Patient Care through Telepharmacy

April 2016

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Agenda

- Origins of Telepharmacy
- Why now?
- Telepharmacy process
- Regulatory environment
- Future Applications

Telepharmacy

Prescription verification

Counseling & Education

History

US Telepharmacy Timeline

2001 North Dakota first state to allow

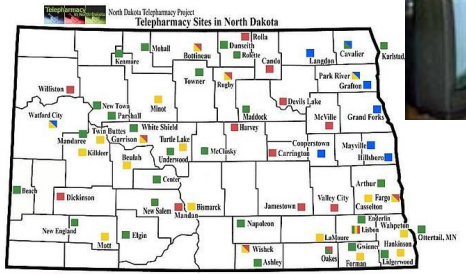
2001 Community Health Association in Spokane, WA launches program

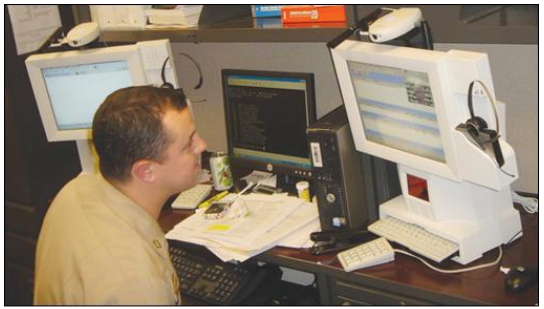
2002 NDSU study begins

2003 Alaska Native Medical Center program

2006 U.S. Navy begins telepharmacy

2012 New generation begins in Iowa





NDSU Telepharmacy Study

Study from 2002-2008

- 81 pharmacies
  - 53 retail and 28 hospital
- Rate of dispensing errors <1%
  - Compared to national average of ~2%
- Positive outcomes, mechanisms could be improved

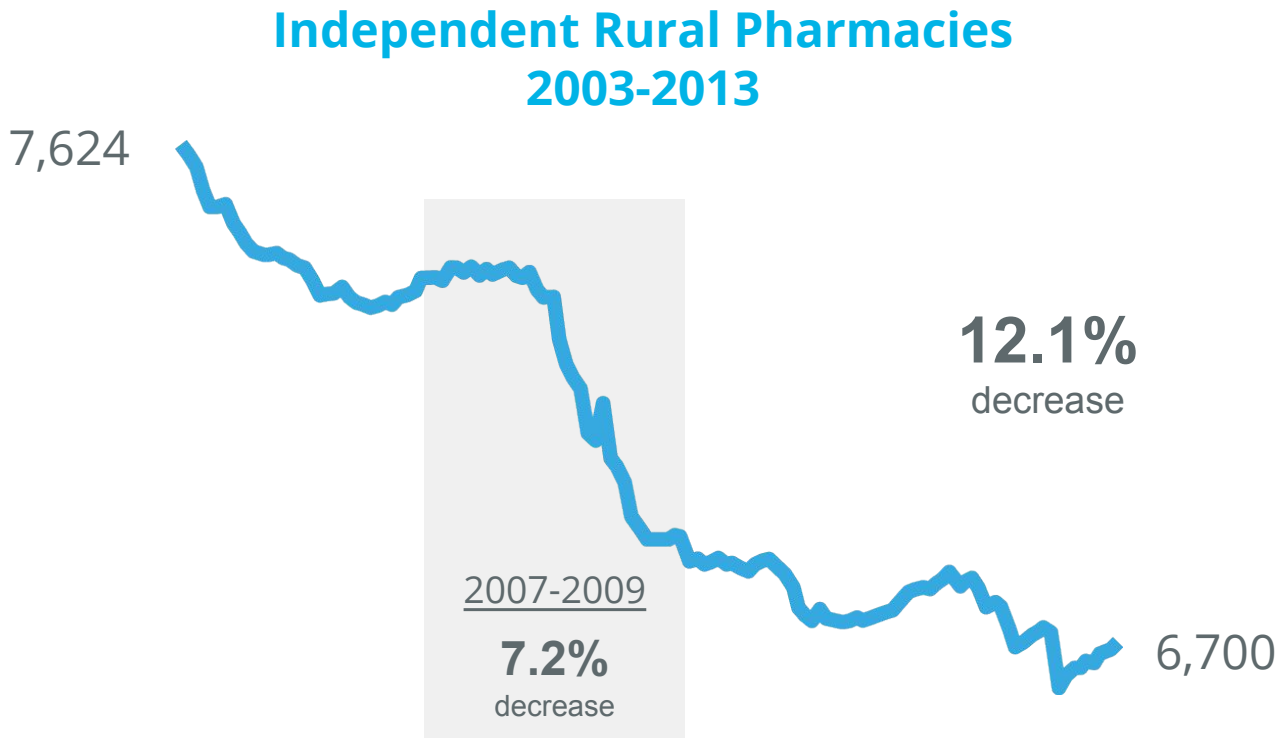
Source: The North Dakota Experience: Achieving High-Performance Health Care Through Rural Innovation And Cooperation. May 2008

Limitations of Early Technology

- Live video feed restrictions
  - Point-to-point
  - Expensive hardware
  - Heavy broadband need
  - Lack of documentation
  - Scalability
  - Workflow obstacles

Industry Changes

Pharmacy Closure Trend



Source: Update: Independently Owned Pharmacy Closures in Rural America, 2003-2013;
RUPRI Center for Rural Health Policy Analysis, Rural Policy Brief June 2014; Fred Ullrich, BA; Keith J. Mueller, PhD

Rural Pharmacy Closures

Mar 2003 - Dec 2013

924

independent rural pharmacies closed

490

rural communities lost their only pharmacy

Source: Update: Independently Owned Pharmacy Closures in Rural America, 2003-2013;
RUPRI Center for Rural Health Policy Analysis, Rural Policy Brief June 2014; Fred Ullrich, BA; Keith J. Mueller, PhD

Consequences of Closures

- Gap in healthcare, fragmentation of care
- Dying Main Street
- Job loss
- Decreased medication adherence

Source: Knowledge, attitudes and beliefs of patients and carers regarding medication adherence: a review of qualitative literature; Dec 2014

Medication Adherence

- 187MM Americans take 1+ prescriptions[1]
- 50% do not take as prescribed[2]
- $100+ billion a year in excess hospitalizations[3]
- 31% of new prescriptions go unfilled[4]
- Readmission costs between $15-25 billion/year.[5]

[1] Osterberg, L., Blaschke, T. (2005). Adherence to medication. N Engl J Med, 353(5), 487-497.

[2] Enhancing Prescription Medicine Adherence: A National Action Plan. National Council on Patient Information and Education (August 2007).

[3] Sokol, M.C., McGuigan, K.A., Verbrugge, R.R., et al. (2005). Impact of medication adherence on hospitalization risk and healthcare cost. Med Care, 43(6), 521-530.

[4] Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions. Fischer MA, Stedman MR, Lii J, et al J Gen Intern Med. 2010; 25:284-290

[5] PriceWaterhouse Coopers' Health Research Institute. (2008). The Price of Excess: Identifying Waste in Healthcare, 2008.

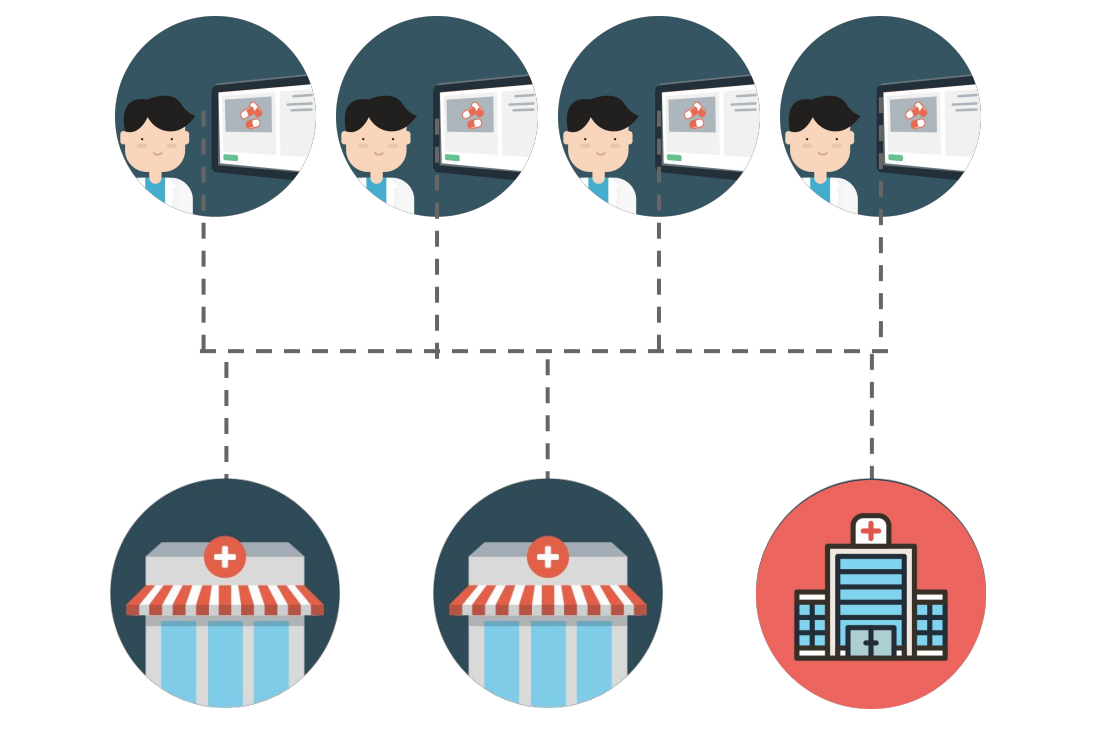
Present

Technology as a Disruptor

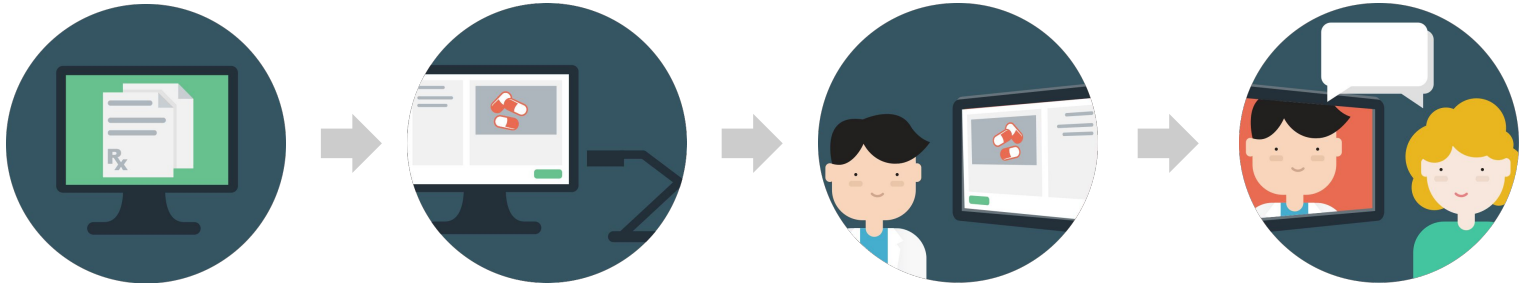
amazon

UBER

Technology Enables Advancement



Modern Pharmacy Workflow

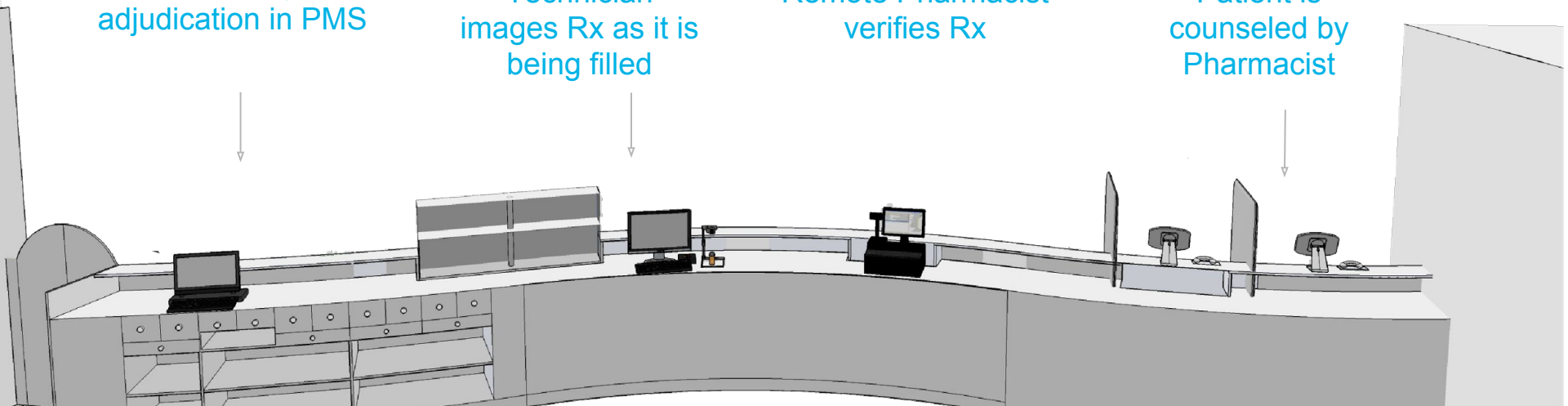


Data entry, adjudication in PMS

Technician images Rx as it is being filled

Remote Pharmacist verifies Rx

Patient is counseled by Pharmacist



victor drug
innovating pharmacy care
GRAND OPENING
smallTownINNOVATION

Rexall
PICK UP
CASHIER
community

Children's
Hospital of Wisconsin
Delafield Clinic

LG
CASIO
T 45.48
HALLS
HALLS
HALLS
Purell
Florajen

Skywalk
Skywalk Delafield is a Prescription Dispensing Center
supervised by a pharmacist located at:
Skywalk Pharmacy New Berlin
Children's Hospital of Wisconsin New Berlin Clinic
4855 S. Moorland Rd. , New Berlin, WI 53151
Phone: (262) 432-7653
skywalkpharmacy.com
A pharmacist is required to speak with you. Either in
person or via anti-camera, each time a prescription is
picked up.
1A5

Benefits of Telepharmacy

Provides access to a healthcare provider

Prevents traveling long distances

Reduces dispensing errors

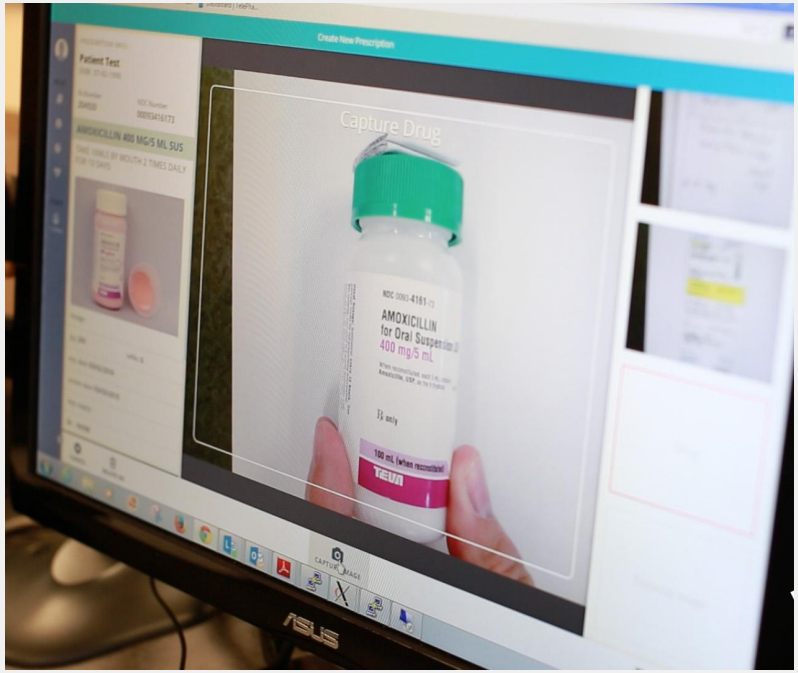
Integrated Health Care

- Retrieve medications easily at the same location
- Only 5% did not fill their initial prescriptions
- Better integration = better adherence

Source: New Prescription Medication Gaps: A Comprehensive Measure of Adherence to New Prescriptions. Andrew J. Karter, Melissa M. Parker, Howard H. Moffet, Ameena T. Ahmed, Julie A. Schmittdiel, Joe V. Selby (October 2009).

Common Questions

- Fill accuracy
- Staff & location safety
- Potential for diversion
- Internet outage protocol
- Retail, Long Term Care, Health Systems

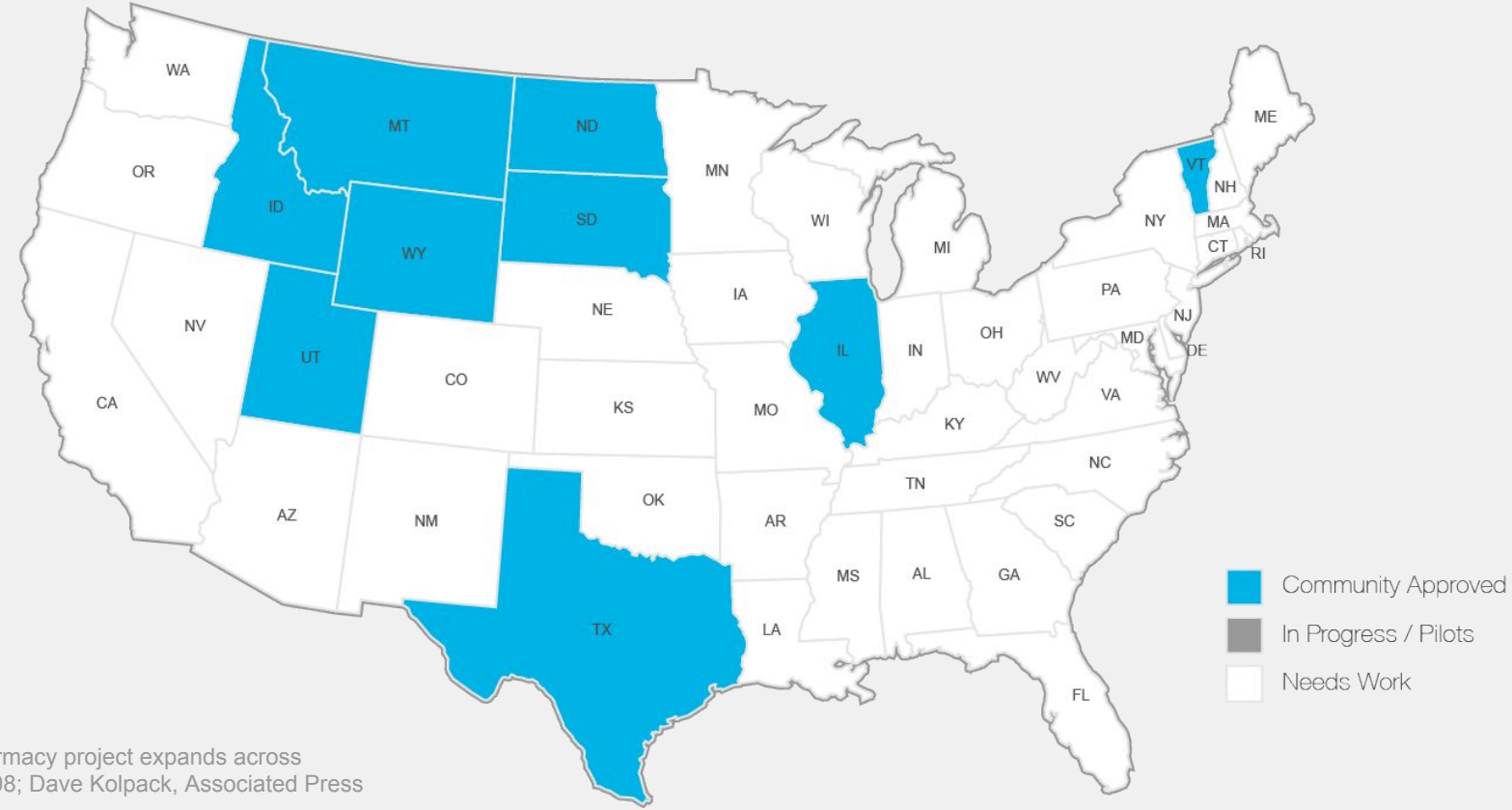


Future Applications

- “Health Hub” for rural communities
- Access to pharmacists from anywhere
  - Direct connection to patient rooms
  - At hospital discharge
  - On your cell phone
- 24 hour pharmacist coverage
- Pharmacist relief

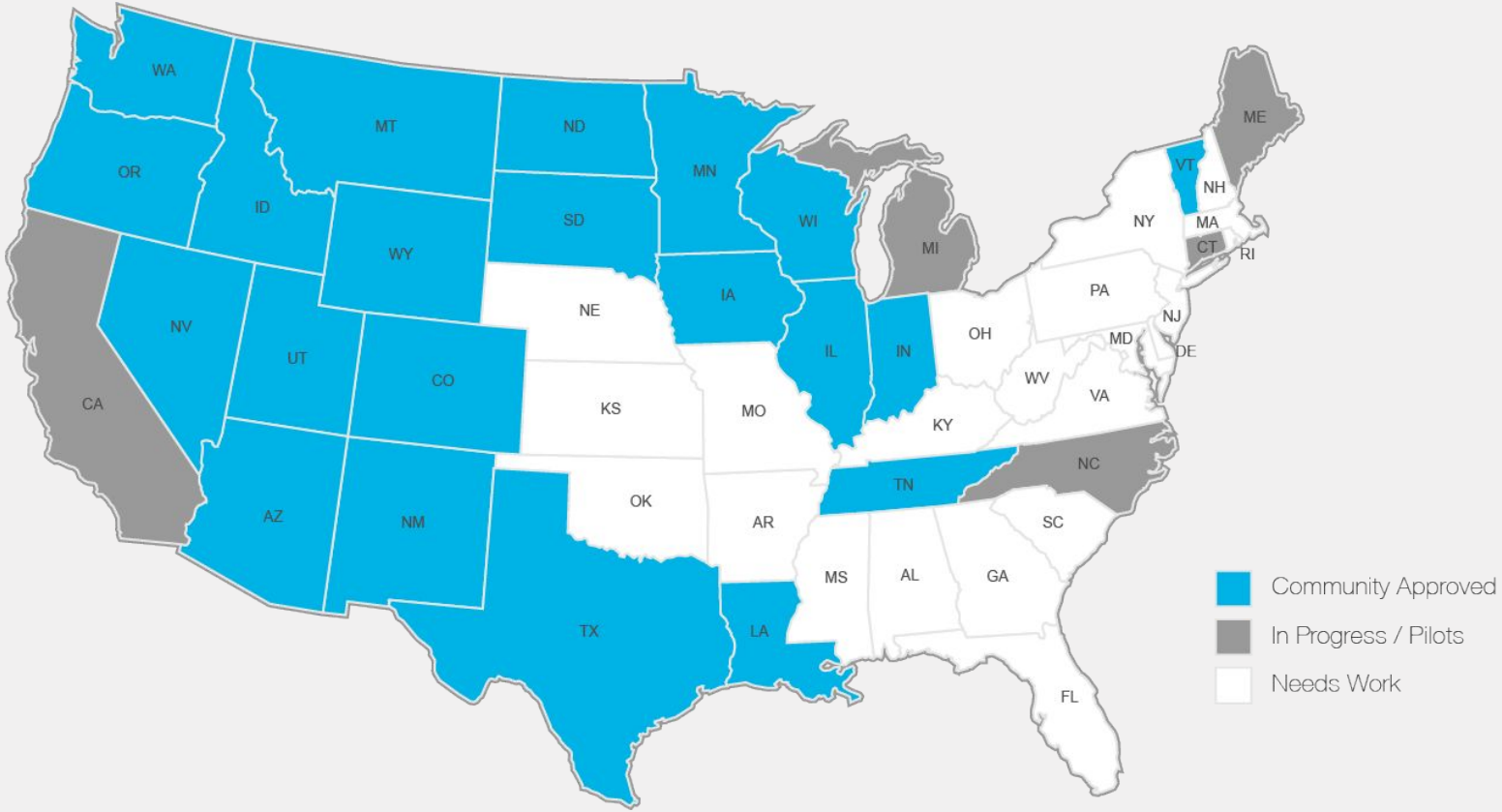
Regulatory

2008 Regulatory Environment



Source: Telepharmacy project expands across country; 9/12/2008; Dave Kolpack, Associated Press

Current Regulatory Environment



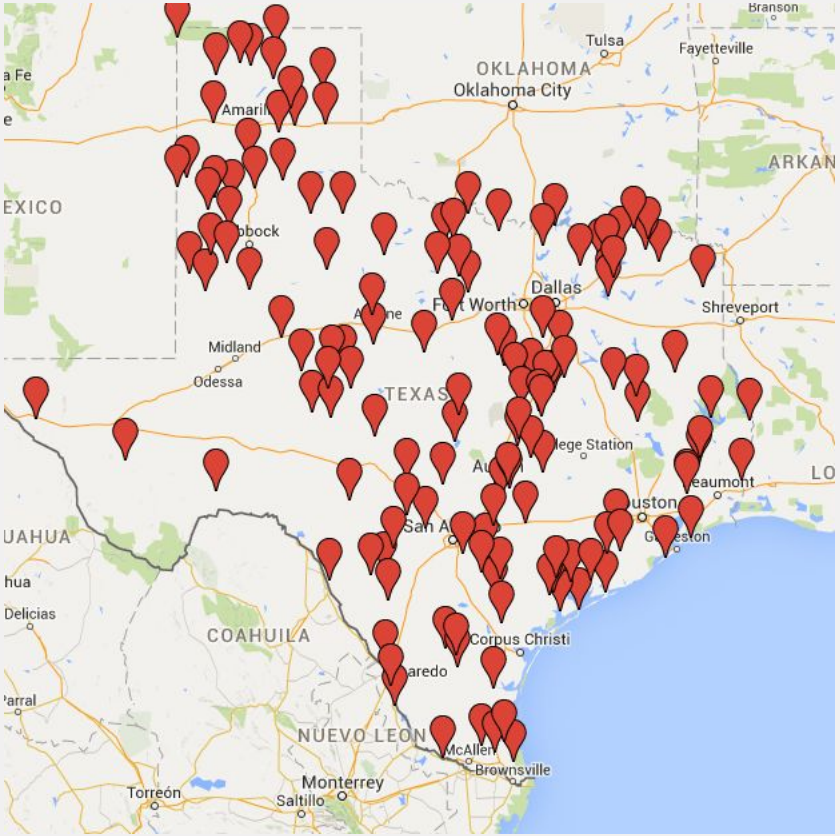
Texas Regulatory

Needs Updating!

- 291.129
- Satellite Pharmacy
  - May not store bulk drugs
  - Pharmacist must be present
- 291.121
- Remote Pharmacy
  - Only dispense unit-of-use
  - Drugs shipped from provider pharmacy
  - Original RX received at provider pharmacy

Texas Statistics

- **Over 470,000** residents in pharmacy deserts
- **584** pharmacy deserts
- **354** at-risk communities



Start Now

- Need is **increasing every year**
  - Physician Dispensing
  - Mail-Order
- Successful programs already in place
- Get ahead of the technology and legislators

Questions?

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Telepharmacy

The Pharmacy Solution for Rural America

Background

Access to a pharmacist has been shown to be highly effective in improving outcomes[1], and the closing of rural pharmacies is having a devastating effect on critical health-care services for residents living in rural areas. According to the Rural Policy Research Institute (RUPRI) 924 independent rural pharmacies closed and 490 communities lost the only pharmacy in their community between 2003-2013. In 2014 246 pharmacies closed in Texas; In 2015 there were 291 closings.

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[2], so making them more readily available should be a top priority.

Rural Pharmacy Solution

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.[3]

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

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[1] 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

[2] 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.

[3] The North Dakota Experience: Achieving High-Performance Health Care Through Rural Innovation And Cooperation. May 2008

there is an increased risk of also losing their local health provider(s). Local pharmacies and clinics are crucial in maintaining the health of citizens in smaller rural communities.

Benefits of Telepharmacy

Telepharmacy is the pharmacy solution for rural America, and has benefits for all stakeholders. These benefits extend beyond the patients to the healthcare providers and the community at large.

Patients	● Prevents traveling long distances to get prescriptions ● Provides readily available access to a pharmacist ● Establishes or maintains over-the-counter medication access ● Potentially increases medication adherence
Communities	● Increases economic development by keeping business local ● Helps attract patients to the local clinic ● Makes it easier to attract local businesses & residents
Independent Pharmacy Owners	● Significantly reduces operating costs ● Makes it possible to save existing or open new locations in underserved areas ● Reduces dispensing errors
Local Clinics	● Easier to attract/retain patient base ● Can provide full primary care services on a local level ● Ability to collaborate with the pharmacist on patient care

Pharmacy Deserts

The USDA, in the 2008 Farm Bill, defines a rural food desert as any area within a 10-mile radius without ready access to fresh, healthy, and affordable food. TelePharm uses the same methodology as the USDA to define a pharmacy desert, only with a reduced radius of 5 miles. This reduced radius is utilized because of the commuting challenges faced by the senior population predominantly served in these areas.

Texas Rural Health Landscape

Texas has 386 designated health professional shortage areas, meaning there is a lack of primary medical care, dental or mental health providers, according to the U.S. Department of Health and Human Services.

In Texas, there are 584 communities without a pharmacy and 354 “at risk” communities with only one pharmacy. There are also 145 rural pharmacy deserts that have access to a primary medical care provider. The total population of all these communities would rank it 7th in the entire state in terms of city population. As evidenced by the Zearing case study (shown below), care providers in rural communities benefit greatly and become more self sustainable when they have a local retail pharmacy.

Case Study: Zearing, IA

Zearing, Iowa is a community located in central Iowa with about 560 residents, and is committed to medical services in town. For almost 2 decades, the Story Medical Clinic located in Zearing, IA operated without a pharmacy, and patients had to drive more than 20 minutes each direction to fill their medications.

Mary O'Connor, the Nurse Practitioner at the clinic, realized how difficult this was making things not only for her practice but also for the overall health of the patients. Many patients simply left town anytime they had a medical need instead of visiting the local clinic - all because they couldn't get their prescriptions filled locally.

O'Connor finally connected with NuCara Pharmacy who agreed to open a telepharmacy in Zearing. To help speed up the process and assist with the success of the pharmacy, they invited the new pharmacy to set up and operate out of one of the exam rooms in the clinic for the first year of operation.

After the pharmacy was open for approximately one year, the space in the adjacent building had been completed and the pharmacy was able to relocate to its own storefront.

With the addition of the pharmacy to town, O'Connor has been able to attract those patients who used to leave town to come to her clinic. Not only has it been a boost to her clinic, adding an additional partner, Kelli Holland ARNP, it has also helped to re-establish a storefront on Main Street and has led to other buildings on the block being renovated.

"It's meant a lot to the people in this town," said Alyssa Young, a Certified Technician who works at the NuCara Pharmacy powered by TelePharm. "Now that the pharmacy is here they've been renovating other buildings on Main Street. In small towns like this usually you see them moving backwards in terms of growth. This was an impetus for the town to continue their growth."

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/Alumni_News2009Telepharmacy_Project_models_coop.pdf
- https://www.ndsu.edu/fileadmin/telepharmacy/RuralElectricMagazineTelepharmacyFeature.pdf

TITLE 22 EXAMINING BOARDS
PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 291 PHARMACIES
SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES

§291.121 Remote Pharmacy Services

XXX

(c) Remote pharmacy services using telepharmacy 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 healthcare facility that is not at the same location as a Class A or Class C pharmacy through a telepharmacy system as outlined in §562.110 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 or §291.31 of this title.

(A) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container for dispensing by a pharmacist to the ultimate consumer.

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

(C) 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 a telepharmacy dispensing system.

(D) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote site.

(E) Still image capture--A specific image captured electronically from a video or other image capture device.

(F) Store and forward--A video or still image record which is saved electronically for future review.

(G) Telepharmacy system--A system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

(i) audio and video;

(ii) still image capture; and

(iii) store and forward.

(H) Unit-of-use--A sufficient quantity of a drug for one normal course of therapy as determined by the pharmacist-in-charge and the prescribing practitioner(s) at the healthcare facility.

(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.

(C) The provider pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than three remote sites that are simultaneously open to provide services. An exception to the supervision limit may be granted by the board in situations where the provider has documented a need for a pharmacist to supervise additional remote sites and has demonstrated that appropriate safeguards are in place to assure proper supervision of each remote site.

(D) Before providing remote pharmacy service, the telepharmacy system at the off-site facility must be tested by the provider pharmacy and found to operate properly. 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 and this section.

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

(4) Operational standards.

(A) Application to provide pharmacy services using a telepharmacy system.

(i) A Class A or class C Pharmacy shall make application to the board to provide remote pharmacy services using a telepharmacy system. The application shall contain an affidavit with the notarized signatures of pharmacist-in-charge, and the medical director or the person

responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief operating officer), and include the following:

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

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

(III) a statement indicating that the provider pharmacy and the healthcare 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;

(IV) documentation that the healthcare facility is:

(-a-) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;

(-b-) a health center as defined by 42 U.S.C. Section 254b, as amended; or

(-c-) located in a medically underserved area as defined by state or federal law; and

(V) documentation that a Class A (Community) or Class C (Institutional) Pharmacy that dispenses prescriptions drug orders to out-patients is not located within the community, as defined in paragraph (3)(B) of this subsection, where the remote site is located.

(ii) Such application shall be resubmitted every two years in conjunction with the renewal of the provider pharmacy's license. The renewal application 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, owner, chief executive officer, chief operating officer) is not required.

(iii) On approval of the application, the provider pharmacy will be sent a registration 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 a telepharmacy 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.

(C) Environment/Security.

(i) A remote site shall be under the continuous supervision of a provider pharmacy pharmacist at all times the site is open to provide pharmacy services. To qualify as continuous

supervision, the pharmacist is not required to be physically present at the remote site and shall supervise electronically through the use of the following types of technology:

(I) audio and video;

(II) still image capture; and

(III) store and forward.

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

(iii) Drugs for use in the telepharmacy system shall be stored in an area that is:

(I) separate from any other drugs used by the healthcare facility; and

(II) locked by key, combination or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.

(iv) Access to the area where drugs are stored at the remote site and operation of the telepharmacy system shall be limited to pharmacists employed by the provider pharmacy or personnel who:

(I) are licensed healthcare providers pharmacy technicians or pharmacy technician trainees;

(II) are designated in writing by the pharmacist-in-charge; and

(III) have completed documented training concerning their duties associated with the telepharmacy pharmacy system.

(v) Remote sites shall have adequate security and procedures to:

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

(II) maintain patient confidentiality.

(vi) The provider pharmacy shall have procedures that specify that drugs may only be delivered to the remote site by the provider pharmacy and shall:

(I) be shipped in a sealed container with a list of drugs delivered;

(II) signed for on receipt by an employee of the healthcare facility;

(III) be quarantined in a locked area, if personnel designated to receive the drugs by the pharmacist-in-charge is not available; and

(IV) be checked by personnel designated by the pharmacist-in-charge to verify that drugs 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 drugs delivered.

(D) Prescription dispensing and delivery.

(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) of this title.

(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.

(iii) The following duties shall be performed only by a pharmacist at the provider pharmacy:

(I) receiving an oral prescription drug order;

(II) interpret the prescription drug order;

(III) verify the accuracy of prescription data entry;

(IV) select the drug product;

(V) interpret the patient's medication record and conduct a drug regimen review as specified in clause (iv) of this subparagraph;

(VI) authorize the telepharmacy system to print a prescription label at the remote site as specified in clause (v) of this subparagraph;

(VII) perform the final check of the dispensed prescription as specified in clause (vi) of this subparagraph to ensure that the prescription drug order has been dispensed accurately as prescribed;

(VIII) counsel the patient as specified clause (vii) of this subparagraph.

(iv) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's agent.

(v) The dispensed prescription shall be labeled at the remote site with the information specified in §291.33(c) of this title except that:

(I) the label shall contain both the name, address, and phone number of the provider pharmacy and the name and address of the remote site; and

(II) the unique identification number of the prescription on the label shall in some manner identify the remote site which dispensed the prescription using a telepharmacy system.

(vi) A pharmacist at the provider pharmacy shall perform the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed

accurately as prescribed. This final check shall be accomplished through a visual check using electronic methods.

(vii) A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as specified in §291.33(c) of this title. This counseling may be performed using electronic methods. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(viii) If the remote site has direct access to the provider pharmacy's data processing system, only a pharmacist, pharmacy technician, or pharmacy technician trainee may enter prescription information into the data processing system. The original prescription shall be sent to the provider pharmacy and a pharmacist shall verify the accuracy of the data entry.

(ix) Drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a pharmacy technician, pharmacy technician trainee, or licensed healthcare provider reconstitutes the product.

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

(i) requires continuous supervision of the telepharmacy system at all times the site is open to provide pharmacy services; and

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

(F) Policies and procedures.

(i) A pharmacy that provides pharmacy services through a telepharmacy 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:

(-a-) have access to the area where drugs are stored at the remote site; and

(-b-) operate the telepharmacy system;

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

(III) a copy of the written contact or agreement between the provider pharmacy and the healthcare facility 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;

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

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the telepharmacy system;

(-c-) sanitation;

(-d-) storage of drugs;

(-e-) dispensing;

(-f-) supervision;

(-g-) drug and/or device procurement;

(-h-) receiving of drugs and/or devices;

(-i-) delivery of drugs and/or devices; and

(-j-) recordkeeping

(ii) A pharmacy that provides pharmacy services through a telepharmacy 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 through a telepharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to electronically supervise the telepharmacy system and the dispensing of prescription drugs at the remote site. The written plan for recovery shall include:

(I) a statement that prescription drugs shall not be dispensed at the remote site, if a pharmacists is not able to electronically supervise the telepharmacy system and the dispensing of prescription drugs;

(II) procedures for response when a telepharmacy 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 medications dispensed from a remote site using a telepharmacy system in the manner required by §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 drug usage by the provider pharmacy and by 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) Patient medication records. Patient medication records shall be created and maintained at the provider pharmacy in the manner required by §291.34(c) of this title.

(D) 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;

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title, 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 at the provider pharmacy.

PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 291 PHARMACIES
SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES

§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 outlines 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.

(f) Records.

(1) Maintenance of records.

(A) Every record required to be kept and §291.34 of this title and under this section shall be;

(i) kept by the provider pharmacy and be available, for at least two years from the date of such inventory or record, 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.

(B) Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(i) the records maintained in the alternative system contain all of the information required on the manual record; and

(ii) the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(C) Prescription drug orders shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(2) Prescriptions.

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

(B) The provider pharmacy must maintain appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performed any processing at the satellite pharmacy.

(C) A provider pharmacy shall keep a record of all prescriptions sent and returned between the pharmacies separate from the records of the provider pharmacy and from any other satellite pharmacy's records.

(D) A satellite pharmacy shall keep a record of all prescriptions received and returned between the pharmacies.