

ASHP Statement on Telepharmacy

Position

ASHP believes appropriately trained and equipped pharmacists can use telepharmacy to remotely oversee pharmacy operations and provide distributive, clinical, analytical, and managerial services. ASHP advocates that telepharmacy be applied to suitable functions of pharmacy operations and patient care to improve patient outcomes, expand access to healthcare, and enhance patient safety. ASHP further advocates that boards of pharmacy adopt compatible regulations that enable the use of United States-based telepharmacy services within and across state lines for appropriate practice settings and that further research be conducted to establish best practices for telepharmacy.

Background

Telemedicine. The Centers for Medicare & Medicaid Services (CMS) describes telemedicine as a means for improving a patient's health by permitting two-way, real-time interactive communication between a patient and a healthcare provider who are geographically separated. This communication is conducted via interactive telecommunications equipment that includes, at a minimum, audio and video equipment, to meet standards for telehealth set by the U.S. Department of Health and Human Services.¹ It is important to recognize, however, that telemedicine is a rapidly evolving field and that new methods of telecommunications, such as texting and mobile applications, are already in use. Standards for interactive telecommunications equipment that include text and binary data must address interaction both

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with and without audio and video. The U.S. Food and Drug Administration (FDA) has established definitions, standards, and methodologies for mobile medical applications.²

Definitions of telepharmacy. The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) defines the “Practice of Telepharmacy” as “the provision of pharmacist care by registered pharmacies and pharmacists located within U.S. jurisdictions through the use of telecommunications or other technologies to patients or their agents at distances that are located within U.S. jurisdictions” and provides definitions of related terms (i.e., coordinating pharmacy, remote pharmacy, remote dispensing site).³ For the purposes of this document, ASHP defines telepharmacy as a method used in pharmacy practice in which a pharmacist utilizes telecommunications technology to oversee aspects of pharmacy operations or provide patient-care services. Telepharmacy operations and services may include, but are not limited to, drug review and monitoring, dispensing, sterile and nonsterile compounding verification, medication therapy management (MTM), patient assessment, patient counseling, clinical consultation, outcomes assessment, decision support, and drug information.

PAI. The ASHP Practice Advancement Initiative (PAI) states that “sufficient pharmacy resources must be available to safely develop, implement, and maintain technology-related medication-use safety standards.”⁴ It further recommends that telepharmacy technology should be available for use in pharmacy departments “to enable remote supervision” and to “allow pharmacists to interact with patients from a remote location.”⁴

Telepharmacy applications

Telepharmacy has demonstrated value in medication selection, order review, and dispensing; intravenous (IV) admixture verification; patient counseling and monitoring; and clinical services.⁵ Telepharmacy may be especially useful in supporting settings that perform medication-use activities when a pharmacist is not physically present or pharmacy resources may be limited, such as geographically isolated ambulatory clinics and healthcare facilities.⁶ Telepharmacy also provides a solution for order review and verification in tertiary medical centers when staffing, particularly in specialty areas such as oncology and pediatrics, is limited (e.g., due to attrition or staff turnover), creating a mechanism for health systems to provide enterprise-level pharmacy services throughout the system even when not all pharmacies operate 24 hours per day.

Medication selection, order review, and dispensing. A 2012 national survey of hospitals revealed that 34% of inpatient pharmacies operating in the United States did not offer 24-hour pharmacy coverage.⁷ Telepharmacy services can extend pharmacy coverage in hospitals that do not offer pharmacy services around the clock. Telepharmacy has been used successfully to enable pharmacists to become directly involved in the medication selection process for patients at geographically remote hospitals, to review new medication orders transmitted by fax or electronically, to remotely enter new orders into the patient's electronic medication profile, to remotely release the ordered medication from an automated medication dispensing cabinet, and to electronically supervise technicians in the performance of full-service pharmacy

operations.⁸⁻¹⁵ In one case, critical access hospitals and rural referral hospitals developed a common workflow and technologies to create a common electronic health record and monitor medication dispensing and administration, improving patient care and medication process quality and safety.¹⁶ Pharmacy companies are now utilizing mobile applications and the Internet to receive requests for refill orders from patients and transfer prescriptions between pharmacies.¹⁷

IV admixture verification. Although technology systems for remote checking of IV admixture preparation were originally designed to reduce contamination risk by reducing the need for pharmacists to physically enter sterile compounding areas to review and verify finished preparations, these and similar technologies can be used for verification of admixtures at different stages of preparation, across multiple sites, and over long distances.¹⁸ The technology also reduces exposure risk by reducing the number of pharmacy personnel and other providers having to handle hazardous medications, such as chemotherapy. Documentation can also be enhanced with these systems, as images capture lot numbers and expiration dates in addition to the step-by-step processes of preparation. Some of these systems perform in-process verification steps (e.g., bar code verification of correct product selection, gravimetric verification of additive quantities), which provide additional assurance to the remote pharmacist that the preparation is correct.

Patient counseling and monitoring. Pharmacists have been using telecommunications technology to counsel patients about the proper use of their medications for as long as

telephone service lines have been available. Early examples of pharmacists employing videoconferencing technology to counsel geographically remote patients include the outreach program by a Federally Qualified Health Center in eastern Washington State¹⁹ and another program in North Dakota.^{20,21} The Indian Health Service has also implemented videoconferencing technology to provide pharmacist services to remote areas of Alaska,²² and the U.S. Navy has deployed use of this technology worldwide.²³ Other examples include the use of videoconferencing to provide MTM,²¹ pharmacist-managed tele-anticoagulation,²⁵ and mental health telepharmacy.²⁶ Implementation of intensive care unit telemedicine services, including telepharmacy, led to reduced hospital length of stay, an increase in institutional best practice adherence, and lower rates of preventable complications.²⁷ Pharmacists are being encouraged to use mobile applications to communicate with patients to help them manage their diseases and medications.^{28,29}

Expanding pharmacy services. Telepharmacy can be utilized to allow onsite pharmacy activities to be fulfilled even if the pharmacist is not physically located at the point of pharmacy operation or patient care. As of 2016, most areas of the country were not experiencing severe pharmacist shortages.³⁰ However, workforce issues continue to plague rural areas.³¹ Many small rural hospitals rely on contracts with local retail pharmacists to provide pharmacy services at the hospital. Telepharmacy can allow those pharmacists to devote their limited onsite time to the oversight of drug therapy management, inventory, controlled substances control, and policy and procedure development, rather than real-time order review verification. In addition, telepharmacy effectively allows for the work of one pharmacist to be spread across several

small-volume hospitals, permitting them to share the expense of such services and creating an opportunity to provide 24-hour pharmacy services. ASHP supports implementation of telepharmacy services in rural areas to increase availability and scope of clinical pharmacy services.³² Other facilities may utilize telepharmacy services for supplemental workload balancing, which includes network workload balancing and on-call assistance.³³

Federal and state regulation

Federal regulation. Federal regulation of telepharmacy has evolved over the course of many years. CMS has established standards for telehealth.¹ The Health Insurance Portability and Accountability Act³⁴ (HIPAA) and Subtitle D of the Health Information Technology for Economic and Clinical Health (HITECH) Act,³⁵ which was enacted as part of the American Recovery and Reinvestment Act of 2009,³⁶ address privacy and security concerns associated with electronic transmission of health information. FDA has jurisdiction over medical software and equipment that may be involved in healthcare whether online, mobile, or in-house.³⁷ Pharmacists communicating with a patient via a mobile application should ensure it is compliant with FDA standards.²

State regulation. The Model Act, while not a federal standard, provides boards of pharmacy with model language for developing state laws or board rules.³ The Model Act defines telepharmacy-related terms and provides requirements for remote pharmacy services. Many states now have specific regulations for telepharmacy.³⁸ These state laws and regulations, however, demonstrate wide variation in the application and control of telepharmacy

systems.^{39,40} States have variously described telepharmacy in terms of remote order management with or without dispensing using automated dispensing cabinets, remote supervision of medication order filling with or without automated medication order dispensing, and inpatient dispensing activities (including IV preparation). These laws and regulations vary on the definition of telepharmacy, licensing requirements, education and training for participating pharmacists and technicians, practice setting restrictions, and geographical limitations for the remotely practicing pharmacist. State laws and regulations also vary widely regarding the technology required to implement telepharmacy. Although most stipulate a camera and some audio exchange between the pharmacy and the remote pharmacist, the specification of the types of technology (video vs. still, telephone vs. voice over internet protocol VoIP) and the types and amounts of transactional information captured vary widely. Some state boards of pharmacy have identified specific training, certification, or experience that pharmacy technicians engaged in telepharmacy must possess.⁴¹

As use of telepharmacy expands, state board of pharmacy regulations and state laws regarding its use will increase. ASHP advocates that state governments adopt laws and regulations that standardize telepharmacy practices across state lines and facilitate the use of U.S.-based telepharmacy services. ASHP further advocates that boards of pharmacy and state agencies that regulate pharmacy practice address the following in regulations for telepharmacy services: (1) education and training of participating pharmacists; (2) education, training, certification by the Pharmacy Technician Certification Board, and licensure of participating pharmacy technicians; (3) communication and information systems requirements; (4) remote order entry, prospective order review, verification of the completed medication order before

dispensing, and dispensing; (5) direct patient-care services, including medication therapy management services and patient counseling and education; (6) licensure (including reciprocity) of participating pharmacies and pharmacists; (7) service arrangements that cross state borders; (8) service arrangements within the same corporate entity or between different corporate entities; (9) service arrangements for workload relief in the point-of-care pharmacy during peak periods; (10) pharmacist access to all applicable patient information; and (11) development and monitoring of patient safety, quality, and outcomes measures.⁴²

In addition, some state legislatures have passed laws ensuring that insurance reimbursement for telemedicine is the same as nontelemedicine services. Whether these statutes can or will be applied to telepharmacy services in those states remains unanswered.

Because telepharmacy utilization is continuously evolving, laws and regulations will need to evolve as well. Prior to any telepharmacy implementation, it is important to review the laws and regulations in the jurisdictions in which the provider and receiver of care are located. The laws and regulations should be reviewed on a regular basis after implementation to ensure continued compliance and to assess the appropriate use of telepharmacy or its potential overuse.

Telepharmacy infrastructure

The technology infrastructure required for the implementation and maintenance of telepharmacy services may be scalable and adjusted to fit the care setting. Two intra-system facilities may already share a network, a pharmacy information system, and possibly an order management system. In this scenario, perhaps the only additional equipment that is needed is

a digital communication system for the transmission of any orders not provided via computerized provider order entry (CPOE).

In contrast, the inter-system model provides telepharmacy services to a facility external to the health system. In extreme situations, a facility may not have a pharmacy information system, necessitating purchase of a pharmacy module to allow for the implementation of remote pharmacy services.

Audiovisual equipment used to verify pharmaceutical products at the remote facility must include high-resolution cameras. While most states do not require video rather than still imaging, one state recommends that equipment include a high-resolution video camera and a document camera for reading unit dose packages or verifying parenteral doses. It is also suggested that equipment be mounted on a mobile cart to be used in the medication preparation area, at the automated dispensing cabinet, or at the patient's bedside. ASHP supports the utilization of properly implemented telepharmacy services and calibrated digital telemedicine devices within health systems that choose to utilize telepharmacy.

Security of information and equipment

The security and integrity of patient data is of paramount importance when determining the information technology setup of a telepharmacy system. Secure access to patient records at the remote site is required by the central site; however, central site patient records should be inaccessible from the remote site.

The remote site must restrict access to the telepharmacy so that only those employees directly involved in processing medication orders or prescriptions at the remote site are

permitted in the dispensing area. Moreover, no employees should be allowed access to the remote telepharmacy site when the pharmacy at the central site is closed.

Not all states allow pharmacists to work from sites not licensed as pharmacies, including home-based practices as well as corporate environments. State regulations must be considered as one develops a telepharmacy service or expands across state lines. Policies relating to HIPAA³³ and HITECH³⁴ compliance at the remote sites may impact telepharmacy by defining levels of security, access to the electronic medical record, and workstation session timeouts following periods of inactivity.

Conclusion

Telepharmacy is a method used in pharmacy practice in which a pharmacist utilizes telecommunications technology to oversee aspects of pharmacy operations or provide patient-care services. Telepharmacy allows expanded coverage, improved patient safety, and improved communication between patients, healthcare providers, and pharmacists, and is supported by ASHP. Variability in laws between states and evolving regulations must be closely monitored when implementing services. ASHP advocates more research be conducted to investigate best practices in implementation of telepharmacy services.

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Organizations

Organizations that can provide assistance for implementing telepharmacy technologies to ensure compliance with federal regulations and national standards include:

- The National Committee on Vital and Health Statistics (NCVHS)
- ANSI Accredited Standards Committee
- Committee on Operating Rules for Information Exchange (CORE), Council for Affordable Quality Healthcare (CAQH)
- NACHA – The Electronic Payments Association (formerly National Automated Clearing House Association)
- National Council for Prescription Drug Programs (NCPDP)
- Workgroup for Electronic Data Interchange (WEDI)
- Medicare Electronic Data Interchange (EDI)

Various agencies have provided grant funding to offset some of the equipment and installation costs. Granting agencies include:

- U.S. Department of Agriculture (USDA)
- Office of the National Coordinator for Health Information Technology (ONC)
- U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA)
 - Office for the Advancement of Telehealth (OAT)
 - Telehealth Resource Center (TRC)
 - Office of Rural Health Policy
- Federal Communications Commission (FCC)
- Universal Service Administrative Company-Rural Health Care Division (USAC-RHCD)
- USDA Distance Learning and Telemedicine Loan and Grant Program (USDA---DLT)
- Centers for Medicare and Medicaid Services (CMS)
- Agency for Healthcare Quality and Research (AHRQ)
- Private foundations