Presentation for Texas Board of Pharmacy

May 3-4\textsuperscript{th} 2016
Agenda

• Introductions (Walgreens, MedAvail)
• MedAvail MedCenter/Walgreens Prescription Center introduction
• Review of Request for Deployment of Systems
• Questions
Introduction to Request

• Walgreens wishes to deploy MedAvail’s dispensing technology (called the Walgreens Prescription Center) in care settings that will help their patients better access pharmacy services

• Walgreens would like to deploy systems in two Communicare Health Clinics servicing a 340B population
Product Introduction

• The Walgreens Prescription Center (WPC) is a patient-facing pharmacist-controlled and administered remote dispensing solution for Rx and OTC medication.

• The system provides private, confidential, real-time professional advice and counselling via a robust audio and video link.

• Safety and accuracy are ensured as the system empowers the pharmacist to inspect each item at several stages during dispense (i.e. inventory retrieval, labelling, dispense to patient)

• The pharmacist must approve every dispense of an Rx to a patient and all transaction records are retained.
Walgreens Prescription Center: Exterior At a Glance

**2-Way Video**
2-way video (w/audio) is presented on the upper screen and with the integrated camera.

**Roles Based Access**
Security Scanner and ID code only grants access to components that the user is authorized to access.

**Secure Inventory Loading**
Stocking is performed using the secure load door. Access can only be granted to approved individuals.

**Benefit Cards & ID**
Versatile card scanner for ID verification and benefits card.

**Prescription Scanning**
Duplex scanner with multi-size and multi-page document handling (system also handles e-scripts).

**Audio**
Hi-fidelity hands free stereo audio system tuned and optimized for privacy. Handset option for additional privacy.

**Touch Screen**
Touchscreen user interface can be software branded and customized.

**Dispense Bay**
Secure dispense bay delivers medication and required printouts at completion of transaction.

**Payment**
Payment support with card reader and PIN pad for credit, debit and loyalty cards.
Walgreens Prescription Center: Video Introduction

Copy and paste link into your browser to view video:

- https://www.youtube.com/watch?v=BFqCrv1tZNQ
Dispensing Process – How Does it Work?

1. Patient provides proof of ID

2. Patient submits or requests their prescription
   • Paper prescription inserted into scanner, OR
   • Technician pulls up e-Rx/refill

3. Pharmacists and Technicians communicate with Patient
   • Live 2 way Audio and Video connection
   • Pharmacists provide medication counseling and verify prescriptions before dispensing.

4. Accuracy and Accountability
   • Pharmacy Management System utilized for prescription processing/adjudication
   • Fully tracked and auditable (all order entry, drug selection and verifications are recorded and these records maintained)
   • Bar code identification of product by unit
   • RPh performs final visual verification of Rx package/ label before dispense.
Prescription Interpretation and Data Entry

- The Walgreens Prescription Center accepts both eRx and paper prescriptions.

- The WPC requires a pharmacy management system to operate (the same that is required for any retail pharmacy)

- When a paper prescription is inserted, the RPh/Technician sees a high resolution scan and can zoom for enhanced viewing.

- The filling process occurs as it does in a retail pharmacy

- A RPh is ultimately responsible for all prescriptions dispensed.

- The same standard for RPh accountability and technician entry of information exists in all types of pharmacy practice today.
Deployments and Approvals in Other Jurisdictions

• Currently Walgreens has approximately 20 systems installed and operational (as of March 2016) in Illinois:
  – Retail Pharmacy
  – Hospital
  – Walgreens locations without pharmacies

• Systems are approved for deployment under a waiver or variance in:
  – Arizona (Hospital, Clinic)
  – Florida (Hospital)
  – New Mexico (Hospital)
  – Indiana (Clinic)
Walgreens: Description of Deployment and Responsibilities

<table>
<thead>
<tr>
<th>Entity</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Support Store</strong></td>
<td>• Stocking of the system (unit of use/pre-packaged/re-packaged meds)  &lt;br&gt; • Basic maintenance and consumable replenishment  &lt;br&gt; • Retrieval of prescription documents  &lt;br&gt; • Filing Rx documents with records of dispensing  &lt;br&gt; • Emptying of medication from the Return bin and return to the Responsible Pharmacy (medication will be re-used, returned to the manufacturer or destruction per SOP)  &lt;br&gt; • Performing periodic inspections per policy and procedures  &lt;br&gt; • Providing supervision for service on system mechanics or computers</td>
</tr>
<tr>
<td>Walgreens:</td>
<td>• Stores located near each Communicare site  &lt;br&gt; • Walgreens Store #03140 (Support for Communicare Health Center – East), 410 W Cypress St, San Antonio, Tx 78220 (Store License No. 15635)  &lt;br&gt; • Walgreens Store #04552 (Support for Communicare Health Center – West), 4703 W Commerce St, San Antonio Tx 78237 (Store license No. 10737)</td>
</tr>
<tr>
<td><strong>Responsible or Hub Location</strong></td>
<td>• Responsible for dispensing activity is accountable to the Board of pharmacy.  &lt;br&gt; • Development of policy and procedures and remote pharmacy operations  &lt;br&gt; • Controlling authority and access to each system (i.e. passwords)  &lt;br&gt; • Following Policies and Procedures assigned by the Responsible Pharmacy  &lt;br&gt; • Answering calls from patients using the MedCenter/WPC  &lt;br&gt; • Processing of prescriptions  &lt;br&gt; • Performs DUR and patient counselling  &lt;br&gt; • Verification of medication to be dispensed (both new and refill)  &lt;br&gt; • Providing counseling to patient for all dispenses</td>
</tr>
<tr>
<td>Walgreens:</td>
<td>• Walgreens Central Pharmacy Operation in Orlando, FL - 8337 S Park Cir, Orlando, FL 32819 License No. 23365</td>
</tr>
<tr>
<td><strong>Medication Supply</strong></td>
<td>• Pre-packaging medications and ensuring accurate bar-coding  &lt;br&gt; • Accurate bar-coding of manufacturer supplied medications  &lt;br&gt; • Shipping medication to local support store based on replenishment needs</td>
</tr>
<tr>
<td>Sourced from a Walgreens Pharmacy</td>
<td>• Providing advanced technical and System service support (all access is controlled by the Responsible Pharmacy)</td>
</tr>
<tr>
<td><strong>MedAvail (Technology Vendor and Support)</strong></td>
<td></td>
</tr>
</tbody>
</table>
Questions?
ScriptCenter®
24/7 Prescription Pickup

May 3, 2016
Problem
– 24 hour accessibility to prescriptions for employees.
– Employee satisfaction.

Solution
– ScriptCenter for 24/7 pickup of patient specific, finished prescriptions.
22 TAC 291.33 – Operation Standards

A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient’s agent when the pharmacy is open or when the pharmacy is closed as specified in subsection (b)(3)(B)(iii) of this section

A. Device deliver refills of the prescription drug orders
B. Device may not be used to deliver a controlled substance

✓ C. Drugs must be stored at the proper temperatures
✓ D. The patient or agent are given the option to use the system
✓ E. Patient has access to the pharmacy by provided telephone
✓ F. The pharmacist in charge is responsible for the device
✓ G. The device has been tested by the pharmacy and results are available to the BOP
✓ H. Device may be loaded by a pharmacist or technician
✓ I. Device must be made available for inspection by the BOP

J. Located within the pharmacy building whereby pharmacy staff has access to the device from within the prescription department... The device may not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru.

✓ K. Device is secure from access and removal of drug orders by unauthorized individuals
✓ L. Has adequate security system
✓ M. Records a digital image of individuals access the device and records maintained for 2 years.
Automated Distribution Systems - History

**John Peter Smith – Fort Worth, TX**

*ScriptCenter®*

- 85% say ScriptCenter is a key reason to use the pharmacy.
- 94% say the convenience of after-hours prescription pickup is an important reason to use the pharmacy.
- 97% Would recommend to a friend or colleague

Go-Live February, 2014

*Number of prescription pickups with error = 0*

*Break in attempts since go-live = 0*

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**Wal-Mart Store #804 – Mineral Wells, TX**

*APM™ Kiosk – Pilot*

Go-Live July, 2007 (pilot no longer in use)

- 77 week pilot
  - Registered Users: 1254
  - Prescription pickups through APM: 3866
  - 10% of Rx’s picked up after hours via APM
  - Number of Incorrect Rx Dispensed: 0
Filling Pharmacy
The Scott & White Round Rock Pharmacy
425 University Blvd
Round Rock, TX

- ScriptCenter to be located ~300 yards across the street in the Baylor Scott & White Medical Center
Proposed ScriptCenter Location 2
Carrollton

Filling Pharmacy
Baylor Medical Plaza Pharmacy at Carrollton
4323 N Josey Ln
Carrollton, TX

• ScriptCenter to be located ~150 yards in the Baylor Medical Center (connected to the Medical Plaza)
Prescription ScriptLink Process

Prescription:

MMC Outpatient Pharmacy
1800 Coffee Rd. Ste 110 Modesto, CA. 95355
Refills: (209) 572-7167 Main: (209) 572-7132
Rx# 7854369 U Dr. TEST, THOMAS M.
TEST PATIENT 03/02/11 K
LISINOPRIL/HCTZ Generic for:
10-12.5MG TAB (LP) #90 ZESTORETIC
TAKE ONE TABLET BY MOUTH DAILY
SC: Y
Security

- 24/7 video surveillance
- On-site security guards monitoring the area
- 100% audit trail
Counseling

- ScriptCenter Video Consult
- 24/7 Access to a pharmacist
- ‘Hold and Release’ feature
- During Pharmacy Hours – each respective filling pharmacy will handle counseling
- After Pharmacy Hours – inpatient pharmacy will handle counseling
(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.
Thank you!
Reference Materials
Enrollment Process
Secure and convenient prescriptions without waiting... Enroll here!

LOG IN

ENROLL

CLAIM CHECK

ESPAÑOL
Scan Your Fingerprint 4 Times

1. Press your finger on the scanner.
2. Remove when image appears.
3. Repeat 4 times with the same finger.

We suggest you use your index finger.

Press your finger firmly on the scanner

NEXT >
Sign to Authorize Enrollment

By Signing below I acknowledge that:

- My eligible prescriptions will be put in ScriptCenter.
- Anyone with my ID and PIN may have access to my prescriptions.

Sign on the pad below
Secure Prescription Transport and Loading Process
Prescriptions filled and verified by Baylor Pharmacist – current policies and procedures followed
Prescription ScriptLink® Process
Inventory Reconciliation – Receipt printed from ScriptCenter compared to activity report by pharmacist

Activity
10 Transactions
Filter: "Today"

- Purchased: 0
- Delivered: 0
- Linked: 10
- Hold: 0
- Returned: 0
- Retrieved: 0
- Unlinked: 0
- Hold Removed: 0.00

- Loaded: 0
- Unloaded: 0
- Deposit: 0

ScriptCenter Inventory Status

- Total Packages: 184
- New Packages Loaded*: 10
- Packages Unloaded*: 0
- Ready to Unload: 0
- Unknown: 0
- Incomplete Orders: 0

- Trays to Inspect: 0
- Missing Trays: 0

*Since 12/17/2013 11:35 AM.

Run by ryan lebowitz at 12:10 PM on 12/17/2013.
Final Verification Check—Activity report verifies prescriptions were loaded
Prescription Pickup Process
Enter Your PIN

User ID: MALFORD

PIN: ****

FORGOT PIN?
### My Shopping Cart

**MADELYNN ALFORD**

<table>
<thead>
<tr>
<th>Name</th>
<th>Item</th>
<th>Rx #</th>
<th>Price</th>
<th>Pick up</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADELYNN A. ALFORD</td>
<td>AMITRIPTYLINE HCL 25MG TAB #30</td>
<td>4963323-003</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LISINOPRIL 10MG TABLET #30</td>
<td>4823111-005</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TOPAMAX 25MG TABLET #30</td>
<td>9640294-003</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total:** $0.00 0 Item(s)

- **PERSONAL CARE STORE**
- **MY SETTINGS**
- **NEXT >**
- **QUIT**
Consult Pharmacy

- Pick up handset
- Touch "Connect"
- Touch "Hang Up" to end

CONNECT

HANG UP
Pharmacist Releases Prescriptions
<table>
<thead>
<tr>
<th>Name</th>
<th>Item</th>
<th>Rx #</th>
<th>Child Safety Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADELYNN A. ALFORD</td>
<td>AMITRIPTYLINE HCL 25MG TAB #30</td>
<td>4963323-003</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>LISINOPRIL 10MG TABLET #30</td>
<td>4823111-005</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>AMITRIPTYLINE HCL 25MG TAB #30</td>
<td>9640294-003</td>
<td>No</td>
</tr>
</tbody>
</table>

- I am picking up these prescriptions.
- I am receiving prescription(s) in non child resistant packaging.
1. Remove your items
2. Take your receipt
3. Verify your items before leaving

⚠️ The bin will close in 4 seconds
§291.33 Operational Standards

(i) Automated devices and systems.

(4) Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient's agent when the pharmacy is open or when the pharmacy is closed as specified in subsection (b)(3)(B)(iii) of this section, provided:

(A) the device is used to deliver refills of prescription drug orders and shall not be used to deliver new prescriptions as defined by §291.31(29) of this title (relating to Definitions);

(B) the automated storage and distribution device may not be used to deliver a controlled substance;

(C) drugs stored in the automated storage and distribution device are stored at proper temperatures;

(D) the patient or patient's agent is given the option to use the system;

(E) the patient or patient's agent has access to a pharmacist for questions regarding the prescription at the pharmacy where the automated storage and distribution device is located, by a telephone available at the pharmacy that connects directly to another pharmacy, or by a telephone available at the pharmacy and a posted telephone number to reach another pharmacy;

(F) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

(G) the automated storage and distribution device has been tested by the pharmacy and found to dispense prescriptions accurately. The pharmacy shall make the results of such testing available to the board upon request;

(H) the automated storage and distribution device may be loaded with previously verified prescriptions only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(I) the pharmacy will make the automated storage and distribution device available for inspection by the board;

(J) the automated storage and distribution device is located within the pharmacy building whereby pharmacy staff has access to the device from within the prescription department and

April 12, 2016
patients have access to the device from outside the prescription department. The device may not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

(K) the automated storage and distribution device is secure from access and removal of prescription drug orders by unauthorized individuals;

(L) the automated storage and distribution device has adequate security system to prevent unauthorized access and to maintain patient confidentiality; and

(M) the automated storage and distribution device records a digital image of the individual accessing the device to pick-up a prescription and such record is maintained by the pharmacy for two years.

SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES

§291.121 Remote Pharmacy Services

(a) Remote pharmacy services using automated pharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Remote site--A facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using an automated pharmacy dispensing system.

(C) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an automated pharmacy system.

(D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(E) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.

(3) General requirements.
(A) A provider pharmacy may provide remote pharmacy services using an automated pharmacy system to a jail or prison operated by or for the State of Texas, a jail or prison operated by local government or a healthcare facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code, provided drugs are administered by a licensed healthcare professional working in the jail, prison, or healthcare facility.

(B) A provider pharmacy may only provide remote pharmacy services using an automated pharmacy system to inpatients of the remote site.

(C) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(D) Before providing remote pharmacy services, the automated pharmacy system at the remote site must be tested by the provider pharmacy and found to dispense accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) Pharmacies) and this section.

(F) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated pharmacy system located at the remote site including supervision of the automated pharmacy system and compliance with this section.

(G) A pharmacist from the provider pharmacy shall be accessible at all times to respond to patient's or other health professionals' questions and needs pertaining to drugs dispensed through the use of the automated pharmacy system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an automated pharmacy system.

(i) A Class A or Class C Pharmacy shall make application to the board to provide remote pharmacy services using an automated pharmacy system. The application shall contain an affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief executive officer), and include the following:

(I) the name, address, and license number of the provider pharmacy;

(II) name and address of the facility where the remote pharmacy services will be provided;

(III) a statement indicating that the provider pharmacy and the facility have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations; and
(IV) documentation that the automated pharmacy system is located where medications are administered by license healthcare professionals and is:

(-a-) a facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code; or

(-b-) a jail or prison, operated by the State of Texas or local government.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license. The renewal petition shall contain the documentation required in clause (i) of this subparagraph except the notarized signature of the medical director or the person responsible for the on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief executive officer) is not required.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a change of location, discontinuance of service, or closure of:

(I) a remote site where an automated pharmacy system is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an automated pharmacy system at the facility.

(C) Environment/Security.

(i) A provider pharmacy shall only store drugs at a remote site within an automated pharmacy system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) An automated pharmacy system shall be under the continuous supervision of a provider pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist.

(iii) Automated pharmacy systems shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel who:

(I) are designated in writing by the pharmacist-in-charge; and
(II) have completed documented training concerning their duties associated with the automated pharmacy system.

(v) Drugs shall be stored in compliance with the provisions of §291.15 of this title (relating to Storage of Drugs) and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs shall only be dispensed at a remote site through an automated pharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated medication system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

(iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy system.

(iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system shall comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

(v) An automated pharmacy system used to meet the emergency medication needs for residents of a remote site must comply with the requirements for emergency medication kits in subsection (b) of this section.

(E) Drugs.

(i) Drugs for use in an automated pharmacy system shall be packaged in the original manufacturer's container or be prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(ii) Drugs dispensed from the automated pharmacy system may be returned to the pharmacy for reuse provided the drugs are in sealed, tamper evident packaging which has not been opened.

(F) Stocking an automated pharmacy system.

(i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the automated pharmacy system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by an FDA approved repackager. The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:
(I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(II) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote site by the provider pharmacy.

(G) Quality assurance program. A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to a written program for quality assurance of the automated pharmacy system which:

(i) requires continuous supervision of the automated pharmacy system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated pharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(H) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have access to the drugs stored in the automated pharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the portion of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated pharmacy system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(IV) date of last review/revision of the policy and procedure manual; and

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the automated pharmacy system;

(-c-) preventative maintenance of the automated pharmacy system;

(-d-) sanitation;
(-e-) storage of drugs;
(-f-) dispensing;
(-g-) supervision;
(-h-) drug procurement;
(-i-) receiving of drugs;
(-j-) delivery of drugs; and
(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to dispense prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an automated pharmacy system in compliance with §291.34(b) of this title.
(iii) If prescription drug records are maintained in a data processing system, the system shall
have a workable (electronic) data retention system which can produce a separate audit trail of
don drug usage by the provider pharmacy and each remote site for the preceding two years as
specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this
title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be
maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) The automated pharmacy system shall electronically record all transactions involving
drugs stored in, removed, or dispensed from the system.

(ii) Records of dispensing from an automated pharmacy system for a patient shall be
maintained by the providing pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) name, strength, dosage form, and quantity of drug accessed; and

(V) name of the patient for whom the drug was accessed.

(iii) Records of stocking or removal from an automated pharmacy system shall be
maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked or removed;

(III) name, initials, or identification code of the person stocking or removing drugs from the
system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the
system has been accurately filled;

(E) Patient medication records. Patient medication records shall be created and maintained
by the provider pharmacy in the manner required by §291.34(c) of this title.

(F) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the
records of the provider pharmacy and from any other remote site’s records; and
(II) keep a perpetual inventory of controlled substances and other drugs required to be
inventoried under §291.17 of this title (relating to Inventory Requirements for All Classes of
Pharmacies) that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at
each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the
same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the
drugs of other remote sites and separately from the drugs of the provider pharmacy.

§291.129 Satellite Pharmacy

(a) Purpose. The purpose of this section is to create a new class of pharmacy for the provision
of pharmacy services by a Class A or Class C pharmacy in a location that is not at the same
location as a Class A or Class C pharmacy through a satellite pharmacy and to provide
standards for the operation of this class of pharmacy established under §560.053 of the Texas
Pharmacy Act.

(b) Definitions. The following words and terms, when used in the section, shall have the
following meanings, unless the context clearly indicates otherwise. All other words and terms
shall have the meanings defined in the Act or §291.31 of this title.

(1) Provider pharmacy--The Class A or Class C pharmacy providing satellite pharmacy
services.

(2) Satellite pharmacy--A facility not located at the same location as a Class A or Class C
pharmacy at which satellite pharmacy services are provided.

(3) Satellite pharmacy services--The provision of pharmacy services, including the storage and
delivery of prescription drugs, in an alternate location.

(c) General requirements.

(1) A Class A or Class C provider pharmacy may establish a satellite pharmacy in a location
that is not at the same location as a Class A or Class C pharmacy.

(2) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy
operations involving the satellite pharmacy including supervision of satellite pharmacy personnel
and compliance with this section.

(3) A satellite pharmacy may not store bulk drugs and may only store prescription medications
that have been previously verified and dispensed by the provider pharmacy.

(4) A Class C pharmacy that is a provider pharmacy dispensing outpatient prescriptions for a
satellite pharmacy shall comply with the provisions of §§291.31 - 291.34 of this title (relating to
Definitions, Personnel, Operational Standards, and Records for Class A (Community) pharmacies) and this section.

(5) The provider pharmacy and the satellite pharmacy must have:

(A) the same owner; and

(B) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function.

(d) Personnel.

(1) All individuals working at the satellite pharmacy shall be employees of the provider pharmacy and must report their employment to the board as such.

(2) A satellite pharmacy shall have sufficient pharmacists on duty to operate the satellite pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(3) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in paragraph (7) of this subsection, to pharmacy technicians and pharmacy technician trainees. Each pharmacist:

(A) shall verify the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(B) shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(4) A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system. Each prescription entered into the data processing system shall be verified at the time of data entry.

(5) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(6) A pharmacist shall ensure that the drug is dispensed and delivered safely and accurately as prescribed. A pharmacist shall ensure the safety and accuracy of the portion of the process the pharmacist is performing.

(7) Duties, in a satellite pharmacy, that may only be performed by a pharmacist are as follows:

(A) receiving oral prescription drug orders and reducing these orders to writing, either manually or electronically;

(B) interpreting or clarifying prescription drug orders;
(C) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, as specified in §291.33(c) of this title;

(D) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

(E) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(F) interpreting patient medication records and performing drug regimen reviews; and

(G) performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act.

(8) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (7) of this subsection. However, a pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(A) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees; and

(B) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist.

(9) Pharmacy technicians and pharmacy technician trainees, in a satellite pharmacy, may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs as follows:

(A) initiating and receiving refill authorization requests;

(B) entering prescription data into a data processing system; and

(C) reconstituting medications.

(10) In a satellite pharmacy, the ratio of pharmacists to pharmacy technicians/pharmacy technician trainees may be 1:3, provided at least one of the three is a pharmacy technician and not a pharmacy technician trainee.

(11) All satellite pharmacy personnel shall wear identification tags or badges that bears the person's name and identifies him or her as a pharmacist, pharmacist intern, pharmacy technician, or pharmacy technician trainee.

(e) Operational requirements.

(1) Application for permission to provide satellite pharmacy services.

(A) A Class A or Class C pharmacy shall make application to the board to provide satellite pharmacy services. The application shall contain an affidavit with the notarized signatures of the
pharmacist-in-charge and the person responsible for the on-site operation of the facility where
the satellite pharmacy will be located and include the following:

(i) the name, address, and license number of the provider pharmacy;
(ii) the name and address of the facility where the satellite pharmacy will be located;
(iii) anticipated date of opening and hours of operation; and
(iv) copy of the lease agreement or if the location of the satellite pharmacy is owned by the
applicant, a notarized statement certifying such location ownership.

(B) Such application shall be resubmitted every two years in conjunction with the application
for renewal of the provider pharmacy's license. The renewal petition shall contain the
documentation required in subparagraph (A) of this paragraph except the notarized signature of
the person responsible for the on-site operation of the facility where the satellite pharmacy will
be located.

(C) Upon approval of the application, the provider pharmacy will be sent a certificate which
must be displayed at the satellite pharmacy.

(2) Notification requirements.

(A) A provider pharmacy shall notify the board in writing within ten days of a change of
location, discontinuance of service, or closure of a satellite pharmacy that is operated by the
pharmacy.

(B) A provider pharmacy shall comply with appropriate federal and state controlled substance
registrations for each satellite pharmacy if controlled substances are maintained at the satellite
pharmacy.

(3) Environment.

(A) The satellite pharmacy shall be arranged in an orderly fashion and kept clean. All required
equipment shall be clean and in good operating condition.

(B) A satellite pharmacy shall contain an area which is suitable for confidential patient
counseling.

(i) Such counseling area shall:

(I) be easily accessible to both patient and pharmacists and not allow patient access to
prescription drugs;

(II) be designed to maintain the confidentiality and privacy of the pharmacist/patient
communication.

(ii) In determining whether the area is suitable for confidential patient counseling and
designed to maintain the confidentiality and privacy of the pharmacist/patient communication,
the board may consider factors such as the following:
(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of
the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the
patient or patient's agent or the pharmacist or agents of the pharmacist.

(C) The satellite pharmacy shall be properly lighted and ventilated.

(D) The temperature of the satellite pharmacy shall be maintained within a range compatible
with the proper storage of drugs in compliance with the provisions of §291.15 of this title
(relating to storage of drugs). The temperature of the refrigerator shall be maintained within a
range compatible with the proper storage of drugs requiring refrigeration.

(E) Animals, including birds and reptiles, shall not be kept within the pharmacy and in
immediately adjacent areas under the control of the pharmacy. This provision does not apply to
fish in aquariums, guide dogs accompanying disabled persons, or animals for sale to the
general public in a separate area that is inspected by local health jurisdictions.

(4) Security.

(A) A satellite pharmacy shall be under the continuous, physically present supervision of a
pharmacist at all times the satellite pharmacy is open to provide pharmacy services.

(B) The satellite pharmacy shall be enclosed by walls, partitions or other means of floor-to-
ceiling enclosure. In addition, to the security requirements outlined in §291.33(b)(2) of this title,
satellite pharmacies shall have adequate security and procedures to

(i) prohibit unauthorized access;

(ii) comply with federal and state regulations; and

(iii) maintain patient confidentiality.

(C) Access to the satellite pharmacy shall be limited to pharmacists, pharmacy technicians,
and pharmacy technician trainees employed by the provider pharmacy and who are designated
in writing by the pharmacist-in-charge.

(D) The provider pharmacy shall have procedures that specify that prescriptions may only be
delivered to the satellite pharmacy by the provider pharmacy and shall:

(i) be delivered in a sealed container with a list of the prescriptions delivered;

(ii) signed for on receipt by the pharmacist at the satellite pharmacy;

(iii) be checked by personnel designated by the pharmacist-in-charge to verify that the
prescriptions sent by the provider pharmacy were actually received. The designated person who
checks the order shall document the verification by signing and dating the list of prescriptions delivered.

(5) Prescription dispensing and delivery. A satellite pharmacy shall comply with the requirements outlined in §291.33(c) of this title with regard to prescription dispensing and delivery.

(6) Equipment and supplies. A satellite pharmacy shall have the following equipment and supplies:

(A) typewriter or comparable equipment;

(B) refrigerator, if storing drugs requiring refrigeration;

(C) metric-apothecary weight and measure conversion charts.

(7) Library. A reference library shall be maintained by the satellite pharmacy that includes the following in hard-copy or electronic format:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules; and

(iv) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules);

(B) at least one current or updated reference from each of the following categories:

(i) patient information:

(I) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient); or

(II) a reference text or information leaflets which provide patient information;

(ii) drug interactions: a reference text on drug interactions, such as Drug Interaction Facts. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(iii) a general information reference text, such as:

(I) Facts and Comparisons with current supplements;

(II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);
(III) Clinical Pharmacology;
(IV) American Hospital Formulary Service with current supplements; or
(V) Remington's Pharmaceutical Sciences; and
(C) basic antidote information and the telephone number of the nearest Regional Poison Control Center.