

1 Improving Public Health by Advancing a 2 Multicomponent Approach to Increasing 3 Prescription Dispensing Safety in U.S. Outpatient 4 Pharmacies

5 **Policy Date:** October 29, 2024

6 **Policy Number:** 20247

7 *Note: Line numbers are included along the left to help quickly identify specific text within the*
8 *policy brief.*

9 **Abstract**

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



26 medication safety. Undertaking the recommended action steps within the selected sector of pharmacies
27 can serve as a springboard for expanding prescription dispensing safety in all pharmacies.

28

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

30

31 **Relationship to Existing APHA Policy Statements**

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

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

51



52 **Problem Statement**

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

61
62 The safety of outpatient pharmacy prescription dispensing practices is a public health concern.
63 The high number of prescriptions dispensed means that even a low dispensing error rate can
64 affect millions. If the commonly cited 1.5% dispensing error rate is applied to 2022 prescription
65 data, an estimated 67.5 million dispensing errors occurred that year.[2] Alarming, reports by
66 pharmacists [5] and the media [6,7] suggest that dispensing errors are rising.

67
68 Dispensing errors include prescriptions dispensed to the wrong person, incorrect medications
69 or strengths dispensed, incorrect prescription label information, dispensing medications that
70 could lead to drug-drug or drug-disease interactions, and failure to provide adequate
71 patient/caregiver counseling.[8–11] The multiple steps involved in prescription dispensing
72 create error opportunities at any point during prescription preparation, review of medication
73 records for therapeutic concerns, and patient counseling.[8] Errors can result in drug-drug
74 interactions, adverse events, hospital admissions, increased health care utilization, and
75 increased risk of death.[9]

76

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

87

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

94

95 ***Paucity of outpatient pharmacy dispensing safety data***

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

101

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

112
113 Reported percentages of dispensing errors causing patient harm range from 4% to 52%.[17,20]
114 An observational study of 50 pharmacies showed that 6.5% of dispensing errors had the potential
115 to cause patient harm,[21] while a mystery shopper study of 255 pharmacies revealed that 52%
116 of pharmacies dispensed two prescriptions that, if taken together, could result in a life-
117 threatening drug interaction.[20] The degree to which harm from dispensing errors contributes to
118 health care expenditures is unknown. The authors of a 2024 systemic review of medication errors
119 called for a common data reporting and analysis framework to determine the financial impact of
120 those errors.[22] Similarly, adoption of common data collection, reporting, and analytical
121 approaches is needed to determine the financial impact of dispensing errors in outpatient
122 pharmacies.[22]

123
124 Certain individuals may be at high risk for error harm, including children, pregnant persons,
125 elderly persons, and those who have multiple or complex health conditions, mental health illness,
126 or developmental or intellectual disabilities; take multiple medications; or take medications with
127 a high potential for serious adverse reactions.[23,24] Individuals with low vision and hearing
128 impairment and those with low health literacy or English as a second language may face



129 challenges in reading prescription labels necessary to detect dispensing errors.[25–29] People
130 with fragmented health care; who face barriers to care (e.g., those residing in rural or
131 underserved areas and those with inadequate health insurance) and/or discrimination within
132 health care settings due to race, ethnicity, gender identity, or mental health illness; or who live in
133 stressful socioeconomic conditions (e.g., homelessness) may face barriers to error
134 remediation.[30,31]

135

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

145

146 Understanding dispensing safety is complicated by the lack of public sources of error data. Food
147 and Drug Administration (FDA) MedWatch,[34] the FDA and the Centers for Disease Control
148 and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS),[35] and the Institute
149 for Safe Medication Practices (ISMP) consumer and health professional reporting systems [36]
150 collect dispensing error reports but do not publicly share such data or allow access to databases.
151 Most outpatient pharmacies do not report dispensing error rates to state boards of pharmacy, and
152 dispensing safety is rarely discussed in corporate annual reports.[37] A growing number of
153 outpatient pharmacies use patient safety organizations (PSOs) that shield error data from public
154 and legal disclosure.[38] While data confidentiality is thought to enhance error reporting,[16]
155 this also means that the public cannot choose pharmacies and payers cannot build pharmacy



156 networks based on dispensing safety criteria. Only crude indicators of pharmacy dispensing
157 safety are publicly available: state data on lack or loss of licensure, lawsuits, whistleblower
158 reports, and media reports. [6,7]

159

160 ***Eroding culture of safety within outpatient pharmacies***

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

168

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

179

180 Collaboration between pharmacists and prescribers and their staffs is essential to prevent
181 dispensing errors; however, the “siloesd” nature of pharmacies within the health care system

182 hinders the prescriber-pharmacist communications and collaborations needed to prevent, detect,
183 and remedy prescription errors. Lack of pharmacy access to electronic health record information
184 prevents detection of errors such as drug-disease interactions and incorrect patient or medication
185 names on prescriptions.[32,40] A Qualtrics survey of 204 pharmacists and 200 physicians
186 revealed that while nearly all believed collaboration between physicians and pharmacists is
187 important, both physicians and pharmacists reported that collaboration was hindered by lack of
188 time and communication challenges.[41]

189

190 ***Lack of external accountability for dispensing safety***

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

200

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

206



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

211

212 **Evidence-Based Strategies to Address the Problem**

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

220

221 ***Increase research and practice-based analysis***

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

229



230 ***One source for data standardization is publicly available***

231 AHRQ Common Formats for Event Reporting-Community Pharmacy Version.[44] By offering a
232 unifying approach to data reporting, this tool encourages data sharing that can lead to early alerts
233 for needed interventions to protect patient safety.

234

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

244

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

250

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



256 ***Strengthen the culture of safety within outpatient pharmacies***

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

263

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

268

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

276

277 A culture of safety links patient care responsibilities among pharmacists, patients/caregivers,
278 prescribers, and other health care providers. Intentional linking of patient care services and
279 electronic health records between pharmacies and patient-centered medical care homes improves
280 coordination of care. [40,54,55] Shared electronic health records help in coordinating care and
281 identifying prescription errors before prescriptions are dispensed. The Office of the National



282 Coordination for Health Information Technology (ONC) has proposed a rule that e-prescriptions
283 include the indication for use, thus providing information that could prevent incorrect patient,
284 medication, and dose dispensing errors.[56]

285

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

294

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

303

304 ***Increase pharmacy accountability for maintaining a strong culture of safety***

305 State boards of pharmacy-mandated pharmacist-patient/caregiver counseling can significantly decrease
306 dispensing errors.[63,64] State laws have mandated error reporting and CQI processes, provided
307 pharmacists legal authority to adequately staff pharmacies, and given pharmacy staff break times.[65–



308 67] While the effect of these mandates is unknown, research on the Omnibus Reconciliation Bill of
309 1990 pharmacy practice requirements suggests that, without financial incentives, the intended benefits
310 may be muted.[68] Irrespective of the laws' impact, their passage suggests that the political will to
311 address system-mediated causes of dispensing errors exists.

312

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

320

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

326

327 As financial awards related to dispensing error lawsuits grow,[69] investors may raise concerns
328 about legal expenditures. Requiring corporations to report information about CQI practices, their
329 impact on prescription dispensing safety, and overall prescription safety expenditures may
330 incentivize them to establish stronger cultures of safety within their outpatient pharmacies.

331

332 Increasing public awareness, interest, and education in dispensing errors could engage patients,
333 caregivers, and the public in taking actions to detect and/or prevent errors.[43] Public

334 prescription dispensing safety programs could empower patients to request pharmacist
335 counseling when receiving a prescription and to check the prescription label and vial contents
336 before leaving the pharmacy.[70] One effective public medication safety program is the Drug
337 Enforcement Agency’s Prescription Take Back Day, which teaches the public how to safely
338 dispose of unused medication to prevent unintentional medication use or poisonings. Between
339 2018 and October 2023, the program collected 8,950 tons of medications through its twice-
340 yearly events.[71]

341

342 **Alternative Strategies**

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

348

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

354

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

359

Action Steps to Implement Evidence-Based Strategies

	Evidence-Based Strategy		Action Steps
1	Increase research and practice-based analysis to characterize dispensing 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.	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 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

			<p>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.</p>
		1d	<p>Congress should request that the DHHS Office of Inspector General assess outpatient pharmacies' CQI programs and their impact on dispensing errors and patient safety.</p>
2	<p>Strengthen the culture of safety within community pharmacies.</p>	2a	<p>Outpatient pharmacies and their corporate owners should do the following:</p> <p>Create a culture of safety that guides pharmacy dispensing activities.</p> <p>Establish medication safety leadership positions to promote a culture of safety from top management to the individual pharmacy level.</p> <p>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.</p>

			<p>Appropriately staff and resource pharmacies to ensure adequate time for prescription review, patient counseling, and meaningful involvement in CQI initiatives.</p> <p>Collaborate with prescribers, other health professionals, community advocates, patients, and caregivers to ensure that dispensing safety policies and practices are responsive to community needs.</p>
		2b	<p>OSHA 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.</p>
		2c	<p>OSHA should conduct and/or fund research on the impact of CQI program requirements on outpatient pharmacy staff health and safety.</p>
		2d	<p>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.</p>
		2e	<p>The FDA, ISMP, outpatient pharmacies, health professional associations, and consumer advocacy groups should</p>

			coordinate an orchestrated effort to enhance consumer interest, awareness, 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	<p>State boards of pharmacy should require and enforce regulations that:</p> <p>Prohibit pharmacy policies, practices, and workplace conditions that contribute to dispensing errors.</p> <p>Require outpatient pharmacy CQI initiatives related to dispensing errors.</p> <p>Mandate the provision and documentation of oral patient counseling for every prescription dispensed.</p> <p>Hold outpatient pharmacies and their corporate owners accountable for consistently following laws and regulations intended to prevent dispensing errors.</p>
		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.

361

362 **Opposing Arguments**

363 ***Dispensing safety data should be confidential and proprietary***

364 Dispensing error reporting may raise concerns that public sharing of patient and pharmacist
 365 personal identifying information within error data may violate patient confidentiality laws and
 366 thus dampen error reporting efforts. For this reason, release of deidentified data only is
 367 encouraged with an emphasis on their educational use for error prevention.[16] As businesses
 368 concerned about their public image and subject to shareholder concerns about liability, pharmacy
 369 corporations may argue that even deidentified aggregate dispensing error data are proprietary and
 370 should not be publicly available. However, state boards of pharmacy have a duty and health care
 371 payers, and the public have a vested interest in being able to review and assess prescription
 372 safety information.[55]

373

374 ***Error increases are a temporary effect of the COVID-19 pandemic***

375 Another opposing argument is that prescription dispensing errors are a result of staffing
 376 shortages exacerbated by the COVID-19 pandemic.[73] Some may state that as the impact of the
 377 pandemic subsides, pharmacy workplace issues will resolve, and workloads will decline.



378 However, responsibilities related to COVID testing and immunizations remain. Staffing
379 shortages were problematic prior to the pandemic.[33]

380

381 ***Errors should be addressed through a focus on individual workers***

382 Some may suggest that individuals rather than systems are the cause of prescription errors.[74]
383 Pharmacists are liable for the errors they cause, but this viewpoint ignores the prevailing
384 perspective that individual sanctions for human errors discourage error reporting and that a
385 systems approach to assessing and improving safety is more effective in preventing recurrent
386 errors.[55,74]

387

388 ***Safety regulations and accountability may lead to unintended negative consequences***

389 Two unintended negative consequences of promoting CQI initiatives may occur. CQI initiatives
390 themselves may add to pharmacy staff responsibilities and, if staff resources are not increased,
391 will contribute to errors by further overwhelming the system.[75] Pharmacy corporations may
392 decide that the costs of safety changes are too high and exit the market, thus limiting public
393 access to pharmacies and increasing workloads for remaining pharmacy staff. They may also
394 adopt dispensing models that complicate external accountability for safety. It may be difficult to
395 prevent such reactions, but the benefits of improving prescription safety and preventing patient
396 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.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/dhbsp/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://ps0.ahrq.gov/ps0/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.



56. Gabriel M. A decade of data examined: the evolution of electronic prescribing. Available at: <https://www.healthit.gov/buzz-blog/health-data/a-decade-of-data-examined-the-evolution-of-electronic-prescribing>. Accessed August 7, 2024.
57. Devraj R, Young HN. Pharmacy language assistance resources and their association with pharmacists' self-efficacy in communicating with Spanish-speaking patients. *Res Social Adm Pharm*. 2017;13(1):123–132.
58. Feichtl MM, Clauson KA, Alkhateeb FM, Jamass DS, Polen HH. Community pharmacists' use of language-access services in the United States. *J Am Pharm Assoc* (2003). 2011;51(3):368–372.
59. Triyasakorn K, Nguyen E. Cross-training pharmacy personnel as community health workers. *J Am Pharm Assoc* (2003). 2024;64(1):39–42.
60. Occupational Safety and Health Administration. Organizational safety culture: linking patient and worker safety. Available at: <https://www.osha.gov/healthcare/safety-culture/>. Accessed January 4, 2024.
61. Bivens J, Engdahl L, Gould E, et al. How today's unions help working people: giving workers the power to improve their jobs and unrig the economy. Available at: <https://www.epi.org/publication/how-todays-unions-help-working-people-giving-workers-the-power-to-improve-their-jobs-and-unrig-the-economy/>. Accessed August 15, 2024.
62. Benton DC, Thomas K, Damgaard G, Masek SM, Brekken SA. Exploring the differences between regulatory bodies, professional associations, and trade unions: an integrative review. *J Nurs Regulation*. 2017;8(3):4–11.
63. Cohen MR, Smetzer JL, Westphal JE, Comden SC, Horn DM. Risk models to improve safety of dispensing high-alert medications in community pharmacies. *J Am Pharm Assoc* (2003). 2012;52(5):584–602.
64. Kuyper AR. Patient counseling detects prescription errors. *Hosp Pharm*. 1993;28(12):1180–1181, 1184–1189.



65. California Legislature. Bill text: AB-1286 Pharmacy. Available at: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202320240AB1286. Accessed January 4, 2024.
66. California Legislature. Bill text: SB-362 Chain Community Pharmacies: Quotas. Available at: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB362. Accessed January 5, 2024.
67. Casetext. Minimum Standards for the Operation of an Outpatient Pharmacy, Ohio Administrative Code 4729:5-5-02. Available at: <https://casetext.com/regulation/ohio-administrative-code/title-47295-dangerous-drugs/chapter-47295-5-outpatient-pharmacies/section-47295-5-02-minimum-standards-for-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.