Chapter Ten

Telepharmacy

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I. Introduction

The purpose of this technical assistance document is to provide valuable information and guidelines for pharmacists, rural communities, and others on how to successfully implement a telepharmacy program designed to restore and retain retail and hospital pharmacy services in communities that are located in remote medically underserved areas. Through use of telepharmacy technology, pharmacy services can be restored and retained in remote rural communities satisfying all board of pharmacy rules and regulations using the same quality standards used in traditional pharmacy practice including pharmacist prescription verification before dispensing, drug utilization review, and patient education counseling. Telepharmacy services produce the same quality of pharmacy services as the traditional mode of delivery and provide additional value-added features that are not found with traditional pharmacy practice.

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Access to quality pharmacy services is very important to the proper use of medications and to the reduction of medication errors. As modern medications become increasingly potent and capable or curing and mitigating disease, pharmacy (and involvement of the pharmacist) becomes more and more important in ensuring rational, safe, and cost-effective use of medications for the public.

Rural communities across the country are struggling with declining and aging populations, shortages of health professionals, declining access to health care and loss of local businesses. In many cases, mail order is the only pharmacy services available to the public unless they are willing to travel great distances to obtain their prescription medications. Often the poor and elderly in these communities are the least able to access and utilize mail order pharmacy services. Patients obtaining their prescriptions by mail order who have questions regarding their medications find no pharmacist to ask. Loss of access to local services sometimes necessitates patients moving to other communities to be closer to services. This can upset both their family and community life. At the same time it causes negative economic consequences for the community they leave. The resulting out migration is one of the most serious problems affecting many rural areas. Rural Health Clinics have done an excellent job of providing basic primary care to patients living in rural areas but often the pharmacy services have not followed.

One of the biggest challenges facing the profession of pharmacy today is closure of rural community pharmacies. Most of these smaller rural communities have only one pharmacy, and one pharmacist who has been faithfully serving the public's health care needs for decades. The pharmacist owners in these communities are at the age when they want to retire and sell their stores, but they are having great difficulty doing so. Rural communities have always had difficulty recruiting health care professionals to practice in the smaller towns. These difficulties are now being compounded by a nation-wide pharmacist shortage. The current pharmacist shortage has driven pharmacist salaries beyond what rural communities can afford and thus they currently have little or no chance of recruiting a pharmacist to take over the local drug store and therefore are being forced to close. For these rural communities, this is a great loss because the

pharmacist is often one of the few health care providers in the community. So by these communities losing their pharmacies they are essentially losing access to health care and over time this will have a major negative impact on the health and wellness of Rural America.

In addition to the closure of their pharmacies, rural communities are also facing severe pharmacist shortages in their hospitals. Experienced hospital pharmacists are a critical part of the hospital health care team. They bring extensive knowledge of the complex issues that arise when dealing with severely ill hospitalized patients who are on multiple medications and have complicating health factors. Attracting and keeping hospital pharmacists in rural communities is as difficult as attracting and keeping retail pharmacists. When a hospital has only one pharmacist, there is severe pressure on that individual to meet all the facility's needs. Burnout is a real problem. The rate of pharmacy staff turnover in small hospitals is twice as large as it is in large hospitals. This problem, especially when combined with the retail pharmacy shortages, presents a serious health risk for rural communities.

Telepharmacy is a unique and innovative way to deliver a full service pharmacy operation including pharmacist drug utilization review and patient education counseling at a remote rural site which incorporates all the safe practices offered by the traditional mode of delivery. Through telepharmacy, rural communities can have their pharmacy services retained or restored without a licensed pharmacist needing to be physically present in the community, pharmacy, or hospital. Potential benefits to these rural communities from telepharmacy services include: restoring access to health care, pharmacy services, and pharmacists; reducing medication errors in hospitals; bringing hospitals into compliance with state boards of pharmacy rules and regulations; providing rural clinicians with expertise in medication issues associated with special populations, such as pediatrics or patients on coagulation therapy; improving community economic development by building new businesses and adding new jobs; improving the chances of recruiting or retaining pharmacists in rural communities to practice pharmacy; and providing new clinical training sites for pharmacy students at the University and teaching

them how to deliver pharmacy services to rural communities in a unique and innovative way utilizing the latest advances in technology.

It should be stressed that this model of providing retail telepharmacy services is different than others being proposed in that it includes and retains the active role of the pharmacist as the primary health care provider in the delivery of pharmacy services. This is done to achieve the highest standard of quality for delivering pharmacy services to rural communities and is also for the protection, safety, and welfare of the public related to ensuring the proper use of pharmaceuticals. This is a value added quality assurance feature which is often lacking in other telepharmacy models that exclude pharmacist involvement resulting in no formal drug utilization review or patient education counseling. Pharmacist involvement is essential. Exclusion of the pharmacist could potentially increase risks to the patient leading to a higher incidence of medication errors, side effects, excessive drug costs, and uncontrolled disease. Examples of models which often exclude the role of the pharmacist, particularly in providing pharmacist patient education counseling, include internet pharmacies, mail-order pharmacies, delegated models which delegate the pharmacist duties to another health professional, and vending machine models.

Types of pharmacy services:

1. Traditional Pharmacy

   Most rural communities want a full service pharmacy which supplies a complete line of health related goods and services. Full service pharmacies provide a complete inventory of prescription and nonprescription drugs, including upfront merchandise such as health and beauty aids, and convenience items. Most full service pharmacies in rural areas will have an inventory of approximately 300 or more prescription drugs. Prescriptions are prepared on location in the pharmacy with the patients picking up their prescriptions at the same store they were prepared. Pharmacists provide drug utilization review and patient education counseling at the point of sale.

2. Remote Consultation Sites

In remote consultation sites, there is no prescription drug inventory at the site and it does not require a registered pharmacy technician. Twice each day a courier picks up and delivers prescriptions filled by a pharmacist at a central pharmacy site a short distance away. Prescriptions are prepared at the central pharmacy, delivered to the remote rural site and the patient education counseling is provided by the pharmacist via an audio and video computer link. This model is used by a pharmacist at a central pharmacy site who is serving a rural community a short distance away and who does not wish to manage two separate prescription drug inventories at both the central pharmacy and remote site.

3. Hospital Telepharmacy

In these locations prescriptions that are issued at rural hospitals are electronically sent to an urban medical center pharmacy, where they are reviewed, processed, and verified by hospital pharmacists. The hospital pharmacist has access to the patient's electronic medical records, and checks the prescription for proper dosing, allergies, duplication of drug therapy and drug interactions. Then the pharmacist electronically authorizes the dispensing of the prescription through a specialized Automatic Dispensing Device (ADD). The prepackaged medication is released electronically via the ADD. A nurse in the rural hospital, with password authorization to the ADD work station, double checks the medication and label, prior to administering the medication to the patient. The pharmacist at the urban medical center is able to electronically monitor the verification process and to oversee the restocking of the ADD via a videoconferencing link. The video conferencing system is also used for consultations between the patient, nurse or physician with the urban hospital pharmacist.

The ADDs used in hospital applications contain a much larger array of medications than the clinic-based ADMs described below. In addition to providing controlled

access to medications, the ADDs provide hospitals with complete inventory control. This not only aids hospitals in managing medication, but also improves their ability to bill for medications dispensed. This has proven to be a significant source of cost recovery for small, rural hospitals.

In many remote rural areas, rural hospitals are served by a local retail pharmacy. In these instances, a full inventory of prescription drugs is located at the hospital and is managed and maintained by a registered pharmacy technician with remote supervision by a licensed pharmacist at the retail pharmacy using telepharmacy technology. In these locations a registered pharmacy technician prepares the medication for final dispensing to the hospital floor, nursing home, or swing bed patient. The medication is checked by the licensed pharmacist, via the telepharmacy links, and is released (dispensed) to the floor or patient. The licensed pharmacist at the retail pharmacy signs a consulting contract with the rural hospital to deliver pharmacy services.

4. Automated Dispensing Machines

Some Rural Health Clinics may have need for an automated dispensing machine. The prescriber's drug order is provided to the licensed pharmacist at a central pharmacy site electronically or by fax. The licensed pharmacist checks the patient profile, does proper drug utilization review and then instructs the dispensing machine to release the medication. The patient is then counseled, by the pharmacist, via the audio and video computer links. Automated Dispensing Machines have limited drug inventory (i.e. generally 20 most frequently used medications) and they are usually designed for an urgent dose or first dose to get the patient initially started on their medications (i.e. initiating antibiotic treatment for infection). Patients still require the services of a traditional pharmacy to obtain their maintenance doses to complete their prescription. Telepharmacy Solutions, Inc is one vendor that supplies automated dispensing units.

II. Background

Telepharmacy in North Dakota allows the delivery of traditional pharmacy services, which include dispensing of medications and providing patient education counseling in rural communities that have lost, or are about to lose, their pharmacy.

In North Dakota a registered pharmacy technician, at the remote telepharmacy site, prepares the prescription for final dispensing by the pharmacist. The pharmacist, at the central pharmacy, checks the prescription for accuracy, and dispenses the prescription to the patient during the counseling session, using the telepharmacy, audio and video link. It is important to understand when dispensing actually occurs in telepharmacy. Dispensing of the product to the patient is always the professional function of a licensed pharmacist, and must not be delegated to the technician. As with telemedicine, nobody would define surgery as being conducted by a technician who lays the patient on the table in preparation for the physician to operate the computer assisted surgery equipment over the long distance communication link. Likewise, nobody would ever consider the radiology technician, who is assisting with the patient's scan (e.g, mobile MRI) at a remote location, to be doing the actual diagnosis of the scan. In the same manner, the dispensing of the pharmaceuticals (an important professional function in the practice of pharmacy) should not be assigned to the technician, when that duty is actually performed by the pharmacist, using the telepharmacy tools. The pharmacy technician prepares the prescription for final dispensing, and the pharmacist does the actual dispensing, at the same time the patient education is provided.

Telepharmacy has been delivered, in other states, using a remote vending model where a limited supply of prepackaged medications is stocked in a vending device. The prescriber's order is entered into the pharmacy dispensing system, verified by the pharmacist and then the pharmacist directs the release of the medication by the vending device at the remote location. In this remote vending model, patient education counseling has been the responsibility of the prescriber.

Description of Hospital Telepharmacy Service in Washington State – The Telepharmacy program in Washington State is focused on addressing the health professionals'

shortage by providing the expertise of hospital pharmacists to small, rural hospitals. In some communities, this service is used by rural hospitals that have lost a pharmacist and have not been able to hire a new one. In others, where local pharmacists are available, the Telepharmacy system is used to assure that the hospital has full 24/7 pharmacist coverage when additional pharmacists are not available.

The hospital Telepharmacy program uses integrated data networks, medication dispensing devices, order verification and video-conferencing systems to allow nursing staff at the rural facility to have complete and timely interactions with hospital pharmacists located in an urban facility and to provide pharmacist oversight of pharmacy operations. Video units are installed on computers placed in the nursing stations and at pharmacy workstations and allow for 24/7 consultation with a pharmacist.

Nursing staff at the rural hospital enter prescriptions into a central pharmacy computer system and send a scanned copy of new prescriptions to the urban hospital pharmacy, where pharmacists review the patient's laboratory data and medication profile to insure the appropriateness of the medication. The hospital pharmacist then authorizes the nursing staff to dispense the medication via the automated dispensing device. Video units are used for consults between the nursing staff, physicians, and the pharmacists, and also to allow the hospital pharmacist to oversee the restocking of automated dispensing devices.

Policies and procedures are developed to address medication order entry, review and verification processes. The procedures also address the use of a remote camera for oversight of restocking automatic dispensing devices by nurse-technicians. Additionally an educational program is used to train selected nurses within participating facilities to gain licensure as certified pharmacy technicians for purposes of order entry and restocking of automated dispensing devices under the supervision of a pharmacist.

Definitions:

A. “Remote site” means a full service pharmacy staffed by a registered pharmacy technician with access by computer, audio and video link to a licensed pharmacist at a central pharmacy site while open. The “remote site” is analogous to “originating site”, where the patient is located.

B. “Rural telepharmacy hospital” means a small rural hospital receiving full- or part-time pharmacy support from an urban hospital pharmacy or local retail pharmacy. Rural hospitals are one category of “remote site.”

C. “Telepharmacy” means a central pharmacy, either retail or associated with a hospital, with one or more remote sites in which all sites are connected via computer, audio, and video link. This is analogous to “distant site”, where the pharmacist is located.

III. Step-by-Step Guide to Creating a Successful Program

A. Starting A Telepharmacy

1. Become Familiar with the Laws and Regulations:

a. General principles & first point of contact

Pharmacy probably has more laws and rules in every state than any other area of health care. A careful analysis of existing state and federal laws and rules related to operating a pharmacy is necessary. In order to operate a telepharmacy program, the state must have laws and rules in place for allowing telepharmacy services to operate in the state, and the remote site must be properly licensed with the State Board of Pharmacy.

The State Board of Pharmacy should be the first point of contact when considering establishing telepharmacy services to ensure that the current rules and regulations allow this type of pharmacy to operate within the state,

and also to ensure that any future plans for establishing telepharmacy services are in full compliance with state law. The State Board of Pharmacy will provide the proper process to follow for officially applying for a telepharmacy permit.

b. License Application

The application for telepharmacy permit must be processed by the licensed pharmacist in charge of owning the businesses of both the central pharmacy and remote telepharmacy sites. In addition to the state license, the applicant must also obtain registration numbers from the National Council for Prescription Drug Programs (NCPDP - formerly NABP number) and the federal Drug Enforcement Administration (DEA). It is important that the licensed pharmacist obtain State Board of Pharmacy, NCPDP, and DEA registration numbers for each remote telepharmacy site which are separate from the central pharmacy site registration. The State Board of Pharmacy, NCPDP, and DEA registration numbers for both the central pharmacy and remote telepharmacy sites are not only important for operating legally within the state, but they also are needed for obtaining reimbursement from third party payers for telepharmacy services. The regulatory approval process may vary depending upon each state's rules and regulations and it may take 2-3 months or longer for approval of the telepharmacy operating permits.

For telepharmacy services that are based in a hospital pharmacy, a new license may not be necessary. In Washington State, the state board of pharmacy approved the program and is notified as each new site is added. In North Dakota, where rural hospitals are generally served by local retail pharmacies, the rural hospital receives its normal Class B permit from the board of pharmacy along with a Subclass K permit to operate a telepharmacy. The local retail pharmacy which serves the rural hospital receives its normal Class A permit along with a Subclass K permit for operating a telepharmacy service to the hospital.

c. Third Party Reimbursement

The North Dakota approach to telepharmacy programs mimic “business as usual”. The telepharmacies feature the same full service pharmacy operation as a traditional pharmacy. They are supervised by a licensed pharmacist; they are approved and licensed by the ND State Board of Pharmacy, NCPDP, and DEA; and satisfying all ND Board of Pharmacy requirements for the practice of pharmacy. In North Dakota, the remote telepharmacy sites are currently receiving reimbursement by third party payers for services rendered to patients.

Once the State Board of Pharmacy, NCPDP, and DEA registration permits are obtained, the remote telepharmacy site is eligible for third party reimbursement claims.

For the rural telepharmacy hospital program, dispensing of medication occurs at the facility where the patient is hospitalized. These hospitals submit claims for patient care, and reimbursement practices are not affected. The central Telepharmacy operation receives its funding from the participating rural hospital sites, which enter into a contractual agreement and pay fees to the Telepharmacy program for the services they receive.

d. Some specific state issues:

As of June 2003, North Dakota has telepharmacy laws and rules to allow a qualified pharmacy technician to operate a telepharmacy at a remote location under the technology-driven supervision of a licensed pharmacist. Nebraska has a delegated dispensing model which delegates the prescription processing function to non-pharmacist health professionals. Washington has a rule which allows remote dispensing devices, and obtained approval from its state Board of Pharmacy to allow pharmacy technicians to restock the remote dispensing devices under video-

conferenced supervision by a licensed pharmacist. Arizona has approved off-site verification of prescriptions, which should make telepharmacy easy. Other states, such as Minnesota and Iowa, approve telepharmacy requests on a case by case basis. The state of Texas is currently conducting a pilot program in implementing telepharmacy services to the western portion of the state. Alaska is currently conducting a demonstration project supported through HHS to bring medication to two remote, previously underserved communities, through the use of remote drug dispensing machines.

Once a state has its laws and rules in place for allowing telepharmacy services to operate in the state, and the remote site is properly licensed with the State Board of Pharmacy, plans can proceed to develop and implement the services.

2. Assess the Need

Rural communities require careful assessment to determine the need for, and the feasibility of, telepharmacy services. Questions need to be answered related to: Are pharmacy (and pharmacist) services currently available in the community? Is there health personnel in the community authorized to prescribe medications (i.e. medical clinic or other health facility) sufficient to support a telepharmacy operation? Is there a convenient cost-effective location to establish telepharmacy services? Is there support for establishing telepharmacy services from the: community, medical personnel, State Board of Pharmacy, local government and businesses, patients, telecommunications company, and pharmacists in the area ? Is there a licensed pharmacist in the area willing to establish and deliver telepharmacy services to the targeted rural community? Has a business plan been developed to assess the projected expenses and revenue necessary for the proposed telepharmacy services can be profitable and sustainable? Are there

sufficient resources available via private, local, and state support to establish such services?

When considering establishing a rural telepharmacy hospital program, a different set of questions should be asked. In particular is the nursing staff of the rural hospital willing to support a telepharmacy program? Is the hospital willing to invest in the technology necessary to support the program, and to pay fees to the central hospital telepharmacy? Is the State Board of Pharmacy willing to allow video conferencing technology as a mechanism for pharmacist oversight of nursing staff?

3. Develop Community Partners

Several community partners are needed to effectively implement telepharmacy services in rural areas. In selecting prospective communities for telepharmacy services, it is important to consider the following issues: community need, interest, and investment in the project; availability of a pharmacist at a central pharmacy site in a nearby community willing to deliver telepharmacy services to the remote site; and support from the State Board of Pharmacy. Priority should be given to those rural communities who have no pharmacy services or who are about to lose their pharmacy services. This will maximize the benefit of telepharmacy services to rural areas and minimize any potential conflict in local pharmacies competing for business.

In determining the level of support for telepharmacy services and defining the scope of services needed in the targeted community, feedback from the following project partners may be beneficial:

1. Individual Patients
2. Senior Citizen Groups
3. Rural Health Clinic Personnel
4. Community Business leaders
5. Local Community Leaders

6. Local Government Officials
7. Pharmacist Practicing in the area
8. State Board of Pharmacy Administrator
9. State Pharmaceutical Association
10. School of Pharmacy

As with retail telepharmacy services, rural communities where the hospital has no pharmacy services or is about to lose those services should be prioritized. If the community has some retail pharmacy capacity, the advocates of the hospital telepharmacy program should communicate with the retail pharmacists to keep them informed and to minimize any potential concerns over competition. These educational efforts should extend to others in the community with an interest in hospital operations, including hospital boards and advisory groups, ombudsmen, senior citizen groups, and labor organizations.

4. Secure a Physical Location

a. Criteria to consider for location of retail telepharmacy services:

1. Convenient Access for the Public
2. Proximity to other Health Clinic Facilities
3. Proximity to Nursing Homes
4. Leased after Development by Local Communities
5. Owned by the Central Pharmacy
6. Leased for the Rural Health Clinic, if present.
7. Lease space in an existing business.
8. Technology Transmission or Connectivity Capabilities in the Community (DSL, T-1 lines available?)

State Board of Pharmacy rules and regulations pertaining to building, security, sanitary standards, and private consultation rooms must be considered in plans for the physical location of the pharmacy. Many

pharmacy wholesalers have departments to assist in pharmacy layout and designs. The area drug wholesaler generally keeps up with the current rules and requirements of the State Board of Pharmacy and they can be an excellence resource for developing construction plans for the pharmacy physical facility.

b. Criteria to consider for starting hospital telepharmacy services:

Hospitals need space convenient to nurses' workstations on patient floors and within the ER to locate automatic dispensing devices and fixed video equipment. The hospital pharmacy must also have space for fixed video equipment. The space around the automatic dispensing device should allow sufficient room for a cart with mobile video equipment, to allow remote supervision of staff loading medications into the dispensing device. All locations where telepharmacy equipment will be placed must be able to be wired for video conferencing connectivity.

Many hospitals already use video conferencing systems and bandwidth requirements should be assessed before implementing telepharmacy services. The concurrent use of multiple video conferencing units within a facility, even with Quality of Service (video packet prioritization) deployed, can cause network congestion if not configured properly.

B. Planning Construction

1. Retail Telepharmacies

a. Design

After the needs assessment is confirmed, design experts at the drug wholesaler will draw plans. The licensed pharmacist at the central pharmacy site will also assist in this stage of development. Once plans are developed, they should be submitted to the State Board of Pharmacy for review and approval.

b. Fixtures

Drug Store fixtures are available through most drug wholesalers or through companies specializing in these areas. Prices can be bid, or previous projects can be consulted, to determine reasonable prices. Used fixtures can sometimes be obtained through the sale or renovation of a local pharmacy store in the area. Drug fixtures for an average size pharmacy may cost $20,000 or more.

c. Inventory

Inventory always requires capital. The up front store merchandise can be stocked and ordering done as demand is assessed. Prescription drug inventory can be expensive. Purchases should initially be conservative and based on expected demand. Generally for a rural community pharmacy, prescription drug inventory may cost between $60,000-80,000 depending on the brands that are stocked. Factors such as frequent deliveries from the drug wholesaler, the ability to move merchandise between the central pharmacy and the remote telepharmacy site, and limiting inventory/potential losses can help control costs. The licensed pharmacist at the central pharmacy, in consultation with area drug wholesalers, will be able to assist with the initial set-up and management of the telepharmacy store merchandise and prescription drug inventory.

Telepharmacy technology is very new, so prices are generally high, but should decline as demand increases. Telephone companies in rural areas seem the most reluctant to lower transmission costs. Transmission costs are often higher when the central pharmacy and the remote site are not being served by the same telephone company. In North Dakota the DSL lines may cost approximately $250 per month (512 K bandwidth), and T-1 lines are considerably more expensive and may cost up to $800 per month (1.544

mbps bandwidth). Prices will vary depending on location, competition, demand, and vendor.

d. Information Technology Considerations

i. Computer

A traditional full service pharmacy has a computer system installed with a specially designed pharmacy operations software (many software vendors are currently available on the market including QS-1, Midco Data, PDX, Rx30, IsoRx and others) which assist pharmacists in dispensing prescriptions to patients. This pharmacy operations software performs functions such as establishing a patient medication profile; screening for drug interactions, generating prescription vial labels with patient instructions, and billing third party payers.

In the telepharmacy model, a computer system containing the same pharmacy operations software is located and fully integrated at both the central pharmacy site and remote telepharmacy site. This allows the pharmacist at the central pharmacy to access the patient medication profile at the remote site, and allows the pharmacist to perform a prospective drug utilization review by computer on each prescription before it is dispensed to the patient. This technology set-up also allows the pharmacist the flexibility to work from either location (i.e. the remote telepharmacy or the central pharmacy site) to process the prescription order. This often occurs, as many of these operations will have only one pharmacist on duty at a time. The pharmacist may want to visit the telepharmacy site on some days and work from there, with the technician at the central site performing the role of the telepharmacy technician.

The technology hardware needed is the same for both the central pharmacy and remote telepharmacy sites including a standard PC with

512 Meg of RAM, 18 inch color monitor, read/write CD with DVD, 3.5 disk drive, speakers, microphone/headset, modem, and printer. This computer system costs approximately $2,000. However, it should be noted that a telepharmacy vendor may dictate the specifications of the PC.. Since the central pharmacy already has a pharmacy computer system, only one additional set-up is needed for the remote telepharmacy site. The cost of the pharmacy operations software may vary depending on the vendor but many can be purchased in the $5,000-$7,500 price range.

ii. Video

This is an important part of the telepharmacy system. The video allows the pharmacist at the central pharmacy site to see the finished prescription, which was prepared by the technician at the remote telepharmacy site. The picture from the digital camera is of sufficient quality to allow the pharmacist to read the prescriber's hand written prescription, the label of the manufacturer's original drug container, the label of the prescription vial handed to the patient, and even zoom in and read the identification code on the individual tablet or capsule. These digital pictures of the prescription processing function can be stored on the computer hard-drive or writeable CD for later recall or they can be printed and filed with the original prescription. This type of documentation provides important quality assurance to validate that the prescription was filled correctly. This prescription validation process is another unique value added feature of telepharmacy operations and is not currently seen or utilized with traditional pharmacy services.

There are several different vendors on the market for video-conferencing. One of our sites began using Microsoft NetMeeting ® as its video conferencing system, where the pictures were projected directly onto the pharmacist's computer monitor. This system was a continuous video, which allowed the pharmacist to continuously monitor the technician's

work if they wished. This exceeded the Board of Pharmacy requirements for the telepharmacy rules in allowing constant communication with the technician. However, when the patient education counseling was performed by the pharmacist, the picture was of poor quality. In addition, patients did not feel comfortable talking with the pharmacist on a computer monitor. This video conferencing system was later replaced by a Polycom-FX H.323 Viewstation with a 20" Sony WEGA television monitor which produced a higher quality picture to allow pharmacists to effectively counsel patients on proper use of their medications. This Polycom system costs approximately $6,500. Two video conferencing set-ups were needed, one for the central pharmacy and one for the remote telepharmacy site.

Polycom has several videoconferencing systems to choose from. The Polycom – SP, FX, and VSX models are just a few of the choices. The SP model is the most basic and least expensive, and the other models have more features which allows for additional connections to a VCR or other equipment. The SP model allows for only point to point videoconferencing. The Polycom-FX and VSX models are more expensive but have the greatest features and capabilities including the ability to add up to 4 sites to be connected simultaneously. Depending on the features for videoconferencing equipment can range between $3,500 – $15,000 or more. Any of these units will work in delivering telepharmacy services and there are other manufacturers to consider such as Tandberg and Sony.

Another remote site initially used a hand held digital camera for their pictures and then transmitted them by setting the camera in a cradle device and downloading them into the telepharmacy system. This provided good quality but proved to be too slow to be practical. This was later replaced by a fully integrated live or real time document camera which is capable of capturing pictures for instant viewing through the

telepharmacy system by the licensed pharmacist at the central pharmacy site. This later set-up proved to be far more efficient and convenient.

In addition, it should be recognized that the audio/video conferencing system can share the same network connectivity as the the pharmacy operations software. This is the most cost effective way of providing connectivity for both applications. However, if the network is interrupted for any reason, both systems will cease to function until the network problem is resolved. Since prescriptions are being processed continuously throughout the day it is imperative that the prescription processing system remain on-line. Therefore, it is highly recommended that a parallel network be developed, so that the prescription processing system can remain on-line in the event of a video conferencing network failure (e.g., separate DSL connection, dial-up modem connection, etc). The importance of network redundancy for telepharmacy can not be overstated.

iii. Transmission

Both the pharmacy computer data and the video conferencing signal can be transmitted over the Internet using DSL lines at 512 K bandwidth. However, because DSL typically operates with different upload and download speeds, the quality of service cannot be guaranteed. Unfortunately, there is no way to know in advance whether the transmission will be acceptable or not. On occasion, when the service has been disrupted between sites preventing the pharmacist from using the video conferencing system, the pharmacist calls the remote site by telephone and the patient consultation is done by phone.

Dedicated T-1 lines would be the ideal transmission mode for delivering telepharmacy services and would eliminate the problem of service distortion or disruption from heavy Internet use. However, in North Dakota

the high cost prohibits their use for retail telepharmacy at this time, unless an existing dedicated T1 network is being used. As demand for telepharmacy services increases, the cost of dedicated T-1 lines may become less of a barrier. Additionally, one site in North Dakota recently negotiated with its local telephone company to purchase a fraction of a T-1 line (512 K bandwidth) for only $150 per month for both connections (central and remote site). This was $100 less than what most DSL lines cost. So it is wise to shop around for best prices on both technology and transmission.

Plain Old Telephone Service (POTS) lines connected via a 56 K modem can also be used for transmitting data when rural communities do not have the technology infrastructure in place to support DSL or T-1 lines. However, using POTS lines causes a significant slow down in the speed with which the pharmacist can process prescription orders because modem placed long distance calls are needed each time communication between the sites is desired. This significantly reduces the operational efficiency of the pharmacist and pharmacy services being offered.

iv. Security of Information – HIPAA Compliance

Since telepharmacies transmit personal and health related information on patients over the Internet via DSL lines, security of information becomes a concern. New federal requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 have established standards for privacy and security of individually identifiable health information regarding electronically transmitted information on patients. It must be stressed that all pharmacy systems including telepharmacy operations must be in full compliance with the new federal HIPAA standards. Care must be taken to ensure the privacy and security of all electronically transmitted health information on patients.

Telepharmacy systems can be secured by installing a VPN (Virtual Private Network)/firewall, a small piece of equipment about the size of a DVD player, at both the central pharmacy and remote telepharmacy sites. The VPN at each site encrypts all information between endpoints and that protects the privacy of the information over the Internet. Some older Polycom videoconferencing systems require the addition of a VPN to make them HIPAA compliant when operated over the commodity Internet. However Tandberg and the newer Polycom units can be deployed with AES encryption which would make them compliant with HIPAA without the need for additional VPN hardware, and when operated over the public Internet. If dedicated T-1 lines are used, they are already secured for privacy by the fact that they do not typically link to the Internet. A VPN/firewall system costs approximately $600. Two units are needed, one for the central pharmacy and one for the remote telepharmacy site.

In summary, patient confidentiality and HIPAA compliance are assured at all telepharmacy operations with DSL/VPN systems using encrypted information for all information transmitted over the Internet. Business Associate Agreements should be obtained for all contractors who handle transmission of patient information, and for hardware and software suppliers who may have access to patient information. Patient Consent Agreements, approved by the Institutional Review Board for the Protection of Human Research Subjects at the University are needed for the collection of any patient specific data for evaluating the project.

2. Hospital Telepharmacies

The majority of the construction, cost and technology issues cited above for retail telepharmacy programs are the same for rural telepharmacy hospital programs. However, there are some distinct differences. Because hospital telepharmacy programs are implemented in facilities with existing pharmacies, necessary fixtures and inventory should already be in place.

One caveat is that rural telepharmacy hospital programs require the use of unit dose packaging. Nurses only deal with unit doses of medication that they load into or dispense from the automated dispensing devices. The hospitals will either have to begin purchasing medications in unit dose form, or will have to arrange for a pharmacy technician or a local retail pharmacist to repackage medications into unit dose form.

Redesign of existing rooms should not be necessary, provided that adequate space is available for the videoconferencing and automated dispensing equipment.

Because of the need for sharing patient information, the rural and the urban hospitals participating in a telepharmacy program will either need to utilize the same hospital information system or to establish an interface between the systems that they operate. This will allow the urban hospital pharmacist access to the medical records for the patients in the rural facility, a necessary step in verifying the appropriateness of the prescription.

3. Central Pharmacy

Although the majority of the construction plans for telepharmacy services generally focuses on the remote site, the central pharmacy also often requires some remodeling. Special consideration should be given for ensuring that sufficient space is allocated for a private patient consultation room to accommodate the patient education counseling equipment. Careful planning and placement of the telepharmacy technology is important and can significantly assist the pharmacist in running a smooth and efficient pharmacy operation. The pharmacist must have quick and convenient access to all necessary telepharmacy equipment including the pharmacy computer system, document camera, and video conferencing system to properly and efficiently serve the remote site. The pharmacist must have the ability to go back and forth between checking prescriptions in the traditional pharmacy,

while monitoring, checking, and counseling via the telepharmacy connections. If a central pharmacy has multiple remote telepharmacy sites which it serves, it may be necessary to have a full-time pharmacist on staff whose job is dedicated to verifying prescription orders and counseling patients at the remote telepharmacy sites.

A central hospital pharmacy that is taking on a telepharmacy program needs to consider expanding its staff to support multiple remote sites. This is especially important in assuring that the remote sites have 24/7 coverage. Additional space and equipment may be necessary in the central pharmacy to support these additional personnel.

C. Personnel Considerations

1. Pharmacy Technician

The responsibilities of the pharmacy technician at the remote telepharmacy site include maintaining the prescription drug inventory and completing all aspects of the drug dispensing process. Activities include but are not limited to: (a) obtaining the prescriber's written prescription order from the patient or taking the order from the prescriber by phone; (b) computer drug order entry; (c) product selection, preparation, packaging and labeling; (d) third party billing; (e) operating the telepharmacy technology to connect the audio and video link to the licensed pharmacist at the central pharmacy site; (f) providing digital pictures of: (1) the written prescription order by the prescriber, (2) the manufacturer's original drug container, (3) the actual tablet or capsule for proper tablet/capsule identification, and (4) the technician generated prescription label for the patient; (g) obtaining the final check of the dispensed product from the licensed pharmacist; and (h) assisting the patient in the use of the telepharmacy technology for the pharmacist

education counseling. A step by step protocol is provided for processing new prescriptions and prescription refills.

The pharmacy technician is, perhaps, the most important element in the telepharmacy program. Without well trained pharmacy technicians, in which the profession of pharmacy has confidence, telepharmacy will have no chance of surviving in any state. The pharmacist is ultimately responsible and liable for what happens to the patients receiving the service. In addition, the prescribers who are expected to communicate prescriptions to the pharmacy technician must be comfortable and confident in their abilities, to transcribe the prescription correctly. The public must also be comfortable and establish trust in working with the pharmacy technician, as their personal contact at the remote telepharmacy site.

Since the pharmacist in this model is delegating a significant amount of responsibly to the pharmacy technician at the remote telepharmacy site, it is critical that the pharmacy technician has appropriate qualifications and training to handle the job. For this reason, the North Dakota Board of Pharmacy has established higher standards for pharmacy technicians working in remote telepharmacy sites than those established for technicians working in traditional pharmacies where the licensed pharmacist is physically present in the store. To work in a remote telepharmacy site, pharmacy technicians are required to be registered by the Board of Pharmacy and have at least one year of work experience in prescription processing as a North Dakota registered pharmacy technician. The pharmacy technician must also have graduated from an American Society of Health Systems Pharmacists (ASHP) accredited program or have received other equivalent training which demonstrates knowledge and experience in preparation of prescriptions for dispensing and working with patients. Reciprocity of

pharmacy technicians from other states requires Pharmacy Technician Certification Board Examination (PTCB certification), as well. Technician PTCB certification is voluntary in North Dakota. North Dakota requirements for a pharmacy technician exceed PTCB standards. All North Dakota registered pharmacy technicians are required to complete 20 hours of continuing education every two years.

During the development of the telepharmacy rule in North Dakota, some thought the pharmacy technician should have an associate of applied science degree from an ASHP accredited school to qualify for work in a remote telepharmacy site. However, such criteria had the potential to create an environment where recruiting a technician would have been as difficult as recruiting a pharmacist to a remote site. In negotiations it was decided to allow a graduate of an ASHP accredited program or equivalent, with one year of experience, to serve as a remote pharmacy technician. This is a high standard in itself, but has served to provide the necessary confidence of the pharmacists, the prescribers, the public, and the profession. Recruitment of pharmacy technicians is still a challenge for the remote telepharmacy sites. In many cases, hourly rates of up to $15.00 per hour or more were needed to attract qualified technicians to these sites. This rate is typically $5-7 per hour more than what urban markets in North Dakota pay for pharmacy technicians.

In situations where a qualified pharmacy technician cannot be recruited to relocate to a remote rural telepharmacy community, an alternative may be to identify someone who already lives in the targeted rural community and deliver an established pharmacy technician training program to them via distance education. This training must take place at the central pharmacy site. The North Dakota State College of Science in Wahpeton North Dakota has an ASHP accredited pharmacist-assisted technician training module program, which can be completed on the job, at the central pharmacy site. After completion of the program and one

year of experience, the registered technician is ready to work at the remote telepharmacy site. Since pharmacy technicians at the remote telepharmacy sites are without the services of a pharmacist at the site, it is extremely important, and cannot be stressed enough, that these individuals need to be properly trained for performing their duties in delivering safe and effective telepharmacy services to rural residents. Training programs used for telepharmacy technicians should be reviewed and approved by the State Board of Pharmacy prior to their implementation.

In the rural telepharmacy hospital program, nurses administer the physician-ordered medications after authorization by a licensed pharmacist at the central hospital pharmacy. In Washington, this is already within the nurses' scope of practice. Additional training and certification is necessary for nurses who restock the automated dispensing devices. The Washington State Board of Pharmacy has permitted nurses to take this on, under the video supervision of licensed pharmacists, provided that the nurses obtain pharmacy technician certification. The Washington program includes training for nurses to assist them in obtaining this certification and filling this role.

2. Licensed Pharmacist

The primary responsibilities of the pharmacist at the central pharmacy site are to provide professional consultative services to the remote telepharmacy site for all prescriptions dispensed at the remote site. These activities include but are not limited to: (a) performing a final check of the prescription prepared by the technician; (b) performing a complete drug utilization review on the patient's medication profile; and (c) performing the mandatory patient education counseling. <u>The pharmacist must remain responsible for all professional aspects of the patient's care, even though greatly assisted by the pharmacy technician.</u>

It is necessary for the pharmacist at the central pharmacy site to have experience in working with pharmacy technicians. The pharmacy technician will be managing the inventory at the remote site, so the pharmacist must have complete confidence and trust in the pharmacy technician's abilities. The pharmacy technician will be preparing the complete prescription for the final check by the licensed pharmacist. Once the prescription is verified by the pharmacist, the pharmacy technician must convince the patient to enter the counseling room, sit down before the television monitor, and be counseled by the pharmacist. This requires an ability to work with people. The personal confidence of the pharmacy technician is very important. They must perform all required tasks, while still feeling comfortable to ask questions whenever verification is needed. A pharmacy technician who pretends he/she knows everything and can do everything can be very dangerous. It must be stressed that the pharmacy technician must rely upon and be dependent on the pharmacist for all non-technical professional aspects of pharmacy practice.

Licensed pharmacists at central pharmacy sites have been very excited and quite positive about delivering telepharmacy services to another rural community. Pharmacists are enjoying the benefits of telepharmacy services such as: the ability to expand their businesses by accessing additional patients; the additional revenue from increased prescription sales (telepharmacy has increased prescription sales in the combined operation by as much as 40-50% in several locations); allowing pharmacists in rural practices to take a day off or a vacation by having someone cover their store from another location; and allowing expansion of pharmacy store hours on weekends without having to add additional staff. Pharmacists are also optimistic that telepharmacy will help enhance their current business environment and make their store

more attractive, which will ultimately increase their chances of selling the pharmacy, when they are ready to retire.

Pharmacists at central pharmacy sites, however, have expressed concern regarding the extra workload they have experienced resulting from delivering telepharmacy services. This workload problem appears to be significant, especially when central pharmacies have more than one remote site to manage. Telepharmacy rules in North Dakota allow a pharmacist to manage up to four remote telepharmacy sites. Due to the increased workload, one of the central pharmacy sites (which manages two remote telepharmacy sites) has hired an additional pharmacist (0.8 FTE) to assist with the extra workload. The decision whether or not to add more pharmacists to the workforce is left up to the licensed pharmacist store owner at the central pharmacy site who is ultimately responsible and accountable to the Board of Pharmacy for ensuring the safe practices.

Similarly, urban hospitals taking on a telepharmacy program need to assure adequate staffing. Since urban hospital pharmacies are already operating on a 24/7 basis, new swing-shift staff should not be necessary. However, if the urban hospital is providing full-time pharmacy services to multiple rural sites, additional staff will likely be needed.

D. Patient Considerations

It is important that patients are comfortable with the telepharmacy technology prior to receiving services. Consideration should be given to formally marketing the telepharmacy concept to the public prior to implementing services. Proper information and education of the patients and public can assist in alleviating any questions or concerns regarding how it works and what it looks like, including the similarities and differences between telepharmacy services and traditional pharmacy services. This

can help the patients and public feel more comfortable and willing to use the services. Special attention and consideration should be given to orientation and education of senior citizens who have not been exposed to, or do not have, extensive experience with technology. Once they have been walked through the system, shown how things work, and have a chance to use the equipment, they generally accept this high tech approach to delivering pharmacy services. Headphones can be helpful for those seniors who have hearing impairments and printed material can assist those who have difficulty in seeing the television monitor. On occasion a patient has been reluctant to talk to the pharmacist over the television monitor and in these situations the pharmacist calls the patient and discusses their medications with them via telephone.

Patient acceptance of telepharmacy services has been very good. Patients living in remote rural communities that have not had pharmacy services for sometime are generally the most enthusiastic and accepting of the telepharmacy technology. Patients are generally more hesitant to use this technology in rural communities that have had traditional pharmacy services and where telepharmacy is deployed to retain these services. However, once patients get their first exposure to telepharmacy, they are generally quite accepting of this approach to delivering pharmacy services. Patients also appear to be more hesitant in communicating with the pharmacist through a computer monitor than they are through a standard television, probably because they are familiar with and exposed to television at home. Patients unwillingness to participate in patient education counseling via telepharmacy services is not any different than that observed with traditional pharmacy practice. With either telepharmacy or traditional pharmacy service, luring the patient into the consultation room for their first counseling session has always presented a challenge for practicing pharmacists. Patient resistance to being counseled appears to play more of a factor than their inherent fear of using technology. Pharmacists need to work on

changing patient expectations and behaviors related to mandatory patient education counseling so that patients learn to expect it as a routine part of pharmacy practice regardless of the mode of delivery.

Since patients entering remote telepharmacy sites do not have a pharmacist at the site, we must stress the importance of the patient interaction with the pharmacist prior to leaving the pharmacy. In North Dakota as an additional quality assurance measure, all patients at remote telepharmacy sites are required to speak to the pharmacist prior to leaving the pharmacy with their prescriptions to ensure that they know and understand the proper use of their medications. Pharmacists at the central pharmacy site must perform patient education counseling on all telepharmacy patients at the remote site. This is a part of the rules and regulations established by the State Board of Pharmacy for telepharmacy operations in North Dakota. This patient consultation requirement exceeds the standards set for traditional pharmacy services by federal law (i.e., OBRA'90) which requires a pharmacist to offer education counseling to the patient, but the patient can decline. In telepharmacy operations, the patient must be counseled by the pharmacist or the patient does not receive their medications at the remote site. This is another value added feature of telepharmacy services, not currently seen or practiced in traditional pharmacy settings.

In the rural telepharmacy hospital program, patients have access to their physicians and nurses, but should be encouraged to consult with the licensed pharmacist via videoconferencing if they need additional information.

E. Quality Assurance

The licensed pharmacist at the central pharmacy site should establish written policies and procedures related to the delivery of telepharmacy services to

ensure the safe and effective distribution of pharmaceutical products and patient care for the central pharmacy and remote telepharmacy sites.

The licensed pharmacist at the central pharmacy site should also conduct ongoing review of incident reports and outcomes related to the delivery of telepharmacy services and keep records of appropriate corrective action taken when necessary, to ensure that there is no abnormal frequency or trends of errors occurring in dispensing drugs or devices to patients.

The licensed pharmacist at the central pharmacy site is responsible for the care of the patient and the final product prepared by the pharmacy technician at both the central pharmacy and the remote telepharmacy sites. Regular visits to the remote telepharmacy site by the licensed pharmacist at the central pharmacy site are required and should be at least monthly.

The State Board of Pharmacy should make periodic inspections of the central pharmacy and remote telepharmacy sites to ensure their compliance with all state and federal laws and rules related to the practice of pharmacy.

In North Dakota, the North Dakota State University College of Pharmacy is conducting research, relative to patient satisfaction and utilization of telepharmacy services by the community. These survey tools are available and can be adapted for use by others.

IV. Useful References

Telepharmacy Rules. North Dakota Century Code 61-02-08. North Dakota State Board of Pharmacy, Rules and Regulations for Practicing Pharmacy, http://www.nodakpharmacy.com/NDBP/law/law-01-31-03.pdf

Peterson CD, Anderson HC. The North Dakota Telepharmacy Project: Restoring and Retaining Pharmacy Services in Rural Communities. J Pharm Technol. 2004 Jan-Feb; 20:28-39.

Lordan D, Vorhees N, Richards C. Telepharmacy offers hope for rural hospitals. National pharmacist shortage prompts innovative approach to hospital-based services in Washington state. Telemed Today. 2002 Oct-Nov; 9(3): 13-15.

Keeys CA, Dandurand K, Harris J, Gbadamosi L, Vincent J, Jackson-Tyger B, King J. Providing nighttime pharmaceutical services through telepharmacy. Am J Health Syst Pharm. 2002 Apr 15; 59(8):716-21.

Bynum A, Hopkins D, Thomas A, Copeland N, Irwin C. The effect of telepharmacy counseling on metered-dose inhaler technique among adolescents with asthma in rural Arkansas. Telemed J E Health. 2001 Fall; 7(3): 207-17.

American Society for Health-System Pharmacists. Focus group on telepharmacy. Am J Health Syst Pharm. 2001 Jan 15; 58(2): 167-9.

Kate, D. Late-night telepharmacy service an asset to hospitals. Drug Topics. 2001; 16:22.

Thigpen AR. The evolution of telepharmacy: a paradigm shift. J Healthc Inf Manag. 1999 Winter; 13(4): 89-94.

Angaran DM. Telemedicine and telepharmacy: current status and future implications. Am J Health Syst Pharm. 1999 Jul 15; 56(14): 1405-26.

Pharmacy Automation Online. Automated Dispensing Technologies: Directory of Vendors. http://www.pharmacyautomation.com/vendors.html

V. Sample Protocols (next page)

STEP BY STEP PROTOCOL FOR
PROCESSING NEW PRESCRIPTIONS
AT REMOTE TELEPHARMACY SITE

New Prescription is received by Pharmacy Technician from:

Patient	Prescriber
Written prescription	phone/fax/computer
[Some pharmacists prefer the prescription be faxed to the central pharmacy for entry.]	[Some pharmacists prefer calls to come to the central pharmacy]

[In North Dakota it is permitted for the pharmacy technician to perform these functions if allowed by the pharmacist]

IF PATIENT IS KNOWN	IF PATIENT IS NOT KNOWN
Verify Insurance	Get demographic/Allergy info
Any new allergies	Insurance / Family history
	Disease status

Verify prescription has all required elements:

Non-controlled substance	controlled substance
NDAC 61-04-06-02	61-04-06-03

Is prescription readable and understandable?
A N Y Questions - contact pharmacist

Enter prescription into the computer patient profile
Pharmacist performs drug utilization review:

No Allergies or Drug-Drug/ Drug-Disease Interactions:	Allergies Drug-Drug/ Drug-Disease Interactions: Contact pharmacist for verification

Proceed to select correct product
Prepare prescription for dispensing & label proper use instructions
Bill through insurance- Clear any 3rd party problems (early refill etc.)
Final check performed by pharmacist
Seat patient in consultation room
Connect patient to pharmacist via audio/video link
Place filled prescription on table in front of patient
Pharmacist performs patient education counseling - Dispensing takes place here
Bag /Package prescription including written product information (PPI's)
Complete financial transaction

Thank you / come back soon

STEP BY STEP PROTOCOL FOR PROCESSING REFILL PRESCRIPTIONS AT REMOTE TELEPHARMACY SITE

Patient requests refill

No Insurance changes ?

Pharmacy Technician processes prescription through computer

No refills remaining
Contact prescriber for refill request

Any drug alert:
Notify the pharmacist

Prepare prescription for dispensing
When ready for final check – contact pharmacist

Final check performed by pharmacist

Invite patient to talk to the pharmacist (not required for a refill)

If patient accepts:

Seat patient in consultation room

Connect patient to pharmacist via audio/video link

Place filled prescription on table in front of patient

Pharmacist performs patient education counseling - Dispensing takes place here

Bag /Package prescription including written product information (PPI's)

Complete financial transaction

Thank you / come back soon