# Improving Public Health by Advancing a Multicomponent Approach to Increasing Prescription Dispensing Safety in U.S. Outpatient Pharmacies

**Policy Date:** October 29, 2024

**Policy Number:** 20247

Abstract

This policy statement addresses one component of medication safety: the safety of prescription dispensing within outpatient pharmacies. In 2022, nearly 4.5 billion prescriptions were dispensed from these pharmacies, yet limited data exist about the types and rate of dispensing errors, the impact of factors such as work pressures and staff training on errors, and the extent to which pharmacies prioritize safety and invest resources to improve safety. While prescriptions should be dispensed without errors, national surveys and media reports indicate that dispensing errors may be increasing because of a lack of organizational commitment to the personnel and resources needed to ensure patient safety. This weak culture of safety may reflect the relative lack of external accountability placed upon pharmacies to ensure that prescriptions are dispensed without error. Three avenues for lowering the risk of dispensing errors are proposed: (1) additional research and practice-based data to determine error types, rates and costs, pharmacy-based factors contributing to errors, and the effectiveness of continuous quality improvement efforts to prevent future errors; (2) further research into defining and measuring the culture of safety within pharmacies and effective ways to strengthen that culture; and (3) increased external accountability for pharmacies to maintain a culture of safety. Prescription dispensing safety is likely to be clearly assessed and continuously improved if a multicomponent, collaborative approach brings together the innovation, support, and accountability needed to address this key component of medication safety. Undertaking the recommended action steps within the selected sector of pharmacies can serve as a springboard for expanding prescription dispensing safety in all pharmacies.

Key words: patient safety; public safety; safety culture; prescription safety

## Relationship to Existing APHA Policy Statements

No active APHA policy statement addresses this public health problem. The APHA policies listed below discuss problems, strategies, or action steps that lay a foundation for this proposed statement. APHA Policy Statement 20109 cites low health literacy as a contributing factor to medication errors. Interdisciplinary education and patient-centered care are supported by Policy Statements 200614, 20088, 202011, and #20215. Policy Statements 20068 and 20223 are foundational for our action step related to organized labor as a means of addressing workplace issues that affect the culture of safety within pharmacies.

- APHA Policy Statement 20109: Health Literacy: Confronting a National Public Health Problem
- APHA Policy Statement 200614: The Role of the Pharmacist in Public Health
- APHA Policy Statement 20088: Promoting Interprofessional Education
- APHA Policy Statement 201011: Reforming Primary Health Care: Support for the Health Care Home Model
- APHA Policy Statement 20215: A Call to Improve Patient and Public Health Outcomes of Diabetes through an Enhanced Integrated Care Approach
- APHA Policy Statement 20068: Resolution on the Right For Employee Free Choice to Form Unions
- APHA Policy Statement 20223: Support Decent Work for All as a Public Health Goal in the United States

Problem Statement

This policy statement addresses prescription dispensing safety within outpatient pharmacies including chain, grocery store, mass merchandiser, independent, and mail order pharmacies. From 2015 to 2018, nearly half of U.S. residents reported using at least one prescription medication in the past 30 days, with 24.0% using three or more medications.[1] In 2022, an estimated 4.5 billion prescriptions were dispensed from these pharmacies,[2] resulting in $64 billion in retail out-of-pocket prescription expenditures.[3] Private insurers and the Centers for Medicare & Medicaid Services (CMS), through Medicare Part D and Medicaid programs, each accounted for about 40% of retail prescription expenditures.[4]

The safety of outpatient pharmacy prescription dispensing practices is a public health concern. The high number of prescriptions dispensed means that even a low dispensing error rate can affect millions. If the commonly cited 1.5% dispensing error rate is applied to 2022 prescription data, an estimated 67.5 million dispensing errors occurred that year.[2] Alarmingly, reports by pharmacists [5] and the media [6,7] suggest that dispensing errors are rising.

Dispensing errors include prescriptions dispensed to the wrong person, incorrect medications or strengths dispensed, incorrect prescription label information, dispensing medications that could lead to drug-drug or drug-disease interactions, and failure to provide adequate patient/caregiver counseling.[8–11] The multiple steps involved in prescription dispensing create error opportunities at any point during prescription preparation, review of medication records for therapeutic concerns, and patient counseling.[8] Errors can result in drug-drug interactions, adverse events, hospital admissions, increased health care utilization, and increased risk of death.[9]

A focus on dispensing errors within outpatient pharmacies is warranted because they lack key safety features that exist within inpatient (hospital/long-term care) pharmacies.[10] Safety differences include the following: (1) outpatient prescriptions are dispensed directly to patients; (2) few outpatient pharmacies face external regulatory pressures that promote a culture of safety[12]; (3) outpatient pharmacies are not required to obtain accreditation approval from organizations such as The Joint Commission[13] or URAC (formerly known as the Utilization Review Accreditation Commission)[14] that provide external verification of prescription safety procedures; and (4) while parent institutions of inpatient pharmacies promote their safety to the public, outpatient pharmacy corporations emphasize fast receipt of prescriptions, prioritizing consumer demand over dispensing safety.[15]

This policy lays out three problem areas that cloud or add to dispensing error concerns. First, we lack a clear understanding of the types, frequency, and associated costs of dispensing errors and their impact on patient health; the degree to which system-mediated factors, such as pharmacy staffing, impact errors; and the interplay of these factors within specific outpatient pharmacy environments. Second, the culture of safety appears to be eroding in a growing number of pharmacies. Third, there is little external pressure to hold back that decline.

Paucity of outpatient pharmacy dispensing safety data: The Institute of Medicine report To Err Is Human: Building a Safer Health System[16] ushered in an era of medication safety research; however, little research has focused on outpatient pharmacy prescription dispensing.[8,17] A 2024 international systematic review of both hospital and community pharmacy dispensing error studies from 2010 to 2023 included only 15 U.S. studies.[18]

Outpatient pharmacy dispensing error studies report significant variations in error rates due to differences in medication error definitions, pharmacy inclusion criteria, study sample sizes, methodologies (e.g., direct observation, mystery shoppers [i.e., individuals hired to pose as shoppers], surveys, claim data analysis), and error reporting metrics.[10] Some studies have defined an error as occurring only when undetected, while others have included errors detected and remedied during the dispensing process (i.e., “near misses”).[19] A 2018 meta-analysis of medication error studies reported dispensing error rates ranging from 0.00003% to 52%, with an overall estimated rate of 1.5%.[19] The lowest error rate was reported from a claims database analysis of selected medications. The highest rate resulted from direct observations related to selected prescriptions requiring patient consultation.

Reported percentages of dispensing errors causing patient harm range from 4% to 52%.[17,20] An observational study of 50 pharmacies showed that 6.5% of dispensing errors had the potential to cause patient harm,[21] while a mystery shopper study of 255 pharmacies revealed that 52% of pharmacies dispensed two prescriptions that, if taken together, could result in a life-threatening drug interaction.[20] The degree to which harm from dispensing errors contributes to health care expenditures is unknown. The authors of a 2024 systemic review of medication errors called for a common data reporting and analysis framework to determine the financial impact of those errors.[22] Similarly, adoption of common data collection, reporting, and analytical approaches is needed to determine the financial impact of dispensing errors in outpatient pharmacies.[22]

Certain individuals may be at high risk for error harm, including children, pregnant persons, elderly persons, and those who have multiple or complex health conditions, mental health illness, or developmental or intellectual disabilities; take multiple medications; or take medications with a high potential for serious adverse reactions.[23,24] Individuals with low vision and hearing impairment and those with low health literacy or English as a second language may face challenges in reading prescription labels necessary to detect dispensing errors.[25–29] People with fragmented health care; who face barriers to care (e.g., those residing in rural or underserved areas and those with inadequate health insurance) and/or discrimination within health care settings due to race, ethnicity, gender identity, or mental health illness; or who live in stressful socioeconomic conditions (e.g., homelessness) may face barriers to error remediation.[30,31]

Data on root causes of dispensing errors are key to prevention. Associations have been found between dispensing errors and high prescription volumes, inadequate staffing levels and education, workplace disruptions, and lack of patient counseling.[11,21,32] Pharmacists consistently report that performance metrics drive work overload, work-related stress, burnout, and moral injury and thus contribute to errors and increased patient safety issues.[33] Technology use lowers dispensing errors, but they still occur as a result of human error and technology limitations.[10] Key questions remain about the impact and interaction of these factors in causing dispensing errors and the interventions that best alleviate their impact on error occurrence and patient safety.

Understanding dispensing safety is complicated by the lack of public sources of error data. Food and Drug Administration (FDA) MedWatch,[34] the FDA and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS),[35] and the Institute for Safe Medication Practices (ISMP) consumer and health professional reporting systems [36] collect dispensing error reports

but do not publicly share such data or allow access to databases. Most outpatient pharmacies do not report dispensing error rates to state boards of pharmacy, and dispensing safety is rarely discussed in corporate annual reports.[37] A growing number of outpatient pharmacies use patient safety organizations (PSOs) that shield error data from public and legal disclosure.[38] While data confidentiality is thought to enhance error reporting,[16] this also means that the public cannot choose pharmacies and payers cannot build pharmacy networks based on dispensing safety criteria. Only crude indicators of pharmacy dispensing safety are publicly available: state data on lack or loss of licensure, lawsuits, whistleblower reports, and media reports. [6,7]

Eroding culture of safety within outpatient pharmacies: Dispensing safety within outpatient pharmacies must be supported by an organizational culture that acknowledges medication risks, strives to protect patient safety, values communication, fosters shared trust, and believes in the value of preventive measures.[10] According to the 2022 National Pharmacist Workforce Study, 82% of pharmacists indicated that patient medication safety is being “reduced” or “significantly reduced” as a result of increasing practice-related activities.[5] Pharmacists’ frustrations may arise from their lack of legal authority over system-mediated causes of errors such as staffing levels and staff education.[5]

The linchpin to a culture of safety is continuous quality improvement (CQI), in which a systems approach is used to improve safety through ongoing error data gathering, assessments, and system improvements. While medication safety is a required component of pharmacist education, pharmacy staff may not have the requisite reporting and communication skills needed for CQI initiatives.[39] A growing number of pharmacies use PSOs approved by the Agency for Healthcare Research and Quality (AHRQ) to collate their error data and recommend safety initiatives.[38] The impact of PSOs on dispensing safety practices is unknown but requires examination because pharmacists practicing at pharmacies affiliated with PSOs report fear of reprisal for reporting errors and state that they do not receive feedback about reported errors[6]—two hurdles to improving medication safety that PSOs were created to overcome.

Collaboration between pharmacists and prescribers and their staffs is essential to prevent dispensing errors; however, the “siloed” nature of pharmacies within the health care system hinders the prescriber-pharmacist communications and collaborations needed to prevent, detect, and remedy prescription errors. Lack of pharmacy access to electronic health record information prevents detection of errors such as drug-disease interactions and incorrect patient or medication names on prescriptions.[32,40] A Qualtrics survey of 204 pharmacists and 200 physicians revealed that while nearly all believed collaboration

between physicians and pharmacists is important, both physicians and pharmacists reported that collaboration was hindered by lack of time and communication challenges.[41]

Lack of external accountability for dispensing safety: State boards of pharmacy have a duty to hold pharmacies and pharmacists accountable for prescription safety through enforcement of pharmacy laws and regulations. However, most state boards of pharmacy do not require outpatient pharmacies to report dispensing errors or undertake CQI activities.[12] A survey of state boards of pharmacy showed that only 16 state boards mandated that community pharmacies implement some component of CQI.[12] Of those, three required complete audits related to medication safety and only one required documentation of quality improvements made. Few state boards take actions to address workplace factors known to influence dispensing error rates or cite pharmacies for neglecting to counsel patients as required by law.[11]

Despite significant prescription expenditures and interest in preventing unnecessary health care costs, health care payers rarely hold pharmacies accountable for dispensing errors. Payer medication safety quality measures do not assess pharmacies' culture of safety or CQI initiatives.[42] Neither CMS nor private payers require outpatient pharmacies to attain national accreditation approval from organizations that assess patient safety practices.[12]

Outpatient pharmacies and their corporate owners face little market pressure to improve prescription dispensing safety. Based on corporate annual report content, shareholders appear to have little interest in prescription dispensing practices, dispensing error rates, or their impact on patient health and liability costs.[37]

## Evidence-Based Strategies to Address the Problem

This policy statement focuses on the following three strategies to protect the public against outpatient pharmacy dispensing errors: (1) increasing research and practice-based analysis to characterize dispensing errors, their impact on patient safety and financial costs, the patient populations affected, and system-mediated factors that are the root cause of errors to inform CQI efforts; (2) strengthening the culture of safety through CQI initiatives and pharmacist, patient, and interprofessional collaboration; and (3) encouraging health care payers, patients and caregivers, and the general public to hold pharmacies accountable for dispensing safety.

Increase research and practice-based analysis: Data-driven interventions to improve dispensing safety are needed. Meaningful safety data requires consistent use of standardized definitions and reporting elements.[10] Government resources and established public databases can provide direction for the development of sustainable surveillance models. While researcher access to established data repositories can inform an understanding of dispensing errors, limitations commonly seen with error reporting platforms include voluntary error reporting, potential reporter bias, lack of root cause analysis of errors, and data limitations.[43]

One source for data standardization is publicly available: AHRQ Common Formats for Event Reporting-Community Pharmacy Version.[44] By offering a unifying approach to data reporting, this tool encourages data sharing that can lead to early alerts for needed interventions to protect patient safety.

FDA MedWatch,[34] VAERS,[35] and ISMP professional and consumer reporting portals [36] also provide insight into error data collection processes and translation into error prevention actions. Together, the FDA and the ISMP identify root causes of common and dangerous dispensing errors and apply this information to improve pharmaceutical product labeling and issue safety alerts.[36] The addition of artificial intelligence (AI) decision support tools holds potential to improve the speed of MedWatch data reviews, leading to better and faster decisions.[45] The VAERS database provides early alerts to health professionals about vaccine administration errors.[46] Increased voluntary reporting participation and deidentified data availability to researchers and analysists could increase the value of these useful databases to outpatient pharmacy CQI efforts.

Another data resource may be outpatient pharmacy error data held within PSOs. PSOs are established through AHRQ,[38] and thus this agency's support of deidentified data access for research purposes is essential. Finally, an evaluation of dispensing safety within outpatient pharmacies by the Office of the Inspector General might be insightful given that a 2018 evaluation of hospital-based medication adverse events conducted by the office produced valuable recommendations.[47]

The Ontario, Canada Assurance and Improvement in Medication Safety (AIMS) program provides a standardized data reporting platform supported by mandatory anonymous dispensing error reporting with data used to support CQI initiatives.[48] AIMS offers educational programs and has a safety interest group and interactive tool that allow pharmacies and other stakeholders to view aggregated AIMS data.[48]

Strengthen the culture of safety within outpatient pharmacies: Strengthening the culture of safety within outpatient pharmacies first requires that a culture of safety be defined and measured. The AHRQ Community Pharmacy Survey on Patient Safety Culture, an online pharmacy-administered survey, provides an initial step toward this goal.[49] It encompasses 11 selected patient safety components including communications, patient counseling, work environment, and staff training. Researchers have used this tool to characterize pharmacy practice environments.[32]

The importance of CQI is illustrated in the creation of a joint patient safety reporting system by the Department of Defense and the Veterans Administration.[50] Both agencies can report incidents and near misses, including those related to prescription dispensing errors, via a standardized methodology for data input, incident investigation, and root cause analysis.

When educated, outpatient pharmacists respond positively to CQI initiatives.[51] A communication network established to support CQI efforts in rural Nebraska pharmacies found that pharmacists valued shared error reports and used them to increase safety vigilance within their pharmacies.[52] Designation of a corporate medication safety officer can facilitate CQI participation, supporting communication among all levels of organizational management and ensuring that pharmacy staff receive intentional, ongoing education regarding medication safety and CQI implementation.[53]

A culture of safety links patient care responsibilities among pharmacists, patients/caregivers, prescribers, and other health care providers. Intentional linking of patient care services and electronic health records between pharmacies and patient-centered medical care homes improves coordination of care. [40,54,55] Shared electronic health records help in coordinating care and identifying prescription errors before prescriptions are dispensed. The Office of the National Coordination for Health Information Technology (ONC) has proposed a rule that e-prescriptions include the indication for use, thus providing information that could prevent incorrect patient, medication, and dose dispensing errors.[56]

Professional collaborations are essential for meeting the needs of those with barriers to understanding prescription vial information. Pharmacies offer large-print and alternative language prescription labels, but pharmacists often lack adequate skills and time to counsel patients with visual or hearing impairments or those with low proficiency in English. [57,58] Partnerships with public health nurses or community health workers who possess unique knowledge, skills, and community ties may be useful. Cross training of pharmacy technicians as community health workers holds promise, but this model of care is limited by time and financial requirements.[59]

A culture of safety supports a work environment that provides adequate resources. As employees, pharmacy staff can take actions to address workplace conditions that negatively affect patient safety. The Occupational Safety and Health Administration enforces federal laws related to employee rights and recognizes the links among an organizational culture of safety, worker rights, and patient safety.[60] Collective bargaining gives employees a voice in decisions related to work issues, such as working conditions that affect employee and patient safety.[61] Drawing on lessons learned from the nursing profession,[62] pharmacy professional associations could play a key role in pharmacy staff efforts to engage in collective bargaining.

Increase pharmacy accountability for maintaining a strong culture of safety: State boards of pharmacy-mandated pharmacist-patient/caregiver counseling can significantly decrease dispensing errors.[63,64] State laws have mandated error reporting and CQI processes, provided pharmacists legal authority to adequately staff pharmacies, and given pharmacy staff break times.[65–67] While the effect of these mandates is unknown, research on the Omnibus Reconciliation Bill of 1990 pharmacy practice requirements suggests that, without financial incentives, the intended benefits may be muted.[68] Irrespective of the laws' impact, their passage suggests that the political will to address system-mediated causes of dispensing errors exists.

Historically, outpatient pharmacy corporations have responded to financial incentives. In response to health plan requirements, corporations have expanded pharmacist responsibilities to include performance metrics linked to health plan quality measures.[33] When the federal government offered pharmacies reimbursement for COVID-19 vaccine administration, many pharmacies prioritized vaccine administration.[6] Establishing private and public payer financial incentives for pharmacy CQI efforts may be reasonable given that dispensing errors can result in increased health care costs.

Some state boards of pharmacy are combining a system-mediated approach to error prevention with financial disincentives by fining outpatient pharmacy corporations, rather than pharmacists, for prescription errors and failure to counsel patients.[6] CMS could build on this approach by requiring that outpatient pharmacies attain national accreditation status to receive Medicare and Medicaid prescription reimbursements.

As financial awards related to dispensing error lawsuits grow,[69] investors may raise concerns about legal expenditures. Requiring corporations to report information about CQI practices, their impact on

prescription dispensing safety, and overall prescription safety expenditures may incentivize them to establish stronger cultures of safety within their outpatient pharmacies.

Increasing public awareness, interest, and education in dispensing errors could engage patients, caregivers, and the public in taking actions to detect and/or prevent errors.[43] Public prescription dispensing safety programs could empower patients to request pharmacist counseling when receiving a prescription and to check the prescription label and vial contents before leaving the pharmacy.[70] One effective public medication safety program is the Drug Enforcement Agency's Prescription Take Back Day, which teaches the public how to safely dispose of unused medication to prevent unintentional medication use or poisonings. Between 2018 and October 2023, the program collected 8,950 tons of medications through its twice-yearly events.[71]

Alternative Strategies

An alternative strategy is continued passive surveillance of dispensing errors. Instead of taking the best practices proactive approach to error prevention,[55] this strategy takes a reactive approach that fails to address preventive measures and blames pharmacy staff without any root cause analysis of the contribution of the pharmacy system. This approach thwarts efforts to prevent dispensing errors and their associated patient harm.

Increasing medication safety training sessions and continuing education programs for pharmacy staff might be proposed as sufficient for addressing error concerns. However, limited educational sessions are often insufficient to address system-mediated medication safety.[72] To be effective, personnel training needs to be one component of a comprehensive safety strategy that builds on a culture of safety.

Human errors may lead to a desire to rely totally on technology (e.g., robots, AI-driven assessments and counseling) to prevent dispensing errors. While technology does lower rates of some types of errors,[43] those requiring complex decision making based on knowledge and experiential skills may not be reliably prevented with today's AI capabilities.

Action Steps to Implement Evidence-Based Strategies

| | **Evidence-Based Strategy** | | **Action Steps** |
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| 1 | Increase research and practice-based analysis to characterize dispensing | 1a | CDC, AHRQ, and the Health Resources and Service Administration, in partnership with researchers and medication safety stakeholders, should conduct and/or fund research related |

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| | errors, their impact on patient safety, the patient populations impacted, and the system-mediated factors that contribute to errors as a means to inform CQI efforts. | | to prescription dispensing errors, the factors that influence their occurrence and prevention, and their effect on patient safety and health care costs. Such work should focus on those most at risk of harm and the culture of safety within outpatient pharmacies and seek to develop common data elements and analytical frameworks. This research should build upon and coordinate with the efforts of the FDA, CDC, and ISMP. |
| | | 1b | The Department of Health and Human Services (DHHS) secretary should direct federal health agencies to develop and implement a system for collective reporting of dispensing errors. |
| | | 1c | AHRQ should support collaborative research between outpatient pharmacies and researchers on the structure, use, and impact of its Community Pharmacy Survey on Patient Safety Culture and Common Formats for Event Reporting-Community Pharmacy Version. Also, the agency should build on its current work related to pharmacy safety to assist outpatient pharmacies in using data to effectively support CQI initiatives. This effort should include tactics for broadly sharing lessons learned with other pharmacies and key stakeholders. Partners in this effort could include the FDA, CDC, ISMP, outpatient pharmacies, pharmacy professional associations, medication safety experts, health informatics experts, health care payers, and consumer advocates. Finally, the agency should examine the effectiveness of PSOs in supporting CQI efforts within pharmacies and support researcher access to deidentified PSO data. |
| | | 1d | Congress should request that the DHHS Office of Inspector General assess outpatient pharmacies' CQI programs and their impact on dispensing errors and patient safety. |
| 2 | Strengthen the culture of safety within community pharmacies. | 2a | Outpatient pharmacies and their corporate owners should do the following:<br>• Create a culture of safety that guides pharmacy dispensing activities. |

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| | | | • Establish medication safety leadership positions to promote a culture of safety from top management to the individual pharmacy level.<br>• Provide intentional training and ongoing education to all pharmacy staff regarding prescription dispensing error prevention, detection, and mitigation with an emphasis on team contributions to CQI.<br>• Appropriately staff and resource pharmacies to ensure adequate time for prescription review, patient counseling, and meaningful involvement in CQI initiatives.<br>• Collaborate with prescribers, other health professionals, community advocates, patients, and caregivers to ensure that dispensing safety policies and practices are responsive to community needs. |
| | | 2b | OHSA should partner with national and state pharmacy associations to educate pharmacists and pharmacy technicians about their right to safe working environments and their right to lawfully organize. |
| | | 2c | ONC should conduct and/or fund research on the impact of CQI program requirements on outpatient pharmacy staff health and safety. |
| | | 2d | ONC should expand the availability of electronic health record content and communication processes between outpatient pharmacies and other network partners to foster the detection, prevention, and mitigation of dispensing errors through noncommercial, patient-centered communications. Partners in this effort should include outpatient pharmacy corporations, health care systems, health professionals, health informatics experts, health information exchanges, and consumer advocates. |
| | | 2e | The FDA, ISMP, outpatient pharmacies, health professional associations, and consumer advocacy groups should coordinate an orchestrated effort to enhance consumer interest, awareness, |

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| | | | and education about outpatient pharmacy dispensing errors and empower patients and their caregivers to take actions to prevent, detect, and mitigate error-related harm and to report errors. |
| 3 | Incentivize health care payers, patients/caregivers, and the general public to hold pharmacies accountable for dispensing safety. | 3a | State boards of pharmacy should require and enforce regulations that:<br>• Prohibit pharmacy policies, practices, and workplace conditions that contribute to dispensing errors.<br>• Require outpatient pharmacy CQI initiatives related to dispensing errors.<br>• Mandate the provision and documentation of oral patient counseling for every prescription dispensed.<br>• Hold outpatient pharmacies and their corporate owners accountable for consistently following laws and regulations intended to prevent dispensing errors. |
| | | 3b | CMS, in partnership with national accreditation organizations, pharmacies, pharmacy professional associations, and consumer advocates, should develop conditions of participation and conditions for coverage that outpatient pharmacies must meet to begin and continue participation in the Medicare and Medicaid programs. |
| | | 3c | Private and public health care payers should work with AHRQ, outpatient pharmacies, pharmacy professional associations, medication safety experts, and health information specialists to develop a standardized data-driven approach to holistically evaluating pharmacies based on their culture of safety. |
| | | 3d | Shareholders should call for publicly traded pharmacy corporations to include information related to their outpatient pharmacy dispensing safety practices in their annual corporate reports. |

Opposing Arguments

Dispensing safety data should be confidential and proprietary: Dispensing error reporting may raise concerns that public sharing of patient and pharmacist personal identifying information within error data may violate patient confidentiality laws and thus dampen error reporting efforts. For this reason, release

of deidentified data only is encouraged with an emphasis on their educational use for error prevention.[16] As businesses concerned about their public image and subject to shareholder concerns about liability, pharmacy corporations may argue that even deidentified aggregate dispensing error data are proprietary and should not be publicly available. However, state boards of pharmacy have a duty and health care payers, and the public have a vested interest in being able to review and assess prescription safety information.[55]

Error increases are a temporary effect of the COVID-19 pandemic: Another opposing argument is that prescription dispensing errors are a result of staffing shortages exacerbated by the COVID-19 pandemic.[73] Some may state that as the impact of the pandemic subsides, pharmacy workplace issues will resolve, and workloads will decline. However, responsibilities related to COVID testing and immunizations remain. Staffing shortages were problematic prior to the pandemic.[33]

Errors should be addressed through a focus on individual workers: Some may suggest that individuals rather than systems are the cause of prescription errors.[74] Pharmacists are liable for the errors they cause, but this viewpoint ignores the prevailing perspective that individual sanctions for human errors discourage error reporting and that a systems approach to assessing and improving safety is more effective in preventing recurrent errors.[55,74]

Safety regulations and accountability may lead to unintended negative consequences: Two unintended negative consequences of promoting CQI initiatives may occur. CQI initiatives themselves may add to pharmacy staff responsibilities and, if staff resources are not increased, will contribute to errors by further overwhelming the system.[75] Pharmacy corporations may decide that the costs of safety changes are too high and exit the market, thus limiting public access to pharmacies and increasing workloads for remaining pharmacy staff. They may also adopt dispensing models that complicate external accountability for safety. It may be difficult to prevent such reactions, but the benefits of improving prescription safety and preventing patient harm support the action steps presented.

References

1. National Center for Health Statistics. Therapeutic drug use. Available at: https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm. Accessed January 4, 2024.

2. IQVIA. Use of medicines in the U.S. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023. Accessed August 14, 2024.

3. Office of the Assistant Secretary for Planning and Evaluation. Trends in prescription drug spending, 2016–2021. Available at: https://aspe.hhs.gov/reports/trends-prescription-drug-spending. Accessed January 4, 2024.

4. Cubanski J, Rae M, Young K, Published AD. How does prescription drug spending and use compare across large employer plans, Medicare Part D, and Medicaid? Available at: https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/. Accessed January 4, 2024.

5. Mott DA, Arya V, Bakken BK, et al. 2022 National Pharmacist Workforce Study: final report. Available at: https://www.aacp.org/sites/default/files/2023-08/2022-npws-final-report.pdf. Accessed December 19, 2023.

6. Le Coz E. Prescription for disaster: America's broken pharmacy system in revolt over burnout and errors. Available at: https://www.usatoday.com/story/news/investigations/2023/10/26/pharmacy-chains-dangerous-conditions-medication-errors/71153960007/. Accessed January 4, 2024.

7. Gabler E. How chaos at chain pharmacies is putting patients at risk. Available at: https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html. Accessed January 5, 2024.

8. Christensen DB, Farris KB. Pharmaceutical care in community pharmacies: practice and research in the US. Ann Pharmacother. 2006;40(7–8):1400–1406.

9. Tariq RA, Vashisht R, Sinha A, Scherbak Y. Medication dispensing errors and prevention. Available at: http://www.ncbi.nlm.nih.gov/books/NBK519065/. Accessed August 7, 2024.

10. Lewis NJW, Marwitz KK, Gaither CA, Haugtvedt CL, Selkow L, Sinha S. Creating a stronger culture of safety within US community pharmacies. Jt Comm J Qual Patient Saf. 2023;49(5):280–284.

11. Kimberlin CL, Jamison AN, Linden S, Winterstein AG. Patient counseling practices in U.S. pharmacies: effects of having pharmacists hand the medication to the patient and state regulations on pharmacist counseling. J Am Pharm Assoc (2003). 2011;51(4):527–534.

12. Hincapie AL, Alyami F, Alrasheed M, et al. Continuous quality improvement regulations for community pharmacy practice in the United States. J Am Pharm Assoc (2003). 2021;61(4):470–475.e2.

13. The Joint Commission. Who we are. Available at: https://www.jointcommission.orghttps://www.jointcommission.org/who-we-are/. Accessed August 14, 2024.

14. URAC. Exceptional health care for all. Available at: https://www.urac.org/about/mission/. Accessed August 14, 2024.

15. National Coordinating Council for Medication Error Reporting and Prevention. Statement advocating for the elimination of prescription time guarantees in community pharmacy. Available at:

http://www.nccmerp.org/statement-advocating-elimination-prescription-time-guarantees-community-pharmacy. Accessed August 14, 2024.

16. Institute of Medicine Committee on Quality of Health Care in America. To err is human: building a safer health system. Available at: http://www.ncbi.nlm.nih.gov/books/NBK225182/. Accessed January 4, 2024.

17. Chui MA. Safety in the retail pharmacy. Available at: https://psnet.ahrq.gov/perspective/safety-retail-pharmacy. Accessed August 14, 2024.

18. Um IS, Clough A, Tan ECK. Dispensing error rates in pharmacy: a systematic review and meta-analysis. Res Social Adm Pharm. 2024;20(1):1–9.

19. Campbell PJ, Patel M, Martin JR, et al. Systematic review and meta-analysis of community pharmacy error rates in the USA: 1993–2015. BMJ Open Qual. 2018;7(4):e000193.

20. Roe S, Long R, Long K. Pharmacies miss half of dangerous drug combinations. Available at: https://www.chicagotribune.com/investigations/ct-drug-interactions-pharmacy-met-20161214-story.html. Accessed January 5, 2024.

21. Flynn EA, Dorris NT, Holman GT, Camahan BJ, Barker KN. Medication dispensing errors in community pharmacies: a nationwide study. Proc Hum Factors Ergonomics Soc Annu Meeting. 2002;46(16):1448–1451.

22. Ranasinghe S, Nadeshkumar A, Senadheera S, Samaranayake N. Calculating the cost of medication errors: a systematic review of approaches and cost variables. BMJ Open Qual. 2024;13(2):e002570.

23. Nobili A, Garattini S, Mannucci PM. Multiple diseases and polypharmacy in the elderly: challenges for the internist of the third millennium. J Comorb. 2011;1:28–44.

24. Yin HS, Neuspiel DR, Paul IM, et al. Preventing home medication administration errors. Pediatrics. 2021;148(6):e2021054666.

25. Ayre MJ, Lewis PJ, Keers RN. Understanding the medication safety challenges for patients with mental illness in primary care: a scoping review. BMC Psychiatry. 2023;23(1):417.

26. Easley W, Kuber R, Ozok AA. An empirical study examining medication management among individuals with visual impairments. Universal Access Inform Soc. 2016;16(2):483–495.

27. Flood B, Henman MC. Case study: hidden complexity of medicines use: information provided by a person with intellectual disability and diabetes to a pharmacist. Br J Learn Disabil. 2015;43(3):234–242.

28. Tkacz VL, Metzger A, Pruchnicki MC. Health literacy in pharmacy. Am J Health Syst Pharm. 2008;65(10):974–981.

29. Law AV, Zargarzadeh AH. How do patients read, understand and use prescription labels? An exploratory study examining patient and pharmacist perspectives. Int J Pharm Pract. 2010;18(5):282–289.

30. Centers for Disease Control and Prevention. Health care access. Available at: https://www.cdc.gov/dhdsp/health_equity/health-care-access.htm. Accessed August 7, 2024.
31. Rodriguez L, Mullen J. Addressing vulnerability through the pursuit of health equity. Available at: https://www.springerpub.com/jonas-and-kovner-s-health-care-delivery-in-the-united-states-9780826173034.html. Accessed January 4, 2024.
32. Aboneh EA, Stone JA, Lester CA, Chui MA. Evaluation of patient safety culture in community pharmacies. J Patient Saf. 2020;16(1):e18–e24.
33. Doucette WR, Matt DA, Kreling DH, et al. The National Pharmacist Workforce Survey final report. Available at: www.aacp.org/sites/default/files/2020-03/2019_NPWS_Final_Report.pdf. Accessed December 26, 2023.
34. Food and Drug Administration. MedWatch: the FDA safety information and adverse event reporting program. Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program. Accessed November 1, 2023.
35. U.S. Department of Health and Human Services. Vaccine Adverse Event Reporting System (VAERS). Available at: https://vaers.hhs.gov/. Accessed January 5, 2024.
36. Institute for Safe Medication Practices. Reporting medication errors. Available at: https://www.consumermedsafety.org/medication-error-reports. Accessed October 11, 2024.
37. Hong K, Hong YD, Cooke CE. Medication errors in community pharmacies: the need for commitment, transparency, and research. Res Social Adm Pharm. 2019;15(7):823–826.
38. Agency for Healthcare Research and Quality. Federally listed PSOs. Available at: https://pso.ahrq.gov/pso/listed?search_api_fulltext=%20&f%5B0%5D=listed_speciality_served%3A17. Accessed January 5, 2024.
39. Ledlie S, Gomes T, Dolovich L, et al. Medication errors in community pharmacies: evaluation of a standardized safety program. Explor Res Clin Soc Pharm. 2023;9:100218.
40. Goode JV, Owen J, Page A, Gatewood S. Community-based pharmacy practice innovation and the role of the community-based pharmacist practitioner in the United States. Pharmacy (Basel). 2019;7(3):106.
41. Kim E, Worley MM, Law AV. Pharmacist roles in the medication use process: perceptions of patients, physicians, and pharmacists. J Am Pharm Assoc (2003). 2023;63(4):1120–1130.
42. Pharmacy Quality Alliance. Medication safety. Available at: https://www.pqaalliance.org/medication-safety. Accessed January 4, 2024.
43. Lester CA, Kessler JM, Modisett T, Chui MA. A text mining analysis of medication quality related event reports from community pharmacies. Res Social Adm Pharm. 2019;15(7):845–851.

44. PSO Privacy Protection Center. Common Formats for Event Reporting-Community Pharmacy Version 1.0. Available at: https://www.psoppc.org/psoppc_web/publicpages/commonFormatsCPV1.0. Accessed January 4, 2024.

45. Dang O. Information Visualization Platform (InfoViP): CDER's new artificial intelligence safety surveillance tool. Available at: https://www.fda.gov/drugs/cder-conversations/information-visualization-platform-infovip-cders-new-artificial-intelligence-safety-surveillance. Accessed August 7, 2024.

46. Institute for Safe Medication Practices. ISMP alerts healthcare practitioners about errors with new COVID-19 vaccines. Available at: https://www.ismp.org/news/ismp-alerts-healthcare-practitioners-about-errors-new-covid-19-vaccines. Accessed January 5, 2024.

47. Office of Inspector General. Adverse events in hospitals: a quarter of Medicare patients experienced harm in October 2018. Available at: https://oig.hhs.gov/oei/reports/OEI-06-18-00400.asp. Accessed August 7, 2024.

48. Ontario College of Pharmacists. Assurance and Improvement in Medication Safety. Available at: https://www.ocpinfo.com/regulations-standards/aims-assurance-and-improvement-in-medication-safety/. Accessed January 5, 2024.

49. Agency for Healthcare Research and Quality. Community Pharmacy Survey on Patient Safety Culture. Available at: https://www.ahrq.gov/sops/surveys/pharmacy/index.html. Accessed January 4, 2024.

50. Cornwell K. Defense Health Agency, Veterans Health Administration collaboration standardizes patient safety reporting. Available at: https://health.mil/News/Dvids-Articles/2024/06/01/news472733. Accessed August 14, 2024.

51. Chinthammit C, Rupp MT, Armstrong EP, Modisett T, Snead RP, Warholak TL. Evaluation of a guided continuous quality improvement program in community pharmacies. J Pharm Policy Pract. 2017;10:26.

52. Galt KA, Fuji KT, Faber J. Patient safety problem identification and solution sharing among rural community pharmacists. J Am Pharm Assoc (2003). 2013;53(6):584–594.

53. Institute for Safe Medication Practices. The case for medication safety officers. Available at: https://www.ismp.org/sites/default/files/attachments/2018-08/MSOS%20White%20Paper_Final_080318_1.pdf. Accessed January 5, 2023.

54. Farris KB, Mitrzyk BM, Batra P, et al. Linking the patient-centered medical home to community pharmacy via an innovative pharmacist care model. J Am Pharm Assoc (2003). 2019;59(1):70–78.e3.

55. Institute of Medicine. Preventing Medication Errors. Washington, DC: National Academies Press; 2007.

506 56. Gabriel M. A decade of data examined: the evolution of electronic prescribing. Available at:
507 https://www.healthit.gov/buzz-blog/health-data/a-decade-of-data-examined-the-evolution-of-electronic-
508 prescribing. Accessed August 7, 2024.
509 57. Devraj R, Young HN. Pharmacy language assistance resources and their association with pharmacists'
510 self-efficacy in communicating with Spanish-speaking patients. Res Social Adm Pharm. 2017;13(1):123–
511 132.
512 58. Feichtl MM, Clauson KA, Alkhateeb FM, Jamass DS, Polen HH. Community pharmacists' use of
513 language-access services in the United States. J Am Pharm Assoc (2003). 2011;51(3):368–372.
514 59. Triyasakorn K, Nguyen E. Cross-training pharmacy personnel as community health workers. J Am
515 Pharm Assoc (2003). 2024;64(1):39–42.
516 60. Occupational Safety and Health Administration. Organizational safety culture: linking patient and
517 worker safety. Available at: https://www.osha.gov/healthcare/safety-culture/. Accessed January 4, 2024.
518 61. Bivens J, Engdahl L, Gould E, et al. How today's unions help working people: giving workers the
519 power to improve their jobs and unrig the economy. Available at: https://www.epi.org/publication/how-
520 todays-unions-help-working-people-giving-workers-the-power-to-improve-their-jobs-and-unrig-the-
521 economy/. Accessed August 15, 2024.
522 62. Benton DC, Thomas K, Damgaard G, Masek SM, Brekken SA. Exploring the differences between
523 regulatory bodies, professional associations, and trade unions: an integrative review. J Nurs Regulation.
524 2017;8(3):4–11.
525 63. Cohen MR, Smetzer JL, Westphal JE, Comden SC, Horn DM. Risk models to improve safety of
526 dispensing high-alert medications in community pharmacies. J Am Pharm Assoc (2003). 2012;52(5):584–
527 602.
528 64. Kuyper AR. Patient counseling detects prescription errors. Hosp Pharm. 1993;28(12):1180–1181,
529 1184–1189.
530 65. California Legislature. Bill text: AB-1286 Pharmacy. Available at:
531 https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202320240AB1286. Accessed
532 January 4, 2024.
533 66. California Legislature. Bill text: SB-362 Chain Community Pharmacies: Quotas. Available at:
534 https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB362. Accessed January
535 5, 2024.
536 67. Casetext. Minimum Standards for the Operation of an Outpatient Pharmacy, Ohio Administrative
537 Code 4729:5-5-02. Available at: https://casetext.com/regulation/ohio-administrative-code/title-47295-
538 dangerous-drugs/chapter-47295-5-outpatient-pharmacies/section-47295-5-02-minimum-standards-for-
539 the-operation-of-an-outpatient-pharmacy. Accessed August 7, 2024.

68. Allan EL, Barker KN, Malloy MJ, Heller WM. Dispensing errors and counseling in community practice. Am Pharm. 1995;NS35(12):25–33.

69. Zentz RR. Four key findings in the 2023 Pharmacist Professional Liability Exposure Claim Report. Available at: https://www.cna.com/web/guest/cna/from-the-experts/authorbio/blogdetails/SA-Ron-Zentz/4-key-findings-2023-pharmacist-professional-liability-exposure-claim-report. Accessed January 4, 2024.

70. Gabler E. Pharmacists make mistakes. You can protect yourself. Available at: https://www.nytimes.com/2020/01/31/health/pharmacists-medication-mistakes.html. Accessed January 5, 2024.

71. U.S. Drug Enforcement Administration. Take Back Day. Available at: https://www.dea.gov/takebackday#results. Accessed January 4, 2024.

72. Grant M, Remines J, Nadpara P, Goode JVKR. Impact of live training on medication errors in a community-based pharmacy setting. Innov Pharm. 2020;11(3):10.24926/iip.v11i3.3291.

73. PBS NewsHour. Pharmacists struggle to keep up with a spike in demand for their services. Available at: https://www.pbs.org/newshour/show/pharmacists-struggle-to-keep-up-with-the-spike-in-the-demand-for-their-services. Accessed January 4, 2024.

74. Rogers E, Griffin E, Carnie W, Melucci J, Weber RJ. A just culture approach to managing medication errors. Hosp Pharm. 2017;52(4):308–315.

75. Mahmoud Z, Angelé-Halgand N, Churruca K, Ellis LA, Braithwaite J. The impact of lean management on frontline healthcare professionals: a scoping review of the literature. BMC Health Serv Res. 2021;21(1):383.