Telepharmacy Offers Convenience, Poses Challenges

Not many years ago, telepharmacy might have been defined as conducting pharmacy business over the telephone – the pharmacist answering a question, for example. With the explosion in communication technology, however, it has come to refer to everything from electronic prescribing in its many variations, to videoconferences that allow the pharmacist to dispense and counsel a hundred miles away from the patient, to Internet sites that facilitate prescription purchases, to the equivalent of automated teller machines (ATMs) that allow patients to pick up their prescriptions in or outside of a pharmacy. While these technologies offer tremendous opportunities for patients and for those interested in promoting the public health, they likewise pose challenges to regulators struggling to take advantage of innovation while maintaining strict standards to protect patients' well-being and privacy.

In its report issued in early 2005, NABP's Committee on Law Enforcement/Legislation (LE/L Committee) for 2004-2005 recommended amending the Association's *Model State Pharmacy Act and Model Rules* to define the "practice of telepharmacy" as "the provision of Pharmaceutical Care by registered pharmacies and pharmacists located within US jurisdictions through the use of telecommunications and technologies to patients at a distance that are located within US jurisdictions."

Beyond the general definition, the ever-increasing and changing permutations of telepharmacy are now requiring state boards of pharmacy to examine their regulations and policies. Moreover, they must also increasingly take into account interstate issues, as implementation of the federal Medicare Prescription Drug, Improvement, and Modernization Act continues to push states toward a common standard for e-prescribing. State boards have had – and are having to – decide how best to protect the public health by encouraging or discouraging the initiatives taking place throughout the world of pharmacy practice.

Increasing Access

The golden promise of telepharmacy lies in its ability to potentially increase access to health care for those patients currently unserved or underserved. The LE/L Committee, in its 2005 report, recommended "that the practice of telepharmacy be restricted to areas that are considered medically underserved or as the Board deems appropriate." The Committee noted some of the driving factors behind the move toward telepharmacy, including "an increasing geriatric population, difficulties in attracting health care professionals, and the closure of existing rural pharmacies."

At the same time, telepharmacy has the potential to hold down some costs in a health care industry in which prices seem to spiral out of control. It appeals to state officials seeking to promote and protect the public health; it also offers benefits to health care systems such as that of the Veterans Health

Administration (VA). As pharmacist Kristie L. Carevic and her colleagues noted in a brief evaluation of a VA pilot program that used telepharmacy to monitor patients on long-term anticoagulation treatment, "Telemedicine using Internet-based, two-way interactive audio/visual technology holds the promise of making high-quality health services more accessible and acceptable to remote patients and less costly to their managed care organizations."

With the current pharmacist shortage heavily impacting rural areas, states with large rural populations have made particular efforts to institute regulations that take advantage of telepharmacy and harness it for its greatest effectiveness. North Dakota in particular has received much attention in recent years for its comprehensive and innovative program to restore and retain pharmacy services throughout the state.

In 2001, the North Dakota State Board of Pharmacy passed rules that allowed a pilot telepharmacy project, established in cooperation with the North Dakota State University (NDSU) College of Pharmacy and the North Dakota Pharmacists Association, to go forward. In 2002, the NDSU College of Pharmacy obtained a federal grant from the Department of Health and Human Services' Division of Health Resources and Services Administration, Office for the Advancement of Telehealth that funded the pilot program of four central pharmacy sites and six remote telepharmacy sites.

The North Dakota Board established permanent telepharmacy rules in 2003. The NDSU College of Pharmacy obtained a second and then a third year of federal grant funding to assist pharmacies with program equipment costs, and telepharmacy continued to expand. As of September 2005, 17 central pharmacy sites were serving 33 remote sites, and the Minnesota Board of Pharmacy was allowing the telepharmacy project to work across its shared border with North Dakota.

Under the rules, a central pharmacy may have responsibility for up to four remote sites. Each remote site is staffed by a registered pharmacy technician who has constant access to the central pharmacy and its pharmacists via a computer, video, and audio link. In addition, the technician must have graduated from an approved pharmacy technician education program and have at least one year of experience as a registered pharmacy technician in North Dakota. This link allows the pharmacist at the central pharmacy to observe and communicate with the technician as he or she prepares the prescription for dispensing by the pharmacist, and to check the prescription and label as normal. The patient must receive a face-to-face, real-time consultation via these links with the pharmacist on all prescriptions – new or refilled – before they are dispensed. "Satellite consultation sites" are also permitted, where prescriptions previously prepared by the pharmacist at the central pharmacy wait for pickup; regular store clerks are authorized to guide patients to the videoconferencing equipment for the required consultation.

By all accounts, the project has been an overwhelming success. According to the NDSU College of Pharmacy, "Approximately 40,000 rural citizens have had pharmacy services restored, retained, or established through the North Dakota Telepharmacy Project since its inception. The project has restored valuable access to health care in remote medically underserved areas of the state

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and has added approximately $12 million in economic development to the local rural economy."

North Dakota is not the only state to aggressively pursue a telepharmacy project. Many state boards have addressed or are addressing the issue of telepharmacy in some form or other.

Texas is another state that has been at the forefront of the telepharmacy movement. Legislation in that state was passed in 2001, permitting remote dispensing via audio and video links. In that state, specific restrictions were placed on the location of these remote sites; telepharmacy services are allowed only in medically underserved areas as defined by state or federal law. "Telemedicine and telepharmacy are not panaceas, they're tools," says then-state Senator (and bill sponsor) Mike Moncrief, currently mayor of Fort Worth. "They should complement, not replace, traditional hands-on, face-to-face consultations." Nonetheless, most public safety officials see telepharmacy as preferable to mail order when ensuring access to prescription medications.

Increasing Convenience

Yet another form of telepharmacy – perhaps more accurately referred to as remote dispensing and/or verification – is arising in the name of increased customer convenience as well as increased access. Often touted in the press as the pharmacy equivalent of an ATM, kiosks that accept prescriptions and others that dispense them are appearing in a number of states throughout the country. When placed in or around community pharmacies in areas of high urban concentration (for example, Southern California or New York City), they are touted specifically as a time-saving convenience for drug store customers. Proponents argue that they do not endanger the public health and, moreover, that they allow overextended pharmacists to spend more time with the patients who most need attention and counseling.

Two manufacturers, Asteres Inc and Distributed Delivery Networks Corp (DDN), are producing substantially similar kiosks. Typically, a customer must register to use the device. After the patient submits a refill request in the usual way, often by phone or computer, the pharmacist fills it as normal and, if no counseling is indicated, places the labeled package in the kiosk for a later pickup. When the patient arrives to pick up the prescription, he or she logs onto the system with a user name and password, swipes a credit or debit card to pay, and the appropriate prescription package drops into the bin for retrieval.

California has become the most widely publicized pioneer in the pharmacy kiosk area. The California State Board of Pharmacy granted a waiver in October 2004, to authorize Longs Drug Stores to install and use 24-hour prescription drop kiosks at its pharmacies. It also waived requirements that

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In agreeing with FDA, the court rejected the arguments of Vermont that the "certification" requirement of the MMA only applies to commercial importations, not individual importations. The court stated that the Vermont argument that the certification requirement was somehow bifurcated was "convoluted and implausible." The court held that the only plausible reading of the statute is to apply the certifications requirement to the whole applicable section of the MMA.

Similarly, the court rejected the argument of Vermont that the certification requirement improperly delegates legislative power to the Executive Branch. Vermont had asked the court to declare unconstitutional that section of the MMA and sever it from the statute. The state argued that if the certification section of the MMA were severed from the statute, it would authorize the commercial and individual importation from Canada.

The court held that the MMA establishes an "intelligible principle" to which the secretary of HHS is directed to conform in certifying safety and costs to Congress. As such, the MMA does not improperly delegate legislative authority. In addition, the court opined that the certification provisions of the MMA were vital to the act and, even if there was merit to Vermont's argument, such provisions could not be severed.

Based upon these and other findings, the court dismissed the Vermont complaint and closed the case on this matter. This opinion represents an essential recognition of the FD&C and its impact upon state initiatives that may not conform to the federal laws. More to come.

State of Vermont v Leavitt, Case No. 2:04-cv-206 United States District Court for the District of Vermont, decided September 19, 2005.

a pharmacist be present when a prescription is dispensed, allowing Longs to install and use what the Board termed an "automated self-service delivery unit" that allows patients access to their refill prescriptions during and after pharmacy hours. Longs unveiled its first prescription kiosk several months later. In the meantime, the Board has granted several other waivers, including to Safeway and Walgreen Co, as well as to the University of California at San Diego, which will conduct a study on the kiosks' impact on pharmacies and consumers.

The California Board of Pharmacy granted the waiver permitting the dispensing kiosk on several conditions, including that the device be used only for refilled prescriptions, though not in cases where the pharmacist feels that patient consultation is warranted; that the kiosk be located "in reasonable proximity" to the licensed pharmacy premises; that it be able to identify the patient and release only that patient's prescriptions; that consultation with a pharmacist be available upon request; and that the patient must "opt in" in order to use the kiosk. The Board has proposed a permanent rule change to permit the devices; a decision is expected from the California Office of Administrative Law in early 2006.

The introduction of prescription drug kiosks has met with some resistance among pharmacists, who fear that they further erode patient care and the face-to-face interaction already threatened by the Internet and mail order pharmacies. Indeed, a group of pharmacists represented by the Pharmacy Defense Fund, a California-based legal foundation, filed suit against the California Board to contest the waiver. "The Board would not have passed or approved the waiver if we felt it impacted patient safety," Patricia F. Harris, the Board's executive director, told *The San Francisco Chronicle*. A second fear is that stores will use the technology as a way of cutting costs by cutting pharmacist hours. Those in favor of kiosks argue that pharmacists must still prepare all the prescriptions, and that the swift pickup of prescriptions not requiring counseling allows pharmacists to spend more time with the patients who do need it. Companies currently installing the kiosks say that they have no plans to cut pharmacist positions.

Virginia and Hawaii have also reportedly issued waivers allowing the pharmacy kiosks. The New York Board of Pharmacy, too, is consulting with its legal counsel to determine whether or not a dispensing device that opened in a Kmart in Penn Station is permitted under existing regulations. "We're looking at it now," says Lawrence H. Mokhiber, the Board's executive secretary. "We're hoping to resolve the situation in the near future." He mentioned restrictions similar to the California Board's; the prescriptions would need to be refills and not require counseling, for example, and could not include controlled substances.

Another type of kiosk has been introduced in New York in the past year or so as well. It receives rather than dispenses prescriptions. This device transmits prescriptions to pharmacies to be filled and picked up there, an activity that fits under existing regulations, says Mokhiber. Introduced by New York pharmacy chain Duane Reade, the kiosks use document-scanning and video conference technology to allow customers to scan in paper prescriptions and consult live with a pharmacist. The customer may then pick up the filled prescription from a pharmacy (handing over the paper prescription at that time) or have it sent by mail. "In the event of any technology to transmit a prescription, the fundamental thing we look at is that the patient *must* have freedom of choice," says Mokhiber. In other words, the patient must be able to choose the pharmacy where he or she sends the prescription for filling. In other ways, however, transmitting kiosks generally fit much more easily under existing regulations than those devices that dispense.

NABP Actions

While each board of pharmacy must grapple with the telepharmacy issues most relevant to the realities in its state, NABP continues to offer guidance.

NABP last convened a task force to discuss telepharmacy and electronic prescribing issues in 1996. At the Association's 2004 Annual Meeting, it was resolved that NABP should revisit the issue. Resolution No. 100-3-04 states "that NABP revise the *Model State Pharmacy Practice Act and Model Rules of the National Association of Boards of Pharmacy* concerning the electronic transmission of prescriptions as a separate provision, and in consideration of the evolving practices of telepharmacy, the central processing of prescriptions, and remote dispensing."

Moreover, among the recommendations listed in its report, NABP's 2004-05 LE/L Committee advised "that the Executive Committee commission a task force to examine the evolving practices of telepharmacy in the context of the regulatory issues that the state boards of pharmacy are being asked to define and address." The Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions met as this issue of the *NABP Newsletter* was going

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to press. Its charge is to review "existing state regulations in regard to the practice of telepharmacy and consider the need for developing model legislation/regulations to address the provision of pharmacist care across state borders that may result from the implementation of the medication management therapy provisions of the Medicare Drug Benefit." The Task Force's report will be available in 2006.

Telepharmacy also took center stage at the December 4 continuing education session at NABP's Fall Educational Conference in Sunny Isles Beach, FL, December 2-4, 2005, "Telepharmacy, Remote Dispensing/ Verification, and Automated Dispensing Devices: Increasing Access to Pharmacist Care Initiatives." It covered the regulatory challenges and opportunities inherent in telepharmacy, and examined various technologies specific to telepharmacy and remote dispensing/verification. Included in the discussion was the topic of automated dispensing devices remote from the pharmacy as well as kiosks located within the pharmacy.

Sponsorship Provides Pre-NAPLEX Vouchers to Schools and Colleges of Pharmacy

NABP, through sponsorship from GlaxoSmithKline, is providing each school and college of pharmacy in the United States that has final-year PharmD candidates with three vouchers to sit for the Pre-NAPLEX®. The Pre-NAPLEX is a practice examination developed by NABP to familiarize candidates with the North American Pharmacist Licensure Examination™ (NAPLEX®) experience.

Distribution of the vouchers shall be at the discretion of each individual school and college of pharmacy.

To redeem their voucher, recipients may register for the Pre-NAPLEX at www.pre-naplex.com and enter their voucher code.

The Pre-NAPLEX was introduced in May 2003 and is currently utilized by 40% of NAPLEX candidates. At the conclusion of each practice examination, candidates receive a scoring estimate of how they may perform on the NAPLEX. Like other practice examinations, a candidate's score on the Pre-NAPLEX is similar to what he or she can expect to receive on the NAPLEX, but may not be the actual score attained, nor is it a guarantee of passing the actual examination.

102nd Annual Meeting Travel Grant Offered

NABP is pleased to announce that it will again offer a travel grant to voting delegates for its 102nd Annual Meeting, held April 8-11, 2006, at the Westin St Francis in San Francisco, CA. This year the maximum reimbursement for the Annual Meeting Travel Grant Program has been raised to $1,000. For more than 100 years, the Association's mission has been to aid and support pharmacy regulators in creating uniform standards that protect the public health. It is for this reason that NABP believes Annual Meeting attendance to be of high importance, for it is during the Annual Meeting that Association policies and priorities are voted upon, Executive Committee members and officers are elected, and members are provided with educational opportunities regarding current issues facing pharmacy regulators.

NABP realizes that budget limitations can prevent state boards of pharmacy from sending representatives to meetings. As such, the Annual Meeting Travel Grant Program will reimburse designated voting delegates up to $1,000 in travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. Monies are limited and grants are available on a first-come, first-serve basis. Grant monies do not include Annual Meeting registration fees.

Grant applications may be obtained by contacting NABP Headquarters and must be received at NABP Headquarters prior to the Annual Meeting. NABP will inform applicants whether or not they have qualified for the grant, which is made possible by Pfizer Inc, prior to the event.