



**Building a
consistent
approach across
broad enterprises**

an interview with
R. Brett Short

“ Most importantly, wear your boots; it is not a matter of if you step in “it,” but when you do, you’ve got to be prepared. ”

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VOLUME 20, ISSUE 8

by Benjamin M. Daniels, Esq. and Alexandra B. Shalom, Esq.

Key considerations in telepharmacy compliance

- » Telepharmacy is on the rise in the United States.
- » There is no single definition or delivery model of telepharmacy.
- » Licensure of pharmacies and pharmacists is critical in telepharmacy.
- » Analysis of state law compliance is critical.
- » Understanding which conflicting laws to follow is a challenge.

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In 2016, US retail pharmacies filled more than 4 billion prescriptions, which does not include prescriptions filled in other pharmacy settings such as nursing homes or hospitals.¹ That number may seem staggering, but more sobering statistics from the United States Centers for Disease Control (CDC) estimate that: (1) between 20% and 30% of new prescriptions are never filled, and (2) medications are not taken as prescribed 50% of the time.²

Failure of patients to obtain medication, or failure to take medication as prescribed, can lead to increased complications and adds costs to the healthcare system that far outweigh the cost of the prescribed drugs. The gap between medication therapy prescribed and medication therapy actually dispensed and administered appropriately presents an important challenge for coordination of patient pharmacy care and medication adherence. A growing, but not new, approach to closing this pharmaceutical therapy gap is the adoption of a number

of pharmacy service delivery models loosely referred to as telepharmacy.

The concept of telehealth is far from new to pharmacies and pharmacists. The pharmacist-patient relationship was traditionally built on long-term trust and cooperation among pharmacists, prescribers, and patients. The relationship was often local, with the pharmacy serving as an institution in patients' health-care experience. Pharmacists are traditionally available to patients for consultation in the pharmacy, or with a simple phone call to answer any questions about prescription labeling or tricky administration issues.

The growth of large chain pharmacies has altered the pharmacist-patient relationship and has even led to gaps in pharmacy access for patients (e.g., rural or medically underserved areas that lack easy access to nearby pharmacies). As such, the healthcare industry is turning to telepharmacy solutions as a safe and effective means to facilitate pharmaceutical care of patients. Further, telepharmacy offers opportunities to insert the pharmacist into collaborative



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practice by making pharmacists more accessible to prescribers and other clinical providers involved in patient care. Although these innovations facilitate access to care for an increased number of patients, additional compliance complexities must be considered when thinking about telepharmacy services.

What is telepharmacy?

A definition of telepharmacy is somewhat elusive due to the largely disjointed regulation of the practice of pharmacy from state to state (discussed below). At its highest level, telepharmacy is the remote delivery of pharmaceutical care via telecommunication pathways and devices. The National Association of Boards of Pharmacy (NABP) defines telepharmacy in its Model Act and Rules as “the practice of pharmacy by registered pharmacies and pharmacists located within US jurisdictions through the use of telepharmacy technologies between a licensee and patients or their agents at distances that are located within US jurisdictions...”³ Various methods of telecommunications include text messaging, email, video conferencing, or personal or in-pharmacy devices and telephone.⁴ The NABP defines telepharmacy technology as “secure electronic communications, information exchange, or other methods that meet applicable state and federal requirements.”⁵

The broad scope of the clinical services that make up the practice of pharmacy provide a number of different opportunities to use telepharmacy approaches to improve the delivery of pharmacy care. For example, Grand River Hospital, a rural 13-bed critical access hospital in western Colorado, recently established an arrangement to have PipelineRx-employed remote pharmacists verify prescriptions, perform drug utilization review, and answer clinical questions before an automated dispensing machine prepares and dispenses the prescribed medication.

The approach saved the rural hospital about \$300,000 in staffing costs, while allowing for 24-hour pharmacy service for its patients.⁶

The actual practice of telepharmacy varies widely based on care delivery models and applicable state rules and regulations. The Grand River Hospital example may not be an option in every state. The first step to ensuring compliant operation of a telepharmacy program is to turn to applicable state law.

Telepharmacy and pharmacy licensure

All pharmacy providers must comply with the state licensure requirement for state(s) where they practice, even when the practice is conducted remotely. This is complicated in the world of telehealth when providers, such as pharmacists, are providing telepharmacy services to patients located in other states. In these situations, the pharmacy and (sometimes) at least one pharmacist may need to be licensed in the patient’s state. In addition, pharmacies that offer interstate mail-order services need to be licensed not only in the state where the facility is located, but also in the state where the prescription drugs are ultimately dispensed. For example, Georgia requires any person, pharmacy, or facility located outside the state to obtain a non-resident pharmacy permit prior to shipping, mailing, or delivering dispensed drugs in Georgia.

Most other states require out-of-state pharmacies to obtain some form of pharmacy license or permit to dispense to patients. The NABP Model Act and Rules is enlightening on this challenge of multi-state pharmacy practice: “the practice of telepharmacy is deemed to occur within the jurisdiction in which the patient is located and the jurisdiction(s) in which the pharmacist and, if applicable, pharmacy are located; therefore, such practice will be subject to the pharmacy practice regulations of all jurisdictions’ boards of pharmacy.”⁷

Analysis is necessary to determine if the proposed business and/or clinical telepharmacy operation constitutes the practice of pharmacy in each applicable jurisdiction. It is important to note that the act of dispensing is not necessarily determinative of whether a telepharmacy operation constitutes the practice of pharmacy. For example, the practice of pharmacy in Texas is defined to include, among other acts:

providing an act or service necessary to provide pharmaceutical care; interpreting or evaluating a prescription drug order or medication order; participating in drug or device selection as authorized by law, and participating in drug administration, drug regimen review, or drug or drug-related research...[and] providing patient counseling...⁸

Thus, the act of counseling a patient on their prescriptions in Texas would require a domestic or non-resident license, even if there were no drugs dispensed to patients. The nuances of varying state laws with regard to pharmacy licensure are a key first consideration for ensuring compliance in all applicable jurisdictions. Compliance professionals should work closely with their legal counsel to assess applicable laws and regulations.

Some state telepharmacy-specific laws

According to a 2017 study conducted by the Rural Policy Research Institute Center, 23 states have authorized retail telepharmacy for “delivery of pharmaceutical care to outpatients at a distance through the use of telecommunication and other advanced

technologies.”⁹ Typically, this involves dispensing medication to patients without direct contact between a licensed pharmacist and the patient.

In contrast, states including Alabama, Florida, Georgia, New York, and Rhode Island do not have rules or legislation specifically authorizing the use of retail telepharmacy. Some states limit the scope of telepharmacy services. For example, Tennessee only allows telepharmacy in Federally Qualified Health Centers, and Connecticut only permits telepharmacy for the purpose of dispensing sterile products in hospitals.

Other states have not established uniform rules to regulate telepharmacy. For example, Nebraska has authorized the use of telepharmacy but has not enacted any implementing rules or regulations. The Minnesota Board of Pharmacy grants waivers for individual telepharmacies on a case-by-case basis. A key challenge in multi-state telepharmacy practice surrounds

The nuances of varying state laws with regard to pharmacy licensure are a key first consideration for ensuring compliance... an attractive option.

the question of which state’s laws govern the operation of a pharmacy. Is it the state where the pharmacy is located or the state where the prescription is ultimately dispensed? Unfortunately, there are no easy answers to these questions, and conflicts in pharmacy laws often arise. For example, Illinois does not impose specific pharmacist to pharmacy technician ratio requirements. In contrast, South Carolina has a strict ratio that it often imposes on non-resident pharmacies hailing from states (like Illinois) that do not have such a ratio.¹⁰

Although the National Alliance for Model State Drug Laws drafted a Model Prescription Drug Monitoring Act, rules surrounding prescription drug monitoring programs (PDMP)

vary by state as well.¹¹ The many variations include which drugs are specifically monitored and reportable under state PDMPs. As of 2016, only 34 states and the District of Columbia collect data on Schedule V drugs in addition to Schedule II-IV.¹² Pharmacy compliance is largely variable from state to state, and proper analysis of any proposed telepharmacy strategy is advisable. State Boards of Pharmacy and their staff are very helpful in identifying solutions when a pharmacy is faced with conflicting laws in a multi-state dispensing scenario.

Some examples of telepharmacy services

Pharmacies are using a variety of telepharmacy models and programs to facilitate ease of use for patients, caregivers, and providers.

Mail order pharmacy model

A traditional example of telepharmacy practice is that of mail order pharmacies that interact with prescribers and patients in an entirely remote manner. The mail order pharmacy receives the prescription from the prescriber via fax, electronically, or by some other telecommunication means. The pharmacist conducts usual and customary drug utilization review with the patient (or reviews the patient's information), then dispenses to the patient via common carrier. For example, upstart pharmacy Pillpack coordinates all of a patient's medications and mails a customized, pre-sorted package of drugs and vitamins to the patient each month. Pillpack further helps patients manage chronic health condition by tracking medication adherence and coordinating refills and renewals.¹³

Adherence programs

Some companies provide adherence-focused programing through telepharmacy. These services involve pharmacists or trained pharmacy technicians periodically contacting patients to ensure they are taking their prescriptions

properly and not encountering adverse side effects. For example, certain drugs will cure Hepatitis C, but the cost is high and the drug schedule must be strictly followed. As such, insurance companies covering these drugs often require that their members opt in to a counseling and consistency program to ensure that patients are complying with the prescription instructions. Aspects of these telepharmacy adherence programs may require state pharmacy and pharmacist licensure. Therefore, any proposed remote adherence programs should be analyzed against applicable state pharmacy practice laws to determine if the program rises to a level of pharmacy practice that would require pharmacy and/or pharmacist licensure and supervision.

Patient counseling

Some telepharmacy models use technology such as mobile applications or kiosks to facilitate patient- or caregiver-pharmacist communications. For example, Walgreens is partnering with New York-Presbyterian to offer customers remote access to doctors through its website and self-service kiosks.¹⁴ Some states require that pharmacies affirmatively offer patients counseling when picking up their prescriptions. This is often satisfied by asking patients if they have any questions for the pharmacist.

However, when mailing drugs to patients out of state, pharmacists should be aware of heightened requirements. For example, Illinois requires pharmacists to provide verbal counseling to patients before dispensing new prescriptions.¹⁵ This obligation can be challenging for pharmacies that operate on a telehealth platform, due to challenges in actually connecting a pharmacist with the patient prior to dispensing a prescription. Compliance professionals should take steps to ensure that pharmacies meet these obligations under applicable state law.

Pharmacist-to-pharmacist consultation

Similarly to patient counseling, telepharmacy allows pharmacists to consult with one another. This is especially critical if a pharmacy faces limited pharmacist staffing. This form of telepharmacy is subject to fewer regulatory compliance concerns than patient counseling. Companies like PiplineRx and Omnicare offer pharmacist-to-pharmacist consulting as a core element of their remote telepharmacy and telepharmacy consulting services.

Remote pharmacy processing

Some pharmacies conduct their processing services remotely to maximize efficiency and provide services to additional patient populations. For example, North Dakota was the first state to allow retail pharmacies to dispense without a pharmacist being physically on site. The North Dakota Telepharmacy Project allows pharmacists to remotely oversee dispensing performed by pharmacy technicians at these rural facilities. Today, there are 81 pharmacies participating in the North Dakota Telepharmacy Project.¹⁶

Connecting pharmacists to care management

Another approach to telepharmacy is to provide technology and systems that better connect the pharmacist to the patient's care management team. Because pharmaceutical care is important to the overall management of chronic conditions, it follows that the integration of the pharmacy and pharmacist is critical. At the same time, hiring pharmacists on a full-time basis is often out of reach for many provider settings, making remote

arrangements with pharmacies and pharmacists an attractive option. Similar to concerns with pharmacy licensure, an important compliance consideration is to review applicable state practice of pharmacy regulations to determine any necessary pharmacy and/or pharmacist licensure to participate in these arrangements.

DEA, FDA, and other federal compliance considerations

From a federal perspective, both the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) regulate pharmacies. The DEA imposes obligations on pharmacies that dispense controlled substances, including registering with the DEA. Another obligation is "Corresponding Responsibility," which is an obligation specifically imposed on the pharmacist who fills a prescription. If a pharmacist fills a prescription that is not issued in the usual course of professional

...hiring pharmacists on a full-time basis is often out of reach for many provider settings, making remote arrangements...

treatment or in legitimate and authorized research, it is an invalid prescription and the pharmacist who knowingly dispensed such a prescription is liable.¹⁷ Corresponding Responsibility becomes a heightened concern for the pharmacist filling prescriptions when the prescriptions are issued in another state with different prescription requirements. Compliance professionals should take precautions to ensure that telepharmacy operations maintain appropriate policies and procedures to ensure compliance with applicable federal controlled-substance regulations.

Telepharmacies must also be aware of federal obligations in the overall drug supply

chain. Under the Federal Drug Supply Chain Security Act (DSCSA), “dispensers” are obligated to follow product tracing and verification requirements.¹⁸ For the purpose of the DSCSA, a dispenser:

means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.¹⁹

Dispensers are required to verify their drugs and receive product tracing information prior to or at the time of a transaction. On March 1, 2018, the Food and Drug Administration issued two guidance documents clarifying these requirements under the DSCSA. One guidance document discusses the interoperable exchange of tracing information between different levels of participants in the drug supply chain to help standardize the tracing process.²⁰

The other guidance defines “suspect products” and “illegitimate products” that dispensers are required to verify.²¹ DSCSA compliance can become particularly challenging for telepharmacy operations with remote dispensing capability. Compliance professionals must ensure that proper tracking and inventory of regulated pharmaceutical products accounts for these dispersed inventory locations.

Conclusion

Telepharmacy is a growing area that offers exciting solutions for coordinating patient pharmaceutical care. However, there is no uniform model of telepharmacy, which broadly

includes operations and services such remote pharmacy processing/dispensing, adherence programs, patient counseling, and mail order pharmacies. As such, pharmacies and pharmacists must be aware of varying state laws, including licensure requirements, when implementing telepharmacy programs. Ultimately, once these compliance requirements are satisfied, telepharmacy services show promise in closing the concerning gaps between the medication therapies prescribed, medications dispensed, and patient adherence. ©

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