# **RELATED ASHP POLICIES DIGITAL HEALTH AND TECHNOLOGIES**

## 2204

# MOBILE HEALTH TOOLS, CLINICAL APPS, AND ASSOCIATED DEVICES

Source: Council on Pharmacy Management

To advocate that patients, pharmacists, and other healthcare professionals be involved in the selection, approval, and management of patient-centered mobile health tools, clinical software applications ("clinical apps"), and associated devices used by clinicians and patients for patient care; further,

To foster development of tools and resources to assist pharmacists in designing and assessing processes to ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices; further,

To advocate that decisions regarding the selection, approval, and management of mobile health tools, clinical apps, and associated devices consider patient usability, acceptability, and usefulness and should further the goal of delivering safe and effective patient care that optimizes outcomes; further,

To advocate that mobile health tools, clinical apps, and associated devices that contain health information be interoperable and, if applicable, be structured to allow incorporation of health information into the patient's electronic health record and other essential clinical systems to facilitate optimal health outcomes; further,

To advocate that pharmacists be included in regulatory and other evaluation and approval of mobile health tools, clinical apps, and associated devices that involve medications or medication management; further,

To encourage patient education and assessment of competency in the use of mobile health technologies; further,

To enhance patient awareness on how to access and use validated sources of health information integrated with mobile health tools, clinical apps, and associated devices.

This policy supersedes ASHP policy 1708.

## Rationale

Digital health technologies, including mobile health (mHealth) applications (apps), hold great potential to improve health and healthcare. There is nearly ubiquitous use of smartphones and an ever-growing and increasingly sophisticated suite of health apps. These apps are providing a wide range of medical functions that span the care continuum from prevention to diagnosis to care management. The adoption of these digital solutions is further amplified by their accessibility, low cost, and personalized features. In addition, their ability to provide practical functions such as health education, tracking of symptoms and side effects, appointment management, and social support make them compelling

healthcare tools. With the proliferation of mHealth tools, clinical apps, and associated devices, healthcare organizations need to address the potential barriers and risks of application use. Particular concerns include (1) assessing the quality of mHealth tools, clinical apps, and associated devices; (2) standardizing choices and use across the organization; (3) ensuring the security of data and data storage; and (4) patient usability, acceptability, and usefulness (e.g., generational differences in acceptance of technology). To maximize the effectiveness of mHealth tools, clinical apps, and associated devices, they must be selected, approved, and managed with the goal of improving care and with input from representatives of all affected parties, including patients, physicians, pharmacists, and other healthcare professionals. In addition, their effectiveness is enhanced when they are interoperable (as described in ASHP policy 1302, Interoperability of Patient-Care Technologies) and the data stored within them can be incorporated into the patient's electronic health record (EHR) and other essential clinical systems.

Providers and patients currently have little guidance regarding use of these resources or the management of the data they provide. The Food and Drug Administration and other regulatory agencies are just beginning to determine the scope of their oversight regarding standardized evaluation and validation processes. As medication-use experts, pharmacists can contribute to the regulatory evaluation and approval of mHealth tools, clinical apps, and associated devices that involve medications or medication management. For example, pharmacists can help assess the quality of information presented (e.g., incorrect or incomplete information, variation in content, incorrect or inappropriate response to patient needs) and mitigate inconsistencies with patient education resources provided by an organization (e.g., discharge education). ASHP is committed to fostering development of resources to help pharmacists ensure safe, accurate, supported, and secure use of mHealth tools, clinical apps, and associated devices. Patient engagement strategies include patient education and competency assessment and enhanced patient awareness of how to access and use validated sources of health information integrated with mHealth tools, clinical apps, and associated devices. Product customer assistance teams for mHealth tools, clinical apps, and associated devices should be leveraged to provide direct support to sustain these efforts. Patient engagement with these tools will: (1) increase communication between patient and providers, leading to increased patient satisfaction; (2) enhance sharing of health information using EHRs; and (3) enable patients to have access to their health data, which empowers them with the knowledge of their health conditions and helps them make informed treatment choices.

#### 2147

# PHARMACIST'S ROLE IN HEALTHCARE INFORMATION SYSTEMS

Source: Council on Pharmacy Management

To strongly advocate key decision-making roles for pharmacists in the planning, selection, design, implementation, and maintenance of medication-use information systems, electronic health records, computerized provider order entry systems, and e-prescribing systems to balance the security and integrity of data with the ability to facilitate clinical decision support, data analysis, and education of users for the purpose of ensuring the safe and effective use of medications; further,

To advocate for incentives to hospitals and health systems for the adoption of patient-care technologies; further,

To recognize that design, maintenance, and cyber-security of medication-use information systems is an interdisciplinary process that requires ongoing collaboration among many disciplines; further.

To advocate that pharmacists must have accountability for strategic planning and direct operational aspects of the medication-use process, including the successful deployment of medication-use information systems and continuity plans when the systems are unavailable.

This policy supersedes ASHP policies 1211 and 1701.

#### Rationale

ASHP recognizes that design, maintenance, and cyber-security of healthcare information systems (e.g., medication-use information systems, electronic health records, computerized provider order entry systems, e-prescribing systems) is an interdisciplinary process that requires ongoing collaboration across many disciplines. Maintaining the privacy of health information, in compliance with the Health Insurance Portability and Affordability Act (HIPAA), and ensuring patient safety in the face of cyberattacks are essential concerns for every healthcare organization. Given the ever-evolving nature of pharmacist patient care, medication use, and health information technology, it is essential pharmacists have key decision-making roles in the planning, selection, design, implementation, and maintenance of such systems in order to help prevent and respond to cyber-attacks. To ensure the safe and effective use of medications, pharmacists must have accountability for strategic planning and direct operational aspects of the medication-use process, including the successful deployment of medication-use-related information systems by assessing vulnerabilities and vendor systems to validate the security and integrity of the data. Increased connectivity with vendor systems creates a mutual need to share access to patient information and other vital data, so risk mitigation must be considered at all points of access. This includes, for example, facilitating clinical decision support by assessing the minimum amount of patient health information vendors require to provide services, data analysis, education of users, and developing and implementing business continuity plans, to include fail-over testing of these plans, for when the systems are unavailable.

## 2015

## NETWORK CONNECTIVITY AND INTEROPERABILITY FOR CONTINUITY OF CARE

Source: Council on Pharmacy Management

To advocate the use of electronic information systems, with appropriate security controls, that enable the integration of patient-specific data that is accessible in all components of a health system; further,

To support the use of technology that allows the transfer of patient information needed for appropriate medication management across the continuum of care; further,

To urge computer software vendors and pharmaceutical suppliers to provide standards for definition, collection, coding, and exchange of clinical data used in the medication-use process; further,

To pursue formal and informal liaisons with appropriate healthcare associations to ensure that the interests of patient care and safety in the medication-use process are fully represented in the standardization, integration, and implementation of electronic information systems; further,

To strongly encourage health-system administrators, regulatory bodies, and other appropriate groups to provide health-system pharmacists with full access to patient-specific clinical data; further,

To advocate that client-vendor agreements include timelines for data destruction; further,

To oppose the selling of data for unauthorized uses; further,

To educate health-system leaders about potential use and misuse of shared data.

This policy supersedes ASHP policy 0507.

### Rationale

For the past two decades, the U.S. health system has been racing to take advantage of the potential that digital health information offers for improved patient care. Each institution and practice has invested in information systems that work for its specific situation. These systems were developed by multiple vendors, each with their own proprietary structures and labels. Information was and continues to be found in silos, within health systems, within institutions, even within departments.

In 2004, an executive order created the Office of the National Coordinator for Health Information Technology (ONC). ONC is the primary federal entity charged with coordination of nationwide efforts to implement and advance health information technology and the electronic exchange of health information. The 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act provided the Department of Health and Human Services with additional authority to promote health information technology, including the secure exchange of electronic health information.

As defined by the Healthcare Information and Management Systems Society (HIMSS), interoperability is "the ability of different information systems, devices, or applications to connect, in a coordinated manner, within and across organizational boundaries to access, exchange and cooperatively use data amongst stakeholders, with the goal of optimizing the health of individuals and populations." ONC has developed a roadmap for interoperability and created calls to action for entities with specific roles in our healthcare system (e.g., the Calls to Action for People and Organizations That Deliver Care and Services).

As government agencies, standards-setting organizations, and professional associations work toward interoperability of health information technology, it is important to ensure this includes the ability of healthcare providers and patients to securely access and use health information from different sources and settings relevant to medication use to ensure patient-centered continuity of care.

Along with secure access and sharing of health information, providers and health systems must be cognizant of how a vendor will handle data, how it plans to safeguard data, and whether and how data will be used for secondary purposes (e.g., research, advertising).

ASHP recognizes that continuity of care is a vital requirement in the appropriate use of medications. Pharmacists have responsibility for ensuring continuity of care as patients move from one

setting to another (e.g., ambulatory care, inpatient care, community pharmacy, home care). Achieving information systems that have the ability to share relevant patient care data securely across care settings is a critical step in optimizing medication use across care settings.

# 1418

#### RISK ASSESSMENT OF HEALTH INFORMATION TECHNOLOGY

Source: Council on Pharmacy Management

To urge hospitals and health systems to directly involve departments of pharmacy in performing appropriate risk assessment before new health information technology (HIT) is implemented or existing HIT is upgraded, and as part of the continuous evaluation of current HIT performance; further,

To advocate that HIT vendors provide estimates of the resources required to implement and support new HIT; further,

To collaborate with HIT vendors to encourage the development of HIT that improves patient-care outcomes; further,

To advocate for changes in federal law that would recognize HIT vendors' safety accountability.

This policy was reviewed in 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

# Rationale

The adoption of HIT in hospitals has been increasing at a quickening pace. The ASHP National Survey – 2012 reports the adoption of the following: full paperless electronic health record (EHR) (18.6%), computerized provider order entry with clinical decision support (CPOE with CDS) (54.4%), bar-coded medication administration (BCMA) (65.5%), and smart pumps (77%). The adoption of HIT has undoubtedly been spurred by the American Recovery and Reinvestment Act (ARRA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions under Meaningful Use (MU) of the EHR. Hospitals have been incentivized to implement EHRs that meet the MU criteria by increased reimbursement through Medicare and/or Medicaid payments. Due to the strict guidelines and the rush to meet incentive payments, many providers are questioning whether some HIT is being implemented too quickly.

The implementation of HIT within the medication-use process has been proven to prevent and decrease errors, improve quality, and prevent waste. A key premise of the Office of the National Coordinator for Health Information Technology (ONC) report "Health Information Technology Patient Safety Action & Surveillance Plan" (July 2013) is that HIT, when fully integrated into health care delivery organizations, facilitates substantial improvements in health care quality and safety as compared to paper records. As hospitals and providers implement HIT within their institutions and practices, however, they often encounter new types of errors and problems. The medical literature is starting to see reports of these unintended consequences of HIT, so continuous monitoring of these systems is required. It has become increasingly important to properly assess the interface between HIT and users to identify whether any new risk has been introduced to the system and implement HIT

appropriately, taking into account medication-use processes and human factors. Critical questions hospitals and health systems face include (1) when do HIT advances exceed the capacity for integration into workflow, (2) when does HIT begin to introduce risk into the medication-use process rather than improve patient safety, and (3) what are the accountabilities of HIT providers, regulators, and providers to ensure the necessary product development and assessments are made before implementation of new HIT.

ASHP advocates that the pharmacy department be part of the implementation team for any medication-related technology within an institution. Technology assessment tools should be applied by pharmacists and others to proactively determine gaps in function prior to implementation, during upgrades, and as part of the continuous evaluation of HIT performance. The use of failure modes effects analysis (FMEA) and other resources should be considered. Risk assessment should also be considered when implementing any new technology to ensure that unintended consequences are minimized.

Regulatory and accreditation organizations include components of risk assessment and quality improvement within their criteria, but hospitals need to incorporate these into their overall plans. Such risk assessments could result in less attention on some HIT implementations. Finally, federal law need to recognize vendors' accountability for the safety of their products as implemented.

#### 1302

# **INTEROPERABILITY OF PATIENT-CARE TECHNOLOGIES**

Source: Council on Pharmacy Management

To encourage interdisciplinary development and implementation of technical and semantic standards for health information technology (HIT) that would promote the interoperability of patient-care technologies that utilize medication-related databases (e.g., medication order processing systems, automated dispensing cabinets, intelligent infusion pumps, electronic health records); further,

To encourage the integration, consolidation, and harmonization of medication-related databases used in patient-care technologies to reduce the risk that outdated, inaccurate, or conflicting data might be used and to minimize the resources required to maintain such databases.

This policy was reviewed in 2018 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

## Rationale

There are significant pharmacy management issues associated with the multiplicity of medication databases in hospitals and health systems. Among the issues are lack of standardization in the medication databases used in pharmacy order-processing systems, automated dispensing cabinets, intelligent infusion pumps, electronic health records, and other patient-care-related technologies dependent on accurate and harmonized medication databases. In addition, there is variability in the primary sources of medication information in these databases and in how the databases are updated. The longstanding issue of lack of interoperability of medication-related information technology compounds the problem. The risk-management implications of this situation are not fully understood, but the urgent need to address this complex issue increases as the dependence on information technologies and the accuracy of associated information proliferates to more aspects of patient care.

Although it is important to recognize the differences among technologies used in patient care, there is a need to have both a standardized format to describe medications as well as means for efficiently managing the medication databases in order to safely populate and update the different technologies that rely on drug information. Coalitions such as the Pharmacy e-Health Information Technology Collaborative are increasingly important in providing expertise, organizing and participating in stakeholder events, and advocating for best practices. It may, however, be necessary for other organizations to convene stakeholders to develop standards for the harmonization of medication-related databases.

#### 1020

# **ROLE OF PHARMACISTS IN SAFE TECHNOLOGY IMPLEMENTATION**

Source: Council on Pharmacy Practice

To affirm the essential role of the pharmacist in the evaluation, implementation, and ongoing assessment of all technology intended to ensure safety, effectiveness, and efficiency of the medication-use process.

This policy was reviewed in 2020 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

## Rationale

Effective use of automation and technology solutions improves efficiency, allows more time for direct patient care, and ensures safe medication management. The Joint Commission Sentinel Event Alert published in December 2008 outlined patient safety concerns specific to technology implementation and recommended specific actions to reduce error and patient harm. The Institute for Safe Medication Practices (ISMP) has published related recommendations for specific technologies and noted recently that one drug delivery device was marketed to promote physician autonomy as a benefit of its use.

#### 2117

# **EDUCATION AND TRAINING IN TELEHEALTH**

Source: Council on Education and Workforce Development

To acknowledge that telehealth is a growing modality that supports the pharmacy workforce in providing direct patient care; further,

To support training and education for the pharmacy workforce in innovative models that support telehealth services; further,

To promote the incorporation of students and residents into virtual modalities of care and interdisciplinary collaboration; further,

To foster documentation and dissemination of best practices and outcomes achieved by the pharmacy workforce as a result of telehealth services.

### Rationale

Continuous development of information technology is rapidly redefining the provision of healthcare.

The expansion of telehealth services creates opportunity to improve access to telepharmacy and telemedicine for patients unable to access health services in traditional modalities. Lack of access to healthcare remains critical for many individuals for a variety of reasons including geographic issues (i.e. rural communities), lack of transportation, physical or fiscal challenges. The provision of medical care using telehealth allows patients to have access when they need it at the time they need it.

To ensure that telepharmacy becomes a strong component of telehealth, training and education must be developed that supports the pharmacy workforce in their delivery of optimal patient care. Expanded access for the pharmacy workforce as well as interoperability and information integrity between organizations where patients may receive care is crucial. Additionally, student learners must have appropriate access levels with oversight to the electronic health record to ensure development of the skills needed for this type of care. Research supporting improved outcomes while maintaining security for patients' health information is needed to foster continued development.

#### 1317

## **EDUCATION AND TRAINING IN HEALTH CARE INFORMATICS**

Source: Council on Education and Workforce Development

To recognize the significant and vast impacts of health-system information systems, automation, and technology changes on safe and effective use of medications; further,

To foster, promote, and lead the development of and participation in formal health care informatics educational programs for pharmacists, pharmacy technicians, and student pharmacists.

This policy was reviewed in 2018 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

## Rationale

With growing use of automation and technology, there is a growing need for informatics-trained pharmacists and pharmacy technicians, yet there are few training programs or residencies. This shortage of trained individuals has led to on-the-job training and potentially less-than-optimal implementation of new information systems and technology. New educational programs, or adaptation of existing ones, would help ease this lack of trained individuals and lead to better technology outcomes. To most effectively accomplish this goal, ASHP must lead the development of such programs and encourage participation by pharmacists, pharmacy students, and pharmacy technicians.

### 2141

#### PHARMACIST ENGAGEMENT IN AND PAYMENT FOR TELEHEALTH

Source: Council on Public Policy

To advocate for pharmacists' provision of telehealth services in all sites of care; further,

To advocate that reimbursement for pharmacists' provision of telehealth services be commensurate with the complexity and duration of service and consistent with other healthcare providers.

#### Rationale

During the COVID-19 public health emergency, hospitals, health systems, and clinics quickly pivoted to providing patient services via telehealth. The Centers for Medicare & Medicaid Services, commercial payers, and state policymakers have indicated that they would like to maintain telehealth services post-pandemic. Because pharmacists are not Medicare-eligible, it has been a struggle to ensure that they can be reimbursed for services provided via telehealth. In particular, it is vital that services be reimbursed at a level commensurate with the complexity and duration of the service and consistent with other healthcare providers, to ensure that patients can maintain access to services.

#### 1310

# **REGULATION OF TELEPHARMACY SERVICES**

Source: Council on Public Policy

To advocate that state governments adopt laws and regulations that standardize telepharmacy practices across state lines and facilitate the use of United States-based telepharmacy services; further,

To advocate that boards of pharmacy and state agencies that regulate pharmacy practice include 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; further,

To identify additional legal and professional issues in the provision of telepharmacy services to and from sites located outside the United States.

This policy was reviewed in 2018 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

# Rationale

In light of continuing advances in technology, there an increasingly urgent need for state board of pharmacy regulation of the provision of pharmacist care services from off-site locations through electronic technology (telepharmacy). It is important to acknowledge the regulatory purview of state boards of pharmacy regarding the use of telepharmacy and recognize that the intent of such regulations should be to balance protection of the public health with the increased patient access to the patient care services of pharmacists provided by telepharmacy. Although such regulations should allow for various arrangements across state borders and within or between health systems, they all need to address a number of common concerns.

ASHP policy 0716 was revised to address the provision of medication therapy management and other direct patient-care services in any regulation of telepharmacy services and to advocate that patient safety, quality, and outcomes measures be developed and monitored. The policy was also revised to include advocacy to state governments to harmonize the practice of pharmacy across state lines and to update requirements for technician functions in the provision of telepharmacy services be performed by technicians that are certified by the Pharmacy Technician Certification Board (PTCB) and licensed by the state board of pharmacy. The revised policy also calls on ASHP to continue efforts to identify additional legal and professional issues in the provision of international telepharmacy services.

#### 2220

# **PROMOTING TELEHEALTH PHARMACY SERVICES**

Source: Council on Pharmacy Practice

To advocate for innovative telehealth pharmacy practice models that (1) enable the pharmacy workforce to promote clinical patient care delivery, patient counseling and education, and efficient pharmacy operations; (2) improve access to pharmacist comprehensive medication management services; (3) advance patient-centric care and the patient care experience; and (4) facilitate pharmacist-led population and public health services and outreach; further,

To advocate for removal of barriers to access to telehealth services; further,

To advocate for laws, regulations, and payment models for telehealth services that are equitable to similar services provided in person by health systems, with appropriate accountability and oversight; further,

To encourage comparative effectiveness and outcomes research on telehealth pharmacy services.

#### Rationale

The definitions and terminology used to describe telehealth vary. Many refer to virtual health, telehealth, telemedicine, and/or telepharmacy interchangeably. 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. 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.

Telehealth is part of a larger digital transformation in healthcare. Patients are increasingly making decisions about who delivers their care and engaging in the delivery of that care digitally. As a result, hospitals and health systems need a strategy for their own digital transformation and to meet patient demands. In general, telehealth includes a broader scope of remote healthcare services than telemedicine and telepharmacy; therefore, ASHP considers telehealth to be the overarching term for the remote delivery of patient care services.

The availability of telehealth services in rural areas facilitates greater access to care by eliminating the need to travel long distances to see a qualified healthcare provider. It promises to save patients time and money, reduces patient transfers, emergency department and urgent care center

visits, and delivers savings to payers (American Hospital Association [AHA]. Fact Sheet: Telehealth; AHA. Optimizing Pharmacy Services: Managing your hospital pharmacy during the COVID-19 pandemic and beyond). Pharmacists' role in telehealth is instrumental, as telehealth serves are a valuable tool for the profession of pharmacy to extend its reach to patients for the provision of medication management and complex patient care (AHA. Optimizing Pharmacy Services: Managing your hospital pharmacy during the COVID-19 pandemic and beyond; ASHP Statement on Telepharmacy). Telehealth services have grown significantly over recent years, especially during the COVID-19 pandemic. Telehealth services have the potential to improve patient access to care, cost efficiencies, and quality while meeting consumer demand. They also offer patients the convenience of remote drug therapy monitoring, authorization for prescriptions, patient counseling, and monitoring patients' compliance with prescriptions, and they can be offered remotely to patients with diabetes, congestive heart failure, and other chronic diseases. Pharmacists may also use telehealth when suitable to remotely verify sterile compounding, offer pre- and postoperative medication order review, provide interactive postoperative patient medication counseling, or deliver drug information to a facility that is geographically isolated (ASHP Statement on Telepharmacy). To ensure the best patient care outcomes and most efficient use of healthcare resources, additional research will be needed to compare telehealth pharmacy services with those offered in person.