECTION 2. The Texas State Board of Pharmacy shall adopt  
23 rules under Section 562.110, Occupations Code, as amended by this  
24 Act, not later than January 1, 2018.

25 SECTION 3. This Act takes effect September 1, 2017.

**RECOMMENDATION  
PETITION FOR A PILOT PROJECT  
Lamb County Telepharmacy**

**PRESENTED FOR BOARD CONSIDERATION  
May 2, 2017**

Report of the Task Force appointed to review a petition for a pilot project presented by Prescription Shop in Littlefield, Texas, to allow provision of pharmacy services through the use of a telepharmacy system. The pilot project proposes to demonstrate expanded pharmaceutical care services which contribute to positive patient outcomes.

**SUMMARY OF DELIBERATIONS**

**Members of the Task Force**

Board President Jeanne Waggoner appointed the following persons to serve on this Task Force:

Suzette Tijerina, R.Ph., Board Member

Allison Vordenbaumen Benz, R.Ph., M.S., Staff Liaison  
Kerstin Arnold, Staff Liaison

**PILOT PROJECT**

**Goal for the Pilot Project**

To collect and analyze data to help determine the role of telepharmacy and its role in the future for Texas pharmacies. The pilot project proposes to demonstrate expanded pharmaceutical care services which contribute to positive patient outcomes.

**Person Responsible for the Project**

Micah Pratt, R.Ph.  
License #44378

**Location for the Project**

Verification Pharmacy:  
Prescription Shop  
1506 A South Sunset Ave  
Littlefield, TX 79339  
License #27958

Remote location:  
Olton Clinic  
524 8<sup>th</sup> St.  
Olton, TX 79064

### **Rules to be Waived During the Pilot Project**

#### **§291.121**

(c) Remote pharmacy services using telepharmacy systems.

XXX

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using a telepharmacy system to:

- (i) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;
- (ii) a health center as defined by 42 U.S.C. Section 254b, as amended; or
- (iii) healthcare facility located in a medically underserved area as defined by state or federal law.

(B) A provider pharmacy may not provide remote pharmacy services if a Class A (Community) or Class C (Institutional) pharmacy that dispenses prescription drug orders to out-patients is located in the same community. For the purposes of this subsection a community is defined as:

- (i) the census tract in which the remote site is located, if the remote site is located in a Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most recent U.S. Census; or
- (ii) within 10 miles of the remote site, if the remote site is not located in a MSA.

XXX

(D) Prescription dispensing and delivery.

(ii) Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use containers that are:

- (I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled as specified in §291.33(c)(6) of this title; or
- (II) in original manufacturer's containers.

### **Summary of the Pilot Project**

- (1) The pharmacist will be physically located at the verification pharmacy and will be readily available to the technicians and patients at the telepharmacy sites at all times. Pharmacists will continue to have ultimate authority over the dispensing process in this model.
- (2) The prescription department is staffed by registered pharmacy technicians. The pharmacist-technician relationship will remain important as the pharmacist will utilize new technologies to maintain safety protocols for patients.

- (3) All pharmacy technicians working at the telepharmacy site will be required to perform only pharmacy technician duties as described in Board rules.
- (4) Prescriptions will be dispensed according to all the standard operating procedures of a pharmacy. As the technician is filling the prescription, he/she will capture images of all steps to provide to the verifying pharmacist. These images, along with any other documentation, will be sent to the pharmacist to verify the dispensing and clinical accuracy of the prescription. The prescription must be verified by the pharmacist before it is able to be dispensed to the patient.
- (5) All of the information about the prescriptions filled at the telepharmacy will be recorded and maintained in secure records with redundant backups for 10 years. This audit trail is readily available for any prescription processed at the telepharmacy.
- (6) Medication counseling and responding to patient questions will be completed through a secure video connection in a private area when the medications are dispensed to the patient. Pharmacists will always be available for consultation with patients, prescribers, and other care providers through a secure video connection.

### **Conditions**

- (1) Unless otherwise stated in this document, the pilot project will operate in accordance with the conditions outlined in the proposed pilot project.
- (2) The pilot project will be conducted at the Prescription Shop and Olton Clinic.
- (3) The time frame for the project will be no more than 18 months from the start of the project, which must occur within 30 days of the Board's approval. The Texas State Board of Pharmacy shall be notified in writing within 10 days of the start of the project. However, the Board may extend the time frame for the project as deemed appropriate by the Board.
- (4) No controlled substances will be will be stored or dispensed by the remote site.
- (5) A pharmacist must visit the remote site at least once every calendar week.
- (6) The pharmacy technician at the remote site shall be included in the ratio at the verification pharmacy.
- (7) Prescription drugs must be delivered from the verification pharmacy to the remote site from the pharmacy (i.e., no wholesaler delivery to the remote site).
- (8) The remote site must be continuously monitored by a security system including camera monitoring.
- (9) When a pharmacy technician or pharmacist is not present at the remote site must be locked by key, combination, or other mechanical or electronic means to prohibit access. The remote site shall not be accessed and no activity shall be occurring at

the remote site unless a pharmacist is present at the remote site or is at the verification pharmacy actively supervising the remote site.

- (10) All phone calls should be directed to the verification pharmacy.
- (11) No over-the-counter medications or devices should be sold at the remote site, except by prescription.
- (12) A sign must be prominently posted at the remote site stating the pharmacy technicians are performing duties under remote supervision. The remote site shall post a photo of the supervising pharmacist(s).