

ADDRESSING MEDICATION SAFETY IN COMMUNITY PHARMACY

**Prepared for the
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Executive Summary

Medication errors pose a serious risk to patient safety. While the majority of prescriptions are prescribed, transcribed, dispensed, and administered without errors, billions of prescriptions are filled each year and even a small error rate can have serious consequences to patients. Studies show that a typical community pharmacy in the U.S. has about two clinically significant medication errors every week. In this white paper, we review the current medication safety landscape and identify and describe strategic opportunities to better position community pharmacists to address medication errors.

There are many players in medication safety and error prevention. Professional and trade associations and non-profit organizations have numerous programs to address errors, and several government agencies have relevant regulations, policies, and programs. Additionally, state laws and State Board of Pharmacy regulations significantly impact the practice of pharmacy and have relevance to medication error prevention.

As shown below, we identified a series of strategic opportunities in five areas to better position community pharmacists to address medical errors. These strategies were chosen due to their promise and their potential to fill gaps in existing policies and programs. Most of the strategies fall into the area of pharmacy practice, and focus on providing pharmacists with the right tools, information, and guidance to succeed in preventing errors. For each strategy, we identified implementation tactics and potential partners.



Background and Overview

The National Academy of Medicine estimates that more than 50 million medication errors occur in the U.S. each year, and about 6.5% of these errors are clinically significant.¹ While not all medication errors result in harm, those that do are considered adverse drug events (ADEs) and are responsible for approximately 700,000 emergency department visits and 100,000 hospitalizations each year in the U.S.²

Community pharmacies fill over 4 billion prescriptions each year,³ and a typical community pharmacy will generate two clinically significant medication errors each week.⁴ Medication errors in community pharmacies have serious consequences for patients, and certain populations may be at an increased risk for harm, such as the chronically ill and elderly patients with complex conditions taking multiple medications. Root-cause analysis has identified common causes for medication errors in community pharmacies, including medications that sound or look alike, lack of concentration due to interruptions, and lack of effective control of prescription, label, and medicine.⁵ Community pharmacists are well positioned to identify, resolve, and prevent certain types of medication errors to reduce ADEs.

Purpose and Objective

The purpose of this paper is to improve understanding of the existing medication safety landscape and identify opportunities to position pharmacists to reduce medication errors. To assess the existing landscape, we first reviewed the existing literature on error types. We then reviewed pharmacist and pharmacy technician roles and training, and differences across states. We also scanned and identified federal and state programs and regulations and non-profit and private sector programs that influence the practice of community pharmacy and attempt to improve medication safety.

Based on these findings, we developed a set of recommended strategies and tactics that have significant potential to better position community pharmacies and pharmacists to address medication errors. These strategies and tactics focus on changes to existing policies, regulations, and programs, as well as ideas for new initiatives. We also prioritized the strategies based on our assessment of their feasibility and potential impact.

The primary focus of our review and recommendations is on medication errors originating in the pharmacy, although we also include prescribing errors that originate outside the pharmacy but may be addressable by community pharmacists.

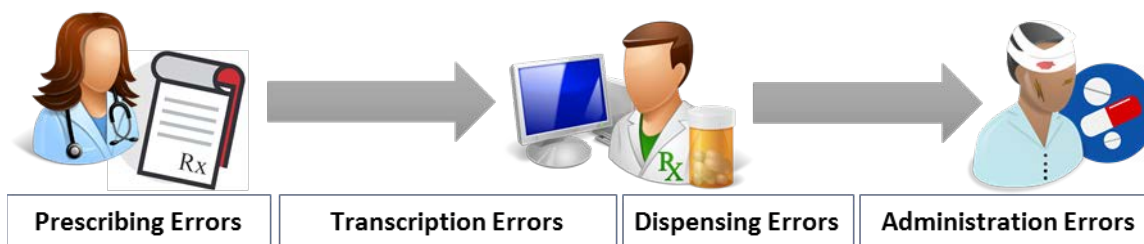
Methods

Our review of the current landscape and our strategy recommendations were informed by literature reviews, internet-based research, and interviewing key organizations in the medication error space. We prioritized strategies based on our independent assessment of their feasibility and potential impact.

Types of Medication Errors

A medication error can occur either out of commission or omission and can occur at any step in the community pharmacy medication process, including prescribing, transcribing, dispensing, or administration. Figure 1 shows where in the medication use process these errors occur. Many medication errors are caught before reaching the patient⁶; however, those that are not may result in an ADE.

Figure 1. Where Different Errors Occur in the Community Pharmacy Medication Process



Pharmacists are in a unique position to intervene when medication errors arise. One study found that of the errors that were prevented from reaching patients, 40% of the interventions were attributed to pharmacists.⁷ A smaller percentage (17%) were prevented by patients, which underscores the importance of patient counseling. Pharmacists are most readily able to address dispensing errors, but may also play a role in addressing prescribing and administration errors.

Prescribing Errors

Most medication errors are generated in the prescribing phase. In one study of over 50 physician offices, 70% of medication errors were generated by errors in prescribing.⁸ Prescribing errors include incorrect diagnosis and dose miscalculations.⁹ Improvements in technology, including electronic prescribing (“e-prescribing”), have shown promise for reducing prescribing errors. E-prescribing provides for a secure bidirectional exchange of information between prescribers, pharmacists, payers, and patients. It automates essential functions such as obtaining prior authorization, checking for any known patient drug allergies or sensitivities, identifying drug-drug interactions (DDIs), accessing patients’ medication histories, and communicating with patients about prescription status.¹⁰

There is evidence that e-prescribing is effective in preventing medication errors, and many providers believe e-prescribing can improve patient safety.¹¹ One study found that as many as 57% of reported medication errors could be prevented by e-prescribing and monitoring tools, which can address both prescribing and transcription errors.¹² Another study showed a nearly sevenfold decrease in errors in community pharmacies that utilize e-prescribing, from 42.5 errors per 100 prescriptions at baseline to 6.6 errors per 100 prescriptions one year after adoption.¹³ However, some studies have shown non-significant differences in errors between handwritten prescriptions and e-prescribing¹⁴ while other studies have cited new challenges created by e-prescribing.¹⁵ The need for more evidence is cited in most studies.

Transcription Errors

Errors of transcription occur when a prescription is correct, but is not accurately communicated by the prescriber or interpreted by the pharmacist. Examples are misinterpreting handwriting on a prescription or mishearing information communicated over the phone. Transcription errors can result in dispensing of the wrong drug and mis-dosing. Notably, the advent and proliferation of e-prescribing has all but eliminated transcription errors.¹⁶

Dispensing Errors

Perhaps the phase in which community pharmacies can most readily intervene to prevent or correct a medication error is the dispensing phase. Like other types of medication errors, pharmacists can commit errors by commission or omission. In the dispensing phase, errors of commission include dispensing the wrong drug or incorrectly entering patient information into the computer. Omission errors are passive and include failing to counsel a patient.

Overall, dispensing accuracy in pharmacies is high. An observational study of 50 U.S. pharmacies found a 98.3% dispensing accuracy rate.¹⁷ However, due to the vast number of prescriptions filled each year in the U.S., even the small error rate (1.7%) amounts to approximately 51.5 million errors annually nationwide.¹⁸ A literature review of 60 papers found that the most common types of dispensing errors were supplying the wrong drug, strength, form, or quantity, and mislabeling medication with incorrect directions.¹⁹ The same review looked at cited factors for dispensing errors. The top factor, cited in 13 of the 60 papers, was workload. Similar drug name was cited in 12 of the reviewed papers, and both similar packaging and staffing levels were cited in nine.

Administration Errors

Administration errors occur when the medication is used in a way that differs from how the prescriber intended. They occur in inpatient settings when a patient is given the wrong medication or dose, or in an outpatient setting when a patient, caregiver, or health care

professional improperly administers the drug, including an improper dosage or alongside a drug known to interact. These errors are difficult for pharmacists to address, although increased patient and caregiver communication and better labeling may help to prevent administration errors committed by patients.²⁰

Administration errors also occur when a patient continues taking a medication after the prescriber intends for the medication to be discontinued. In some cases, a pharmacy may have incorrectly refilled a prescription, either as requested with a group of prescriptions by the patient or as part of an auto-refill program. This type of error can be addressed through an e-prescribing function called Cancel Rx, by which the prescriber can notify the pharmacy of the change in therapy.

Pharmacy Staff and Roles

Pharmacist and pharmacy technician education and licensure requirements have evolved over time. Moreover, scope of practice for pharmacists and technicians differs in significant ways across states. It is important to understand similarities and differences in education, training, and scope of practice across the U.S. when considering how to position community pharmacies to reduce medication errors.

Pharmacists²¹

Education and Licensure

To be licensed, practicing pharmacists must successfully graduate from an Accreditation Council for Pharmacy Education (ACPE)-accredited college of pharmacy and pass examinations required by a State Board of Pharmacy, including the North American Pharmacist Licensure Exam (NAPLEX). Pharmacists may hold a Doctor of Pharmacy (PharmD) or Bachelor of Science (BS) in Pharmacy; beginning in 2000, only the PharmD degree has been offered by colleges of pharmacy. Specific licensure and renewal requirements vary by state.

Students enrolled in a professional PharmD degree program are required to complete a minimum of six years of post-secondary education, one additional year up from the minimum of five years required by previous accreditation standards for a BS in Pharmacy, which required a minimum of five years.

The pharmacy program curriculum has changed over the years to provide pharmacy students with additional clinical training. A primary reason for requiring this additional clinical training is to ensure that pharmacists could work more effectively with physicians, nurses, and other health care professionals. Of relevance to medication errors, the most recent ACPE accreditation standards require colleges of pharmacy to teach quality improvement practices.

Scope of Practice ²²

Pharmacy scope of practice refers to the boundaries in which pharmacists may practice, as outlined by the terms of their licensure. The scope of practice is established by each state legislature and regulated by the state's Board of Pharmacy. Consequently, scopes of practice for pharmacists vary greatly across states.

Today, the pharmacy scope of practice includes a variety of services, including patient education, medication therapy management (MTM), administering immunizations, and coordinating patient care with other health care professionals. In most states, pharmacists may enter into a collaborative practice agreement with a physician or other prescriber to provide additional services, particularly to individuals with chronic conditions. These services include drug therapy initiation, monitoring, and modification. Four states (California, Montana, New Mexico, and North Carolina) have further expanded pharmacists' scope of practice with the creation of the advanced pharmacy practicing (APP) designation. ²³

Pharmacy Technicians

Education and Licensure

A pharmacy technician works under the supervision of the licensed pharmacist and assists in pharmacy activities, including filling prescriptions and processing insurance claims. In 2016, there were more than 402,000 pharmacy technicians, with an anticipated growth of 12%.²⁴

An increasing number of State Boards of Pharmacy are regulating pharmacy technician practice. Pharmacy technicians may be nationally certified, which typically requires initial and ongoing assessment of the individual's knowledge, skills, and/or experience. Additionally, states may require registration (i.e., list of pharmacy technicians) or licensure. At present, 45 states and the District of Columbia regulate pharmacy technicians through licensure, certification, or registration²⁵ and the majority require some level of training or education. As a part of their regulation of technicians, some State Boards of Pharmacy have examination requirements that must be completed, such as the Pharmacy Technician Certification Examination (PTCE) offered by the Pharmacy Technician Certification Board and the ExCPT examination offered by the National Healthcareer Association.

Scope of Practice

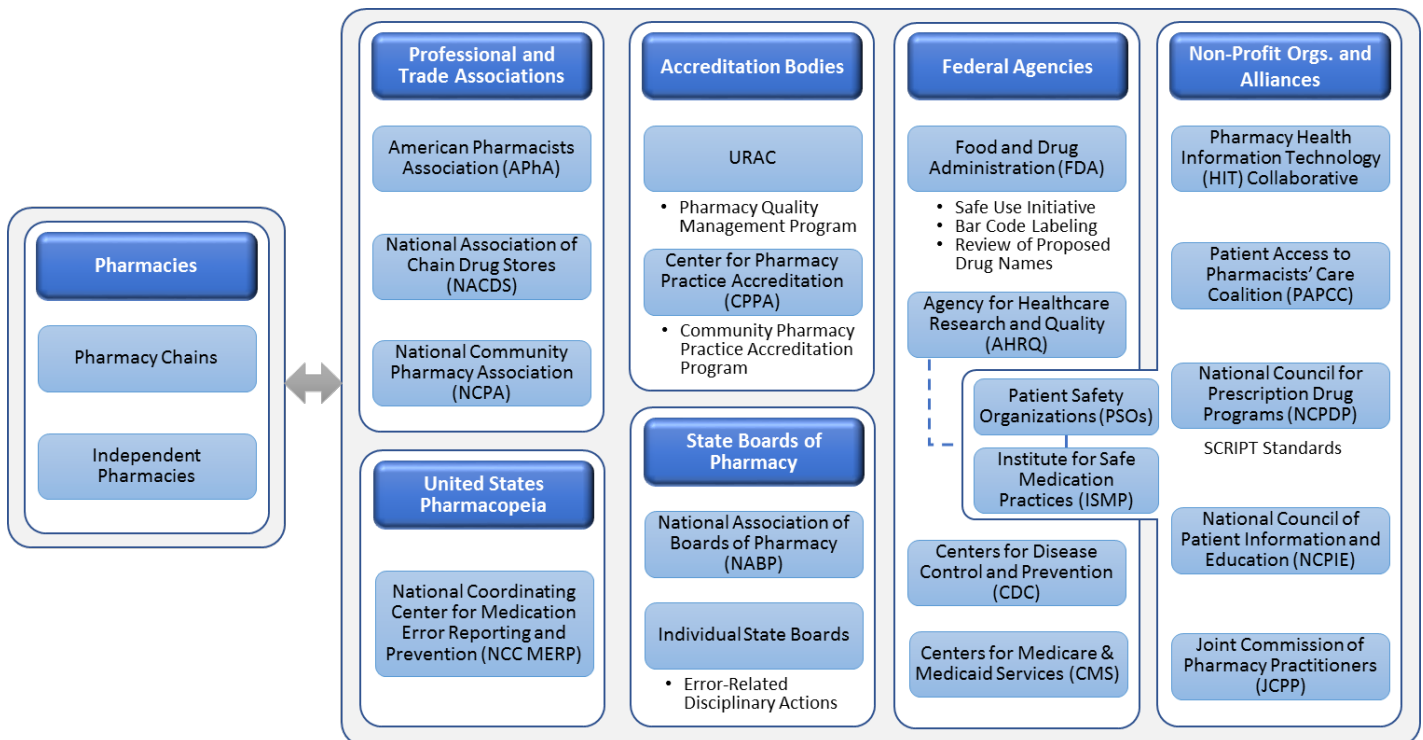
The pharmacy technician's scope of practice varies greatly between states due to differences in state requirements for registration, licensure, and certification. Generally, their essential functions are to assist in dispensing medications, monitoring and maintaining stock, and processing insurance claims. More progressive states allow for expanded technician roles,

including verifying medication orders with prescribers and participating in quality assurance activities.²⁶

Scan of Existing Programs and Policies

To better understand the current medication safety landscape, we conducted a scan to identify leading organizations and their programs, as well as key state and federal government entities and policies. Figure 2 shows these organizations and their programs and policies, and descriptions of each are provided below.

Figure 2: Medication Safety Organizations, Programs, and Policies



Professional and Trade Associations

The primary professional organization of relevance to medication errors in community pharmacy is the American Pharmacists Association. There are two trade associations for pharmacies, one for chain pharmacies and one for independent pharmacies, and other member organizations that represent multiple stakeholders in community pharmacy and medication safety.

American Pharmacists Association (APhA)

The American Pharmacists Association (APhA) is an organization that represents over 62,000 practicing pharmacists, pharmaceutical scientists, pharmacy students, and pharmacy

technicians. The association's goal is to advance the role of pharmacists, improve medication use, and advance patient care. APhA activities include advocating for pro-pharmacy practices and providing education on topics of importance to pharmacists, such as medication error prevention. Additionally, APhA publishes guidance on medication safety best practices. One publication—Pharmacists' Impact on Patient Safety— outlines actions that pharmacists can take to improve patient safety. Recommendations that were cited to reduce medication errors include providing medication information, evaluating medication appropriateness, and coordinating transitions of care.²⁷

[National Association of Chain Drug Stores \(NACDS\)](#)

The National Association of Chain Drug Stores (NACDS) is a trade association for traditional drug stores, supermarkets, and mass merchants with pharmacies, and their supplier partners. Chains operate 40,000 pharmacies, and NACDS' member companies include national chains and regional chains with at least four stores. Chains employ more than 3.2 million people, including 178,000 pharmacists. NACDS' primary function is advocating for pro-patient, pro-pharmacy issues on both the federal and state level. Member benefits include a state legislation tracking service (iStateLink), training opportunities, state and federal advocacy, and a syndicated data program.

[National Community Pharmacy Association \(NCPA\)](#)

The National Community Pharmacy Association (NCPA) is a professional association that represents independent pharmacies and their employees. NCPA member benefits include advocacy at the state and federal levels, a medication synchronization program (Simplify My Meds[®]), and exclusive benefits from Digital Pharmacist that assists pharmacies with patient engagement, communication, and adherence.

[United States Pharmacopeia \(USP\) and the National Coordinating Center for Medication Error Reporting and Prevention \(NCC MERP\)](#)

The United States Pharmacopeia (USP) is a non-profit organization dedicated to protecting and improving the health of individuals around the world. USP serves as the Secretariat for the National Coordinating Center for Medication Error Reporting and Prevention (NCC MERP), an independent body of 27 organizations, including non-profit organizations, federal agencies, patient safety organizations (PSOs), and national boards. The Center develops recommendations on behalf of member organizations and standards for safe medication practices. NCC MERP recommends the use of non-punitive punishment for pharmacists committing a medication error. Additionally, NCC MERP created a taxonomy of medication errors, designed to be used as a structured way to capture error data.²⁸

Accreditation Bodies

Accreditation in community pharmacy is strictly voluntary, and only a small percentage of community pharmacies are part of existing programs. Nonetheless, accreditation presents an opportunity for a community pharmacy to demonstrate the quality of services it provides, and existing programs include components that aim to prevent medication errors. Below we highlight the two existing accreditation programs.

URAC

URAC is a non-profit dedicated to promoting the quality and efficiency of health care management through accreditation, education, and measurement. URAC provides accreditation through quality programs, including the Pharmacy Quality Management Program, which includes a specific accreditation for community pharmacies. The accreditation recognizes community pharmacies that meet URAC standards, one of which is requirements for policies and procedures for identifying drug safety and efficacy issues and risks that may compromise consumer safety. Additionally, the URAC-accredited community pharmacies must have the capacity to support e-prescribing.

Center for Pharmacy Practice Accreditation (CPPA)

The Center for Pharmacy Practice Accreditation (CPPA) is a partnership, established between APhA, the National Association of Boards of Pharmacy, and the American Society of Health-System Pharmacists (ASHP), that develops pharmacy practice standards and accredits pharmacies that meet those standards. CPPA used an expert consensus-based approach to develop a specialized Community Pharmacy Practice Accreditation Program that recognizes community pharmacies who provide innovative, high-quality, safe, and effective care. The accreditation process takes approximately six to nine months. To be considered for accreditation, a pharmacy must submit an application and supporting documentation, and complete a site survey.

State Boards of Pharmacy

Each state has a Board of Pharmacy whose purpose is to ensure public safety by regulating the practice of pharmacy. Each State Board must determine a process for addressing medication errors committed by pharmacists. These regulations vary by state and influence the processes undertaken by pharmacies to reduce errors. Some State Boards fail to emphasize the use of corrective action plans, process improvement elements, and education on medication safety for pharmacists.²⁹

While some states have chosen to focus on limiting the workload of pharmacists, other State Boards have focused on relieving pharmacists of technical duties to allow time for more focus

on cognitive duties (e.g., clinical review of prescriptions and patient medication history, patient counseling). Innovative approaches implemented to allow pharmacists the time to focus on patient care roles include allowing increased pharmacy technician responsibilities, allowing expanded pharmacists authority through collaborative practice agreements, standing orders, and adaptive prescribing.

Below we highlight activities of the National Association of Boards of Pharmacy and boards in select states that are pursuing innovative strategies to reduce errors.

National Association of Boards of Pharmacy (NABP)

The National Association of Boards of Pharmacy (NABP) is a non-profit that assists member boards of pharmacy to promote safe pharmacy practices. They have three broad categories of activities — (1) licensing and accreditation programs for pharmacists and pharmacies, (2) consumer and provider education, and (3) guidance to State Boards.

NABP has a wide range of programs including licensure (e.g., verified pharmacy program), examination (e.g., North American Pharmacist Licensure Examination[®], NAPLEX), and accreditation (e.g., Verified-Accredited Wholesale Distributors, VAWD). Additionally, NABP has a prescription drug safety program, AWARe, that aims to educate consumers on how to safely acquire, use, and dispose of their prescription medications and has resources for pharmacists regarding how to identify and handle drug abuse scenarios.

NABP provides guidance to State Boards on implementing pharmacy best practices and enforcement actions to promote patient safety and reduce medication errors.³⁰ Additionally, NABP has developed the Model State Pharmacy Act and Model Rules to provide State Boards with language they can use to develop state laws or board rules for regulating the practice of pharmacy and the distribution of drugs and related devices. Finally, NABP publishes its Survey of Pharmacy Law on an annual basis, which provides data and information surrounding current pharmacy issues (e.g., pharmacy technicians, transmission of prescriptions, patient counseling requirements).³¹

States' Responses to Errors - Error-Related Disciplinary Actions³²

Disciplinary actions against pharmacists and technicians in response to a medication error differ across states. State Boards of Pharmacy typically learn of a medication error incident when a patient or caregiver files a complaint. At that time, the Board is required to investigate the complaint, which includes compiling information on the responsible pharmacist and staffing levels at the time of the error. The Board can take a variety of different actions, ranging from

dismissal to revocation of the pharmacist's license. Other actions may include continuing education requirements and monetary fines.

In addition to actions taken against the pharmacist by the state board, pharmacists may see additional punishment from their employers based on discipline from a board. For instance, some pharmacies (e.g., Walmart) have a policy that pharmacists who have had board action against them are not eligible for employment.

Wisconsin

Wisconsin is one of four states piloting a Tech Check Tech (TCT) program, which allows pharmacy technicians to do the final check to ensure the right medication is in the bottle. This delegation of responsibility reduces the workload of pharmacists, which is often cited as a contributing factor to medication errors. A key requirement in the Wisconsin TCT program is the use of validated technicians. Every TCT technician must (1) average 20 hours per week at the pilot pharmacy, (2) have a minimum of 2,000 hours of experience and at least six months of employment at the participating pharmacy, (3) have additional didactic and practical training (e.g., common dispensing medication errors and concepts; organizational policies and procedures on reporting errors), and (4) undergo validation and revalidation (99.8% accuracy on checks). There are 17 approved TCT programs in Wisconsin to date.

Other pharmacy pilot programs in Wisconsin include the pharmacy technician ratio program and the automated technology final check. The purpose of the pharmacy technician ratio program is to study the safety, quality, and efficiency of waiving the technician to pharmacist ratio if a pharmacy meets eligibility requirements (i.e., has a continuous quality improvement program in place). The automated technology final check pilot program aims to study the safety, quality, and efficiency of automated technology to make the final check on the accuracy and correctness of the final dispensed medication with the goal of increasing the pharmacist's availability for other patient care activities.

Idaho

Idaho's State Board of Pharmacy has taken the approach of enabling pharmacists and technicians to practice to the top of their knowledge in order to reduce medication errors. Idaho has successfully shifted some of the pharmacists' responsibilities to technicians to reduce pharmacist workload and reduce distractions (e.g., phone calls) that may result in pharmacists committing errors. As part of this shift in responsibilities, Idaho has also implemented TCT. In response to the increasing role of technicians in the pharmacy, the Idaho board passed regulations so that they may discipline technicians in the same way they do pharmacists in the case of an error.

Idaho follows NABP's guidance regarding sanctions for medication errors. Instead of taking punitive action against pharmacists who make minor errors (e.g., errors with lack of intent), the Idaho Board sanctions pharmacists with 18 hours of continuing education. In comparison, pharmacists who do not commit an error have an annual continuing education requirement of 15 hours.

Texas

Texas is another state that has taken significant steps to reduce errors. The Texas State Board of Pharmacy issued a joint position statement with the Texas State Board of Nurse Examiners regarding medication errors. The position statement calls for a comprehensive and varied approach to reduce errors, citing three major elements — (1) individual practitioner knowledge (e.g., up-to-date on new medications, technologies, and procedures); (2) available resources (e.g., adequate staffing); and (3) systems designs, problems, and failures, which call for a quality program that tracks and analyzes errors.

Texas has a technician certification process that requires a nationally accredited examination for pharmacy technicians. Pharmacy technicians are required to complete 20 hours of education for renewal of their certification. Pharmacists must complete 30 hours of continuing education every two years.

California

California has passed several laws and regulations related to medication errors. For instance, California requires every pharmacy to have a quality assurance program that documents medication errors attributable to the pharmacists or other pharmacy personnel. They have extensively outlined requirements for these programs, including requirements for pharmacists if an error has occurred (e.g., communicate error to both patient and prescriber) and using findings from the program to develop systems and workflow processes designed to prevent errors. Their continuing education requirements are 30 hours of education every two years.

Federal Agencies

In response to the 1999 Institute of Medicine report, *To Err Is Human: Building a Safer Health Care System*, the federal government increased its role and presence in medication safety. In 2000, the Department of Health and Human Services (HHS) established the Quality Interagency Coordination Task Force, which issued a plan for reducing all medical errors. In 2001, a Patient Safety Task Force was created with involvement from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), and the Agency for Healthcare Research and Quality (AHRQ). While these task

forces are no longer active, they helped establish priorities and led to several important initiatives that are still in place.

FDA Programs and Policies

While several federal agencies have policies and programs that relate to medication safety, FDA is the most active and far reaching. In 2002, FDA formed a Division of Medication Error Prevention and Analysis (DMEPA) within the Center for Drug Evaluation and Research (CDER), which has since issued regulations and implemented initiatives focused on medication safety. Key activities are highlighted below.

Safe Use Initiative³³

The Safe Use Initiative is a multi-stakeholder health care collaborative with the goal of reducing preventable harm from prescription medications. To that end, the Initiative identifies specific and preventable medication risks and partners with other groups and organizations that are also committed to safe medication use. Their work products include white papers, multimedia campaigns, and tools for both consumers and health care professionals. Current areas of interest include acetaminophen, medication adherence, and unintentional medication overdoses in children.³⁴

Bar Code Labeling³⁵

The bar code label final rule took effect in 2004, requiring manufacturers and distributors of prescription and certain over-the-counter (OTC) drugs to ensure drug labels contain a bar code with the national drug code (NDC) number. The purpose of the regulation was to help health care professionals ensure the right drugs are being administered to the right patients in the right way, with the goal of reducing the number of medication errors. Although this rule targets hospital pharmacies, scanners are being used in community pharmacies as well. The National Association of Chain Drug Stores (NACDS) reports that there are 515,000 scanners being used in 55,000 community and chain pharmacies, or pharmacies in supermarkets and mass merchants.

Review of Proposed Drug Names³⁶

DMEPA is responsible for reviewing all proposed drug names prior to marketing of the product. There are both promotional and safety reviews. The promotional review, conducted by CDER's Division of Drug Marketing, decides if the name of the drug is misleading. DMEPA conducts the safety review and considers factors such as spelling, pronunciation, and appearance of the name when written. Database searches, medication error data, and name simulation studies, where health care professionals are given a prescription and tasked with simulating the ordering process, are all used during the safety review. As a result, FDA rejects approximately one out of every three proposed names.

Patient Safety Organizations (PSOs)

The Patient Safety Organization (PSO) program was created by the Patient Safety Improvement Act of 2005 (“Patient Safety Rule”) in response to national concern regarding the influx of preventable medical errors. PSOs are designated by AHRQ and aim to improve quality of care and patient safety by reducing the incidence of events that adversely affect patients. PSOs allow health care providers to voluntarily, and without legal repercussions, report patient safety events. The collected information, termed patient safety work product (PSWP), enables PSOs to develop patient safety interventions and solutions.

PSOs are responsible for collection and analysis of PSWP, patient safety information development and dissemination, PSWP security and confidentiality, and operation of a patient safety evaluation system. Of the 84 federally designated PSOs, 45 specialize in pharmacy. Of those focusing on pharmacy, the Alliance for Patient Medication Safety (APMS); PSO Advisory, LLC; Patient Safety Research Foundation, Inc.; and the Institute for Safe Medication Practices (ISMP) take a more active role specifically in medication safety.

Since PSOs were developed under the Patient Safety Rule, HHS has provided guidance on two issues regarding PSOs and how they handle PSWP. In 2010, HHS provided guidance regarding PSO disclosure obligations of PSWP to both the FDA and the PSO’s parent organization. More recently in 2016, there was further guidance from HHS regarding what information constitutes PSWP, as well as additional instructions on satisfying external reporting and recordkeeping obligations.³⁷

Institute for Safe Medication Practices (ISMP)

The Institute for Safe Medication Practices (ISMP) is a national non-profit dedicated to medication error prevention and safe medication use. It is also a federally designated PSO. Their mission is to collect and analyze ADEs, disseminate information, provide education on safe medication practices, collaborate with other stakeholders, advocate for adoption of safe medication practices, and conduct research to provide evidence-based safe practices.

ISMP provides a variety of resources for pharmacies, health care professionals, and consumers including:

- High-alert medication consumer leaflets
- Assessment of bar code verification system readiness in community pharmacies
- Root cause analysis workbooks for community pharmacies
- A manual entitled *Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change*

- Medication Safety Self-Assessment for Community Pharmacy
- Tall man lettering recommendations

ISMP also has one of the largest Medical Error Reporting Programs (MERPs). It is a confidential and voluntary medical reporting program ISMP uses to collect PSWP. The ISMP MERP's impact is extensive, and ISMP has used data collected to inform the development of many of the programs listed above. Among the most influential activities include:

- Early warning systems to make providers and the public aware of hazards and errors
- Dissemination of trends and strategies
- Recommendation for changes, including:
 - Drug and device packaging, labeling, and nomenclature
 - Organization systems
 - Individual practice
- National safety guidelines, standards, and goals (e.g., tall man lettering)
- Public policy advocacy

Non-Profit Organizations and Alliances

Outside of associations and government agencies, there are a number of influential non-profit organizations and multi-stakeholder alliances focused on reducing medication errors or improving pharmacy practice. A select group of noteworthy organizations are highlighted below.

Pharmacy Health Information Technology (HIT) Collaborative³⁸

The Pharmacy HIT Collaborative was founded in 2010 by nine pharmacy professional associations. The Pharmacy HIT Collaborative's three overarching goals are access (HIT supports pharmacists in health care service delivery), connectivity (pharmacists' integration within HIT), and quality (national quality initiatives are enabled by HIT). The Collaborative provides resources for consumers, advocates, and health care professionals on their website. Additionally, the Pharmacy HIT Collaborative does outreach to federal organizations, such as the Office of the National Coordinator (ONC), CMS, and HHS, and responds to public comments to advance HIT initiatives.

Patient Access to Pharmacists' Care Coalition (PAPCC)³⁹

The Patient Access to Pharmacists' Care Coalition (PAPCC) is a diverse group of stakeholders who advocate for federal legislation and policies to support Medicare access and payment for services provided by pharmacists in medically underserved communities. Their mission is centered around allowing pharmacists to practice to the top of their knowledge while

increasing pharmacy services to underserved, older adults. The coalition has over 40 member organizations, including pharmacies and professional and trade associations.

National Council for Prescription Drug Programs (NCPDP)^{40,41}

The National Council for Prescription Drug Programs (NCPDP) is a non-profit, multi-stakeholder organization with a dual aim of improving patient safety and health outcomes while decreasing costs. NCPDP engages in activities such as creation of national standards for electronic exchange of health care information and development of best practices for patient safety. Its standard development process utilizes a consensus-based approach and focuses on exchange of information related to prescription prescribing, dispensing, monitoring, management, and payment.

NCPDP's work with standards has influenced federal legislation regarding the Health Insurance Portability and Accountability Act (HIPAA), Managed Medical Assistance (MMA) Program, Health Information Technology for Economic and Clinical Health (HITECH) Act, and Meaningful Use Program. In addition, NCPDP develops and standardizes best practices related to product labeling, dosing instruction, patient communication and education, and other pertinent information for patients.

*SCRIPT Standards*⁴²

One of the most important sets of standards that NCPDP has developed related to medication errors is the SCRIPT Standards for e-prescribing. The SCRIPT e-prescribing standards apply to new prescription requests, changes of prescriptions, fill status notifications, and Cancel Rx, which allows the prescriber to electronically transmit to the pharmacy a request to discontinue a patient's existing prescription.

National Council on Patient Information and Education (NCPIE)^{43,44}

The National Council on Patient Information and Education (NCPIE) is a non-profit coalition of members from consumer, business, health care professional, and non-governmental standard-setting organizations, and from government agencies with the common goal of improving health and stimulating conversation about safe and appropriate medication use. NCPIE develops information and programs targeting consumer education which include the safe use of acetaminophen, importance of medication management and medication adherence, medication safety issues for older adults, and resources for community action against prescription drug abuse. Additionally, its campaign "Talk Before You Take" provides tools to promote effective dialogue between patients and health care providers to better and more effectively communicate medication safety.

Joint Commission of Pharmacy Practitioners (JCPP) ⁴⁵

The Joint Commission of Pharmacy Practitioners (JCPP) is a group of 13 national pharmacy organizations who serve as a forum to discuss issues important to pharmacists, pharmacies, and the health care system. As part of this work, JCCP developed the Pharmacists’ Patient Care Process in 2014, which was a strategic effort to standardize pharmacists’ delivery of care. The goal of this effort was to create consistency in the delivery of care and promote quality outcomes for patients. The reduction in variability in pharmacy practice should allow pharmacists to better address medication errors.

Opportunities for Pharmacists to Reduce Errors

Based on background research and key informant interviews, we identified a set of strategic opportunities to influence medication errors in community pharmacies. These strategic opportunities would fill gaps in current policies and programs aimed at reducing errors in community pharmacy.

In this section, we identify five priority areas of opportunity, shown in Figure 3 below, and detail specific strategies, tactics, and partners in these areas. In addition, we prioritized the strategies based on an analysis of feasibility and impact. Appendix 1 includes a summary table of all strategies, including needed partners and prioritization level.

Figure 3: Strategic Opportunities to Reduce Medication Errors in Community Pharmacy



Area 1: Error Reporting

Strategy 1: Increase Voluntary Error Reporting

Opportunity: Understanding the scope, prevalence, and magnitude of medication errors is an important first step in prevention. PSOs are established so pharmacies can voluntarily and anonymously report errors, without legal repercussions. However, in practice, many pharmacists still do not report medication errors. Barriers for reporting of errors in community pharmacy mirror those in hospital pharmacy and for other health care professionals. Some factors that contribute to low rates of error reporting among pharmacists include:

- No clear definition of what constitutes a medication error
- Complex reporting processes
- Lack of time and resources
- Fear of punishment or ridicule
- Reluctance to report incidents involving other staff members
- Concerns about medication error rates⁴⁶

Discussions with key informants indicate that it is important to find ways to increase reporting without making reporting mandatory.

Tactics and Partners: Tactics for increasing reporting and its impact include increased education for pharmacists about the importance of error reporting and the creation of an umbrella data repository for error reporting. For this data repository, PSOs would be able to submit anonymous data to an overarching PSO who would collect, aggregate, and report on the state of medication errors. Key partners for these types of initiatives include APhA, schools of pharmacy, state pharmacy associations, and PSOs.

Area 2: Education

Strategy 2: Improve and Standardize Pharmacist Education on Medication Error Prevention

Opportunity: There remains a general gap in knowledge in community pharmacies around quality improvement and processes, and the importance of policies and procedures to reduce medication errors. In recent years, educators have attempted to increase knowledge on structured quality improvement processes among practicing pharmacists. For example, a group of pharmacy educators recently published *Quality & Safety in Pharmacy Practice*, which includes information on implementing a pharmacy quality improvement program. The guide covers identifying key steps, applying the process with real-world examples, and assessing the challenges of applying in pharmacy settings.⁴⁷

While colleges of pharmacy are required to provide medication safety education, each school develops its own curriculum and there is variation in course content between schools.⁴⁸ A standardized approach with core competencies may be useful in reducing variation.

Tactics and Partners: Incorporating core standardized competencies of quality improvement early in a pharmacist's training both during pharmacy school and early in their pharmacy career could help fill the gap in knowledge around quality improvement. Necessary partners would include the American Association of Colleges of Pharmacy, NACDS, and PSOs.

In addition, non-profit organizations, such as ISMP, have a plethora of educational resources for pharmacists. A partnership with medication safety organizations could increase dissemination of valuable information, increase awareness of specific errors, and promote proactive prevention of medication errors among practicing pharmacists.

Strategy 3: Improve Patient Education

Opportunity: Increasing patients' knowledge about their medications is another safeguard in preventing medication errors. Informed patients understand their medications in more depth, ask the right questions to pharmacists, take the medication as directed, and are better prepared to identify a medication error in the event one occurs.

An important part of education for patients with complicated medication regimens is medication therapy management (MTM) services, which rely on collaboration between the patient, pharmacist, physician, and other health care providers. MTM services focus on assessing and evaluating a patient's complete medication therapy regimen as opposed to an individual medication.⁴⁹

Tactics and Partners: Education regarding active ingredients (e.g., acetaminophen) across a patient's prescription and over-the-counter medications could help decrease cases of medication overdosing. FDA's Safe Use Initiative and NCIPIE's *Be Medwise* campaign could serve as key partners for patient education initiatives. Expanding patient counseling and MTM can include partnering with the APhA, the National Community Pharmacists Association, NACDS, and other pharmacy professional associations. More widespread MTM will require changes in reimbursement policies (see Strategies 12 and 13).

Area 3: Pharmacy Practice

Strategy 4: Expand Evidence Base and Use of Tech Check Tech (TCT)

Opportunity: TCT allows the technicians to complete the final check to ensure that the right prescription is in the medication bottle, which allows the pharmacist to focus on other tasks

such as reconciling medications, following up with prescribers, and counseling patients. Critics of TCT believe this practice is unsafe because technicians do not have the same level of experience or training as pharmacists. However, proponents argue that technicians are fully capable of ensuring the right drug is in the bottle and emphasize that the drug utilization review is still being completed by a pharmacist.

Tactics and Partners: The first step to pursuing wider adoption of TCT is to better understand the policy and scope of practice landscape for technicians across states. There is good evidence that TCT is effective in the hospital setting in the four states that have implemented TCT (Wisconsin, Tennessee, South Dakota, and Idaho), but less is known about TCT in the community pharmacy setting. Additional research is needed to provide the evidence base for TCT in community pharmacy. With this information, the Moore Foundation could work with State Boards of Pharmacy in other states to implement TCT.

Strategy 5: Avoid Prescription Time Guarantees

Opportunity: Some pharmacy chains have implemented prescription time guarantees, promising customers that they will receive their prescriptions quickly. While this seems like a benefit for the customer, it could be a safety concern, as pharmacists rushing to fill prescriptions may be more likely to cause a medication error. For this reason, many organizations and individuals, including NCC MERP, advocate for the elimination of prescription time guarantees.

Tactics and Partners: This strategy would involve outreach to pharmacy chains to provide information on the safety concerns from time guarantees and advocate that they not use them. Partners such as NCC MERP that hold this view on prescription time guarantees would be important partners.

Strategy 6: Develop Practice Guidelines

Opportunity: Community pharmacy does not have widely accepted practice guidelines focused on operational processes and procedures. There are clinical practice guidelines for medication management of patients with a variety of conditions, and standards exist in community pharmacy accreditation program standards. However, there are no general practice guidelines that include specific recommendations on quality improvement and reducing medication errors.

Tactics and Partners: Experience gained from pharmacy best practices, accreditation standards, and residency accreditation program standards can be translated into practice guidelines. Currently, APhA is developing an array of guidelines on specific topics, including health care

team collaboration and roles of support staff. Condition-specific guidelines will help pharmacists use best practices and interventions for patient care services for specific conditions. Their areas of initial focus will be immunizations beyond influenza (e.g., shingles), tobacco cessation, diabetes/cardiovascular disease complex patients, and COPD. There is an opportunity to work with APhA to build medication error prevention approaches into these guidelines, and to work with other organizations to develop other sets of guidelines.

Strategy 7: Promote Community Pharmacy Accreditation

Opportunity: Two accreditation bodies, URAC and CPPA, have developed pharmacy accreditation programs for community pharmacy. These accreditation programs have rigorous requirements for reporting and reviewing medication errors, and standards for processes and procedures in place to avoid errors. This type of accreditation would provide the infrastructure for continuous quality improvement. To date, uptake of these programs has been minimal due to a lack of incentives for accreditation. Currently, CVS is the only pharmacy that has obtained URAC Community Pharmacy Accreditation.

Tactics and Partners: This strategy would require partnering with accrediting bodies to promote accreditation programs, and perhaps partnering with payers and others to make contractual relationships with pharmacies conditioned on accreditation status.

Strategy 8: Build Evidence Base and Consensus on Priority Drug/Drug Interactions (DDIs)

Opportunity: Research and evidence regarding DDIs are insufficient, which has resulted in a lack of consensus on which are the most significant interactions about which pharmacists should be concerned. Health care organizations, compendia, and drug knowledge vendors use varying methods to evaluate and synthesize evidence on DDIs. Without such clinical evidence, trivial DDI alerts may cause pharmacists or technicians to experience alert fatigue. (Alert fatigue is discussed in more detail in Strategy 10.)

AHRQ funded researchers from the University of Arizona College of Pharmacy and U.S. Pharmacopeia in 2014/2015 to provide recommendations for a review of DDI evidence. They convened a workgroup which concluded evidence regarding DDIs needs to be consistent, systematic, and transparent. Additional and ongoing work is needed in this area.

Tactics and Partners: Agencies like ONC, the National Institutes of Health (NIH), AHRQ, CDC, and non-profits should be encouraged to allocate grant funding to efforts to build the evidence base of DDI and convene a national panel to build consensus regarding DDIs that should be emphasized. Researchers at the University of Arizona College of Pharmacy have led ongoing work in this area but indicated that additional funding is needed for ongoing work.

Strategy 9: Distribute Information on High-Alert Drugs

Opportunity: As part of its broader initiatives to reduce medication errors, ISMP has developed valuable information on 13 high-alert drugs. Information regarding these drugs could be better distributed as well as incorporated into standards and guidelines for community pharmacy practice, as well as into IT systems.

Tactics and Partners: Organizations such as ISMP, APhA, and NACDS would be key partners for this type of initiative. Knowledge vendors, electronic medical record vendors, and pharmacy dispensing system vendors should be encouraged to incorporate information on high-alert drugs into their system.

Strategy 10: Address Pharmacist Alert Fatigue

Opportunity: As seen in other parts of health care practice, an abundance of automatic alerts in computerized decision support tools in pharmacy dispensing systems have led to alert fatigue. The aim of these alerts is to decrease medication errors and prevent ADEs. As pharmacists and pharmacy technicians are inundated with what they perceive to be too many unnecessary alerts, the alerts are being overridden by pharmacists and, in some cases, pharmacy technicians.

Tactics and Partners: Significant research has been done on the pervasiveness of alert fatigue in other health care settings, specifically with computerized decision support tools in electronic health records intended to reduce medical errors. Much of this work has been done by investigators at the Brigham and Women's Hospital Center and has been focused on physicians/prescribers. It would be valuable to encourage collaboration between researchers focused on this issue at the University of Arizona College of Pharmacy and the work being done at Brigham & Women's.

With this research in hand, efforts can be taken to reduce unnecessary alerts to avoid fatigue. This would require working with IT vendors, pharmacy chains, and others to implement changes to existing alert systems.

Area 4: Scope of Practice

Strategy 11: Increase Pharmacist Access to Patient Information

Opportunity: Pharmacists could more often identify and address medication errors if they had access to patients' electronic health records (EHRs) and lab results, or if the prescription indication was consistently written or transmitted on the prescription. This information would allow pharmacists to identify medications that may be the wrong drug dose, quantity, or

strength for the patient. Additionally, pharmacists could detect possible interactions between medications prescribed by different doctors.

Verifying patient and provider information, medication information, and the validity of a prescription are responsibilities of the pharmacist. Usually these questions are resolved by communicating with the physician or a physician office staff member. However, some organizations and physician offices viewed the communication needed between physicians and pharmacists as disruptive. Consequently, the American Medical Association (AMA) passed Policy D-35.981, which states “inappropriate inquiries from pharmacies to verify the medical rationale behind prescriptions, diagnoses, and treatment plans to be an interference with the practice of medicine and unwarranted.”⁵⁰

Policies that discourage communication between prescribers and pharmacists could be avoided if there was adequate access to patient information and interoperable communication between physicians and pharmacists.

Tactics and Partners: Partners key for advocating for pharmacist access include APhA and the Pharmacy HIT Collaborative. Other influential organizations include ONC and EHR vendors.

Strategy 12: Recognize Pharmacists as Providers under Medicare Part B

Opportunity: Pharmacists are not currently recognized as health care providers under federal law and thus cannot be compensated for providing medical services under Medicare Part B. This prevents pharmacists from practicing to their fullest capability or training due to lack of reimbursement. There is federal, bipartisan legislation (H.R. 592/S. 109) that would amend Medicare to allow pharmacists to be compensated for care provided to underserved older adults.

Medicare Part D *does* include medication therapy management (MTM) programs operated by Prescription Drug Plans (PDPs) in the Part D prescription drug benefit for patients that meet certain criteria, but this only covers a small portion of Medicare patients. MTM and counseling represent key strategies for educating patients on proper use of their medications and reducing administration errors.

Tactics and Partners: This strategy would require advocacy to inform and influence Congressional discussions about the current legislation. Key allies for this initiative include APhA, patient and consumer advocacy organizations, and the Patient Access to Pharmacists’ Care Coalition (PAPCC).

Strategy 13: Expanding Pharmacists' Role and Reimbursement under State Medicaid Programs

Opportunity: Similar to Medicare, most state Medicaid programs do not compensate pharmacists to provide crucial services, such as MTM. As state legislatures across America search for ways to improve patients' health and lower health care costs, interest in pharmacist-provided care is increasing. Legislation that has been introduced includes (1) pharmacist designation as a provider, (2) scope of practice laws and regulations, and (3) payment for services.

Tactics and Partners: Addressing lack of reimbursement would require advocacy efforts to influence state legislative discussions. Key partners would be state pharmacy associations, patient and consumer advocacy organizations, NACDS, and APhA.

Area 5: Prescribing Technology

Strategy 14: Expand E-prescribing

Opportunity: There has been a major push to adopt e-prescribing through the development of standards and new regulations and laws. NCPDP created, and continually manages, the SCRIPT Standard, which outlines specifications for pharmacies, prescribers, payers, etc. In a recently published proposed rule, CMS has proposed updating the current e-prescribing standard to NCPDP SCRIPT (version 2017071) effective January 1, 2019.^{51,52}

Many state and federal laws have been updated to promote or even require e-prescribing, and organizations have started to develop standards for e-prescribing operations. For instance, Minnesota enacted a mandate in 2008 requiring prescribers, pharmacists and pharmacies, and pharmacy benefit managers to be e-prescribing by January 1, 2011.⁵³ A New York law requiring e-prescribing went into effect in 2016.

However, most states lack laws requiring e-prescribing, despite the fact that it has all but eliminated transcription errors and has dramatically reduced prescribing errors. Additional federal regulation and laws could expand adoption of e-prescribing, as well.

Tactics and Partners: Important partners would be the Pharmacy HIT Collaborative, NCPDP, SureScripts, and e-prescribing vendors.

Strategy 15: Expand Adoption of Cancel Rx Standard

Opportunity: As a result of the Cancel Rx standard, prescribers can use their EHR systems to request a prescription be canceled that is already in the pharmacy's system. Pharmacists receive the request and respond accordingly. This technology is useful because prescribers often modify prescriptions during consultation with patients but may not communicate this

information to the patient's pharmacist. Cancel Rx provides a way to safely and efficiently cancel outdated prescriptions.

Tactics and Partners: NCPDP has established a Cancel Rx standard. The standard lacks widespread industry adoption by prescribers and e-prescribing vendors. Efforts to work to increase adoption of the standard would involve outreach to these entities.

Conclusion

While the vast majority of prescriptions are prescribed, transcribed, dispensed, and administered without error, medication errors result in significant harm for hundreds of thousands of Americans each year. The average community pharmacy is responsible for two harmful errors each week. While there are many successful policies and programs aimed at reducing errors, there are gaps and additional progress is possible.

We identified five broad areas of opportunity—error reporting, education, pharmacy practice, scope of practice, and prescribing technology—for positioning community pharmacists to reduce errors. Specific strategic opportunities include additional voluntary error reporting, education for pharmacists on error prevention, pharmacy practice guidelines and accreditation, building evidence on DDI, addressing alert fatigue, and increasing pharmacists' access to patient information.

As health care in the U.S. continues to evolve, all possible steps must be taken to reduce the incidence of medication errors. The changes in health care delivery and payment and the growing emphasis on quality provide an opportunity to reassess the role of pharmacists and pharmacies in patient care and position them to reduce errors. This is an opportune time to work with partners to pursue additional strategies to reduce medication errors.

Appendix 1. Strategic Opportunities Summary Table

Potential Partners	Area 1: Error Reporting	Area 2: Education	Area 3: Pharmacy Practice						Area 4: Scope of Practice				Area 5: Prescribing Technology		
	Strategy Number														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Error Reporting	Pharm. Edu. on Error Prevention	Patient Edu.	Tech Check Tech	Time Guarantee	Practice Guidelines	Accreditation	DDI	High-alert Drugs	Alert Fatigue	Access to Patient Info	Medicare Provider Status	Medicaid Programs	E-prescribing	Cancel Rx
	Priority Level														
Professional and Trade Associations															
APhA															
NACDS															
NCPA															
United States Pharmacopeia															
NCCP MERP															
Accreditation Bodies															
Accreditation Organizations															
State Boards of Pharmacy															
NABP															
Individual State Boards															
Federal Agencies															
FDA															
ONC															
NIH															
AHRQ															
CDC															
Patient Safety Organizations (PSOs)															
PSOs															
ISMP															
Non-Profit Organizations and Alliances															
Pharmacy HIT Collaborative															
PAPCC															
NCPIE															
NCPDP															
Other Key Players															
Pharmacy Chains															
Payers															
Consumer advocacy groups															
Univ. of Arizona College of Pharmacy															
Schools of Pharmacy															
AACP															

Acronyms

AACP	American Association of Colleges of Pharmacy	ISMP	Institute for Safe Medicine Practice	NCPDP	National Council of Prescription Drug Programs
AHRQ	Agency for Healthcare Research and Quality	NABP	National Association of Boards of Pharmacy	NCPIE	National Council for Patient Information and Exchange
APhA	American Pharmacist Association	NACDS	National Association of Chain Drug Stores	NIH	National Institutes of Health
CDC	Centers for Disease Control and Prevention	NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention	ONC	Office of the National Coordinator for Health Information Technology
FDA	Food and Drug Administration	NCPA	National Community Pharmacist Association	PAPCC	Pharmacists' Care Coalition

Critical Partner

Optional Partner

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