B3: **Improving Public Health by Advancing a Multi-component Approach to Increasing Prescription Dispensing Safety in U.S. Outpatient Pharmacies**

1   **I. Title: Improving Public Health by Advancing a Multi-component Approach to Increasing**

2   **Prescription Dispensing Safety in U.S. Outpatient Pharmacies**

3

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35   Not applicable

36

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38   Not applicable

39

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41   Health Administration, Pharmacy, Occupational Health and Safety, Medical Care and Foot and

42   Ankle Health Sections

43

44 **VI. Summary**

45 This policy statement addresses one component of medication safety: the safety of prescription dispensing

46 within outpatient pharmacies. In 2022, nearly 4.5 billion prescriptions were dispensed from these

47 pharmacies, yet limited data exist about the types and rate of dispensing errors, impact of factors such as

48 work pressures and staff training on errors, and extent to which pharmacies prioritize safety and invest

49 resources to improve safety. Past research provides a clouded picture of dispensing safety due to

50 variations in error definitions, measurement approaches, and scope of medications studied. While

51 prescriptions should be dispensed without errors, national surveys and media reports indicate that

52 dispensing errors may be increasing due to lack of organizational commitment to the personnel and

53 resources needed to ensure patient safety. This weak culture of safety may reflect the relative lack of

54 external accountability placed upon pharmacies to ensure prescriptions are dispensed without error.

55

56 Three avenues for lowering the risk of dispensing errors are proposed: (1) additional research and

57 practice-based data to determine current error types, rates and costs, pharmacy-based factors contributing

58 to errors, and effectiveness of continuous quality improvement (CQI) efforts to prevent future errors; (2)

59 further research into defining and measuring the culture of safety within pharmacies and effective ways to

60 strengthen the culture of safety; (3) increasing external accountability for pharmacies to maintain a culture

61 of safety.

62

63 Prescription dispensing safety is likely to be clearly assessed and continuously improved if a multi-

64 component, collaborative approach brings together the innovation, support and accountability needed to

65 address this key component of medication safety. Undertaking the recommended action steps within the

66 selected sector of pharmacies can serve as a springboard for expanding prescription dispensing safety in

67 all pharmacies.

68

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

70

71   **VII. Relationship to Existing APHA Policy Statements**

72   No active APHA policy statement addresses this public health problem. The APHA policies listed below

73   discuss problems, strategies or action steps that lay a foundation for this proposed policy statement.

74   Policy #20109, APHA support for addressing health literacy, cites low health literacy as a contributing

75   factor to medication errors. Interdisciplinary education and patient-centered care are supported by policies

76   #200614, #20088, #202011 and #20215. Policies #20068 and #20223 are foundational for our action step

77   related to organized labor as a means of addressing workplace issues that impact the culture of safety

78   within pharmacies.

79   ● 20109: Health Literacy: Confronting a National Public Health Problem

80   ● 200614: The Role of the Pharmacist in Public Health

81   ● 20088: Promoting Interprofessional Education

82   ● 201011: Reforming Primary Health Care: Support for the Health Care Home Model

83   ● 20215: A Call to Improve Patient and Public Health Outcomes of Diabetes through an Enhanced

84   Integrated Care Approach

85   ● 20068: Resolution on the Right For Employee Free Choice to Form Unions

86   ● 20223: Support Decent Work for All as a Public Health Goal in the United States

87

88   **VIII. Rationale for Consideration**

89   The safety of outpatient pharmacy prescription dispensing practices is a public health concern. Our policy

90   statement seeks to address a public health problem not identified by APHA or included within existing

91   APHA policy statements. Prescription dispensing errors are important to address through APHA's policy

92   statement process because of the breadth of population affected by prescription safety and volume of

93   prescriptions dispensed by US pharmacies.

94

95   Outpatient pharmacies dispensed an estimated 4.5 billion prescriptions in 2022. Application of the

96   commonly cited dispensing error rate of 1.5% translates to over 67.5 million prescriptions dispensed with

97   an error that year. These errors hold the risk of causing adverse events, medical visits, hospitalizations or

98   death. National pharmacist surveys, media reports, and state board of pharmacy investigations suggest

99   errors are increasing due to stress and mental fatigue related to inadequate staffing, which is exacerbated

100   by pharmacy closings throughout the country leading to pharmacy deserts. However, no current public

101   data about dispensing error types, rates, or associated costs exist.

102

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103 Given rising concerns about dispensing errors among patients, the media and pharmacists, data are
104 essential to characterize the safety of current dispensing practices and provide a baseline for the analysis
105 of CQI initiatives. Error data analysis can discover the number, what types and frequency of errors occur,
106 what factors contribute to their occurrence, types and degree of patient harm experienced, financial
107 impact, and suggest pharmacy system changes needed to improve safety and measure their effectiveness.
108 However, data can only be appropriately interpreted if they are reported in an organizational environment
109 that prioritizes safety, realizes the danger of errors to patient heath, and focuses on system policies and
110 practices that can be improved. If errors are viewed as individual failures, data will not be reported out of
111 fear of retribution and safety will not improve. Thus, the organizational culture that surrounds the
112 assessment of dispensing errors and drives CQI efforts strongly influences the degree to which safety is
113 improved. This culture is not only internally driven, but influenced by laws, regulations and customer
114 expectations.
115
116 The for-profit retail business nature of pharmacies can foster a culture focused on meeting profit goals
117 and market share growth, thus reducing dispensing errors to a "cost of doing business." The drive for
118 management efficiency and provision of profitable services, such as immunizations, can impede
119 pharmacy staff efforts to ensure patient safety through clinical reviews of prescriptions, communications
120 with prescribers on pertinent clinical issues, and patient/caregiver counseling. As the U.S. healthcare
121 system increasingly takes a business-like approach to healthcare services, strategies that strengthen the
122 culture of safety within pharmacies may be a useful template for protecting patient safety in other
123 healthcare settings.
124
125 While concerns about rising prescription drug prices, medication shortages, limits on access to
126 prescriptions by pharmacy benefit managers (PBMs), and rise of pharmacy deserts due to closings are
127 paramount to many, a focus on prescription dispensing safety is foundational for patient safety. Putting
128 numbers to dispensing errors and their impact on patient health makes these visible. When problems are
129 visible, people look for solutions. In this case, the solution is the adoption of a culture of safety by
130 outpatient community pharmacy corporations. Adopting a culture of safety requires the entire corporation
131 to focus on patient safety and health. Getting for-profit entities to adopt a culture of safety will require
132 prescription payers to offer financial incentives or disincentives. If these efforts are successful in changing
133 corporate culture, outpatient pharmacy corporate leaders will gain insight into the interrelationships that
134 exist between their pharmacies' staffing, its system processes and patient's health and well-being. If they
135 make this connection, there is an opportunity that their realizations will be shared with affiliated PBMs

136   and health insurance companies so they, too, can view anew the relationships between their policies and

137   patient health and well-being.

138

139   APHA is well positioned to advocate for safety improvements in prescription dispensing. Its membership

140   includes patients and caregivers who benefit from dispensing safety; prescribers and other health

141   professionals who rely on accurate prescription dispensing to carry out therapeutic plans; public health

142   nurses, community health workers (CHW), health educators and patient advocates who want pharmacies

143   that their clients and communities can depend upon; health administrators and health regulators who are

144   entrusted to protect the safety of their patients or the public; health technology experts who need access to

145   accurate data; and policy makers and prescription payers who need to consider dispensing safety to

146   appropriately invest in prescription benefit programs and provider networks that prioritize patient safety.

147   APHA can bring these voices together to advocate for a safer prescription dispensing system within the

148   U.S.

149

150   **IX. Problem Statement**

151   This policy addresses prescription dispensing safety within outpatient pharmacies including: chain,

152   grocery store, mass merchandiser, independent and mail order pharmacies. From 2015 to 2018, nearly

153   half of U.S. residents used at least one prescription medication in the past 30 days, with 24.0% using three

154   or more medications.[1] In 2022, an estimated 4.5 billion prescriptions were dispensed from these

155   pharmacies[2] resulting in $64 billion retail out-of-pocket prescription expenditures.[3] Private insurers

156   and CMS, through Medicare Part D and Medicaid programs, each accounted for about 40% of retail

157   prescription expenditures.[4]

158

159   The safety of outpatient pharmacy prescription dispensing practices is a public health concern. The high

160   number of prescriptions dispensed means that even a low dispensing error rate can affect millions. If the

161   commonly cited 1.5% dispensing error rate is applied to 2022 prescription data, an estimated 67.5 million

162   dispensing errors occurred that year.[2] Alarmingly, reports by pharmacists[5] and the media[6,7] suggest

163   dispensing errors are rising.

164

165   Dispensing errors include prescription dispensed to the wrong person, wrong medication or strength

166   dispensed, incorrect prescription label information, dispensing medications that could lead to drug-drug or

167   drug-disease interactions, and failure to provide adequate patient/caregiver counseling.[8-11] The multiple

168   steps involved in prescription dispensing create error opportunities at any point during prescription

169   preparation, review of medication records for therapeutic concerns, and patient counseling.[8] Errors can

170 result in drug-drug interactions, adverse events, hospital admissions, increased healthcare utilization, and

171 increased risk of death.[9]

172

173 A focus on dispensing errors within outpatient pharmacies is warranted because they lack key safety

174 features that exist within inpatient (hospital/long-term care) pharmacies.[10] Safety differences include:

175 (1) outpatient prescriptions are dispensed directly to patients; (2) few outpatient pharmacies face external

176 regulatory pressures that promote a culture of safety[12]; (3) outpatient pharmacies are not required to

177 obtain accreditation approval from organizations such as The Joint Commission (TJC)[13] or URAC

178 (formerly known as Utilization Review Accreditation Commission)[14], that provide external verification

179 of prescription safety procedures; and, (4) while parent institutions of inpatient pharmacies promote their

180 safety to the public, outpatient pharmacy corporations emphasize fast receipt of prescriptions, prioritizing

181 consumer demand over dispensing safety.[15]

182

183 This policy lays out three problem areas that cloud or add to dispensing error concerns. First, we lack a

184 clear understanding of the types, frequency, and associated costs of dispensing errors and their impact on

185 patient health; the degree to which system-mediated factors, such as pharmacy staffing, impact errors; and

186 the interplay of these factors within specific outpatient pharmacy environments. Second, the culture of

187 safety appears to be eroding in a growing number of pharmacies; and third, there is little external pressure

188 to hold back that decline.

189

190 <u>Paucity of outpatient pharmacy dispensing safety data</u>

191 The Institute of Medicine report, *To Err is Human: Building a Safer Health System*[16], ushered in an era

192 of medication safety research, however, little research focused on outpatient pharmacy prescription

193 dispensing.[8,17] A 2024 international systematic review of both hospital and community pharmacy

194 dispensing error studies from 2010 to 2023 included only 15 U.S. studies.[18]

195

196 Outpatient pharmacy dispensing error studies report significant variation in error rates due to differences

197 in medication error definitions, pharmacy inclusion criteria, study sample sizes, methodologies (e.g.,

198 direct observation, mystery shopper (i.e., individual hired to pose as a shopper), surveys, claim data

199 analysis) and error reporting metrics.[10] Some studies defined an error as only occurring when

200 undetected, and others included errors detected and remedied during the dispensing process (i.e., "near

201 misses").[19] A 2018 meta-analysis of medication error studies reported dispensing error rates ranging

202 from 0.00003% to 52% with an overall estimated rate of 1.5%.[19] The lowest error rate was reported

203 from a claims database analysis of selected medications. The highest rate occurred from direct

204 observations related to selected prescriptions requiring patient consultation.

205

206 Reported percentages of dispensing errors causing patient harm range from 4% to 52%.[17,20] An

207 observational study of 50 pharmacies determined that 6.5% of dispensing errors had the potential to cause

208 patient harm,[21] while a mystery shopper study of 255 pharmacies found that 52% of pharmacies

209 dispensed two prescriptions that, if taken together, could result in a life-threatening drug interaction.[20]

210 The degree to which harm from dispensing errors contributes to healthcare expenditures is unknown.

211 Authors of a 2024 systemic review of medication errors called for a common data reporting and analysis

212 framework to determine the financial impact of those errors.[22] Similarly, the adoption of common data

213 collection, reporting and analytical approaches are needed to determine the financial impact of dispensing

214 errors in outpatient pharmacies.[22]

215

216 Certain individuals may be at high risk for error harm, including children, pregnant persons, elderly

217 persons, have multiple or complex health conditions, mental health illness, developmental or intellectual

218 disabilities, take multiple medications, or take medications with a high potential for serious adverse

219 reactions.[23,24] Individuals with low vision and hearing impairment, low health literacy or English as a

220 second language may face challenges in reading prescription labels necessary to detect dispensing

221 errors.[25-29] Those with fragmented healthcare, barriers to care (e.g., rural or underserved areas,

222 inadequate health insurance) and/or discrimination within healthcare settings due to race, ethnicity, gender

223 identity, or mental health illness, or living in stressful socioeconomic conditions, such as homelessness,

224 may face barriers to error remediation.[30,31]

225

226 Data on root causes of dispensing errors is key to prevention. Associations are found between dispensing

227 errors and high prescription volumes, inadequate staffing levels and education, workplace disruptions and

228 lack of patient counseling.[11,21,32] Pharmacists consistently report performance metrics drive work

229 overload, work-related stress, burnout and moral injury and thus contribute to errors and increased patient

230 safety issues.[33] Technology use lowers dispensing errors, but they still occur due to human error and

231 technology limitations.[10] Key questions remain about the impact and interaction of these factors in

232 causing dispensing errors and which interventions best alleviate their impact on error occurrence and

233 patient safety.

234

235 Understanding dispensing safety is complicated by the lack of public sources of error data. FDA

236 MedWatch[34], FDA and CDC Vaccine Adverse Event Reporting System (VAERS)[35], and the Institute

237   for Safe Medication Practices (ISMP) consumer and health professional reporting systems[36] collect

238   dispensing error reports, but do not publicly share such data or allow access to databases. Most outpatient

239   pharmacies do not report dispensing error rates to state boards of pharmacy and dispensing safety is rarely

240   discussed within corporate annual reports.[37] A growing number of outpatient pharmacies use Patient

241   Safety Organizations (PSOs) that shield error data from public and legal disclosure.[38] While data

242   confidentiality is thought to enhance error reporting[16], it also means the public cannot choose

243   pharmacies, and payers cannot build pharmacy networks, based on dispensing safety criteria. Only crude

244   indicators of pharmacy dispensing safety are publicly available: state data on lack or loss of licensure,

245   lawsuits, whistleblower reports, and media reports.[6,7]

246

247   <u>Eroding culture of safety within outpatient pharmacies</u>

248   Dispensing safety within outpatient pharmacies must be supported by an organizational culture that

249   acknowledges medication risks, strives to protect patient safety, values communication, fosters shared

250   trust, and believes in the value of preventive measures.[10] The 2022 National Pharmacist Workforce

251   Study reported 82% of pharmacists indicated patient medication safety is being "reduced" or

252   "significantly reduced" due to increasing practice-related activities.[5] Pharmacist frustrations may arise

253   from their lack of legal authority over system-mediated causes of errors, such as staffing levels and staff

254   education.[5]

255

256   The linchpin to a culture of safety is continuous quality improvement (CQI) which uses a systems

257   approach to improve safety through on-going error data gathering, assessment and system improvements.

258   While medication safety is a required component of pharmacist education, pharmacy staff may not have

259   the requisite reporting and communication skills needed for CQI initiatives.[39] A growing number of

260   pharmacies use Agency for Healthcare Research and Quality (AHRQ)-approved PSOs to collate their

261   error data and recommend safety initiatives.[38] The impact of PSOs on dispensing safety practices is

262   unknown, but requires examination because pharmacists practicing at pharmacies affiliated with PSOs

263   report fear of reprisal for reporting errors and state they do not receive feedback about reported errors[6]

264   – two hurdles to improving medication safety that PSOs were created to overcome.

265

266   Collaboration between pharmacists and prescribers and their staff is essential to prevent dispensing errors,

267   however, the "silo" nature of pharmacies within the healthcare system hinders prescriber-pharmacist

268   communications and collaborations needed to prevent, detect and remedy prescription errors. Lack of

269   pharmacy access to electronic health record information prevents detection of errors such as drug-disease

270   interactions and wrong patient or medication name on the prescription.[32,40] A Qualtrics survey of 204

271 pharmacists and 200 physicians found while nearly all believed collaboration between physicians and

272 pharmacists is important, both physicians and pharmacists reported collaboration was hindered by lack of

273 time and communication challenges.[41]

274

275 <u>Lack of external accountability for dispensing safety</u>

276 State boards of pharmacy have a duty to hold pharmacies and pharmacists accountable for prescription

277 safety through enforcement of pharmacy laws and regulations. However, most state boards of pharmacy

278 do not require outpatient pharmacies to report dispensing errors or undertake CQI activities.[12] A survey

279 of state boards of pharmacy found only 16 state boards mandated community pharmacies to implement

280 some component of CQI.[12] Of those, three required complete audits related to medication safety and

281 only one required documentation of quality improvements made. Few state boards take actions to address

282 workplace factors known to influence dispensing error rates or cite pharmacies for neglecting to counsel

283 patients as required by law.[11]

284

285 Despite significant prescription expenditures and interest in preventing unnecessary healthcare costs,

286 healthcare payers rarely hold pharmacies accountable for dispensing errors. Payer medication safety

287 quality measures do not assess pharmacies' culture of safety or CQI initiatives.[42] Neither CMS nor

288 private payers require outpatient pharmacies to attain national accreditation approval by organizations that

289 assess patient safety practices.[12]

290

291 Outpatient pharmacies and their corporate owners face little market pressure to improve prescription

292 dispensing safety. Based on corporate annual report content, shareholders appear to have little interest in

293 prescription dispensing practices, dispensing errors rates, or their impact on patient health and liability

294 costs.[37]

295

296 **X. Evidence-based Strategies to Address the Problem**

297 This policy focuses on strategies to protect the public against outpatient pharmacy dispensing errors in

298 three areas: (1) increasing research and practice-based analysis to characterize dispensing errors, their

299 impact on patient safety and financial costs, patient populations impacted, and system-medicated factors

300 that are the root cause of errors to inform CQI efforts; (2) strengthening the culture of safety through CQI

301 initiatives and pharmacist, patient and interprofessional collaboration; and, (3) encouraging healthcare

302 payers, patients/caregivers and the general public to hold pharmacies accountable for dispensing safety.

303

304 <u>Increase research and practice-based analysis</u>

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305 Data-driven interventions to improve dispensing safety are needed. Meaningful safety data require

306 consistent use of standardized definitions and reporting elements.[10] Government resources and

307 established public databases can provide direction for the development of sustainable surveillance

308 models. While researcher access to established data repositories can inform an understanding of

309 dispensing errors, limitations commonly seen with error-reporting platforms include: voluntary error

310 reporting, potential reporter bias, lack of root cause analysis of errors, and data limitations.[43]

311

312 One source for data standardization is publicly available: AHRQ Common Formats for Event Reporting-

313 Community Pharmacy Version.[44] By offering a unifying approach to data reporting, this tool

314 encourages data sharing that can lead to early alerts for needed interventions to protect patient safety.

315

316 FDA MedWatch[34], VAERS[35], and ISMP professional and consumer reporting portals[36] also

317 provide insight into error data collection processes and translation into error prevention actions. Together,

318 FDA and ISMP identify root causes of common and dangerous dispensing errors and apply this

319 information to improve pharmaceutical product labeling and issue safety alerts.[36] The addition of

320 artificial intelligence decision support tools holds potential to improve the speed of MedWatch data

321 reviews, leading to better and faster decisions.[45] The VAERS database provides early alerts to health

322 professionals about vaccine administration errors.[46] Increased voluntary reporting participation and de-

323 identified data availability to researchers and analysists could increase the value of these useful databases

324 to outpatient pharmacy CQI efforts.

325

326 Another data resource may be outpatient pharmacy error data held within PSOs. PSOs are established

327 through AHRQ[38], thus, this agency's support of de-identified data access for research purposes is

328 essential. Finally, an evaluation of dispensing safety within outpatient pharmacies by The Office of the

329 Inspector General (OIG) may be insightful given that a 2018 OIG evaluation of hospital-based medication

330 adverse events produced valuable recommendations.[47]

331

332 The Ontario, Canada Assurance and Improvement in Medication Safety (AIMS) program provides a

333 standardized data reporting platform supported by mandatory anonymous dispensing error reporting with

334 data used to support CQI initiatives.[48] AIMS provides educational programs and has a safety interest

335 group and interactive tool that-allows pharmacies and other stakeholders to view aggregated AIMS

336 data.[48]

337

338 Strengthen the culture of safety within outpatient pharmacies

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339 Strengthening the culture of safety within outpatient pharmacies first requires that a culture of safety be
340 defined and measured. The AHRQ Community Pharmacy Survey on Patient Safety Culture, an online
341 pharmacy-administered survey, provides an initial step towards this goal.[49] It encompasses 11 selected
342 patient safety components related to safety including communications, patient counseling, work
343 environment and staff training. Researchers have used this tool to characterize pharmacy practice
344 environments.[32]
345
346 The importance of CQI is illustrated in the Departments of Defense and the Veterans Administration
347 creation of a Joint Patient Safety Reporting system.[50] Both agencies can report incidents and near-
348 misses, including those related to prescription dispensing errors, via a standardized methodology for data
349 input, incident investigation, and root cause analysis.
350
351 Outpatient pharmacists respond positively to CQI initiatives when educated.[51] A communication
352 network established to support CQI efforts in rural Nebraska pharmacies found pharmacists valued shared
353 error reports and used them to increase safety vigilance within their pharmacies.[52] Designation of a
354 corporate medication safety officer can facilitate CQI participation supporting communication among all
355 levels of organizational management and ensuring pharmacy staff receive intentional, on-going education
356 regarding medication safety and CQI implementation.[53]
357
358 A culture of safety links patient care responsibilities among pharmacists, patients/caregivers, prescribers
359 and other healthcare providers. Intentional linking of patient care services and electronic health records
360 between pharmacies and patient-centered medical care homes improves coordination of care.[40,54,55]
361 Shared electronic health records can coordinate care and help identify prescription errors before the
362 prescription is dispensed. The Office of the National Coordination for Health Information Technology
363 (ONC) has proposed a rule that e-prescriptions include the indication for use; thus providing information
364 that could prevent wrong patient, wrong medication and wrong dose dispensing errors.[56]
365
366 Professional collaborations are essential for meeting the needs of those with barriers to understanding
367 prescription vial information. Pharmacies offer large-print and alternative language prescription labels,
368 but pharmacists often lack adequate skills and time to counsel patients with visual or hearing impairments
369 or those with low proficiency in English.[57,58] Partnerships with public health nurses or community
370 health workers (CHW) who possess unique knowledge, skills and community ties needs may be useful.
371 Cross-training of pharmacy technicians as CHW holds promise, but this model of care is limited by time
372 and financial requirements.[59]

373

374 A culture of safety supports a work environment that provides adequate resources. As employees,

375 pharmacy staff can take actions to address workplace conditions that negatively affect patient safety.

376 OSHA enforces federal laws related to employee rights and recognizes the links between organizational

377 culture of safety, worker rights and patient safety.[60] Collective bargaining gives employees a voice in

378 decisions related to work issues, such as working conditions that affect employee and patient safety.[61]

379 Drawing on lessons learned from the nursing profession,[62] pharmacy professional associations could

380 play a key role in pharmacy staff efforts to engage in collective bargaining.

381

382 <u>Increase pharmacy accountability for maintaining a strong culture of safety</u>

383 State boards of pharmacy-mandated pharmacist-patient/caregiver counseling can significantly decrease

384 dispensing errors.[63,64] State laws have mandated error reporting and CQI processes, provided

385 pharmacists legal authority to adequately staff pharmacies, and give pharmacy staff break times.[65-67]

386 While the effect of these mandates is unknown, research of the Omnibus Reconciliation Bill of 1990

387 pharmacy practice requirements suggest that, without financial incentives, the intended benefits may be

388 muted.[68] Irrespective of the laws' impact, their passage suggests the political will to address system-

389 medicated causes of dispensing errors exists.

390

391 *Prescription payer efforts*

392 Historically, outpatient pharmacy corporations have responded to financial incentives. In response to

393 health plan requirements, corporations expanded pharmacist responsibilities to include performance

394 metrics linked to health plan quality measures.[33] When the federal government offered pharmacies

395 reimbursement for COVID-19 vaccine administrations, many pharmacies prioritized vaccine

396 administration.[6] Establishing private and public payer financial incentives for pharmacy CQI efforts

397 may be reasonable given that dispensing errors can result in increased healthcare costs.

398

399 Some state boards of pharmacy are combining a system-medicated approach to error prevention with

400 financial disincentives by fining outpatient pharmacy corporations, rather than pharmacists, for

401 prescription errors and failure to counsel patients.[6] CMS could build on this approach by requiring

402 outpatient pharmacies attain national accreditation status to receive Medicare and Medicaid prescription

403 reimbursements.

404

405 As financial awards related to dispensing error lawsuits grow,[69] investors may raise concerns about

406 legal expenditures. Requiring corporations to report information about CQI practices, their impact on

407 prescription dispensing safety, and their overall prescription safety expenditures may incentivize

408 corporations to establish stronger cultures of safety within their outpatient pharmacies.

409

410 *Empowering the public to improve dispensing safety*

411 Increasing public awareness, interest and education in dispensing errors could engage patients, caregivers

412 and the public in taking actions to detect and/or prevent errors.[43] Public prescription dispensing safety

413 programs could empower patients to request pharmacist counseling when receiving a prescription and to

414 check the prescription label and vial contents before leaving the pharmacy.[70] One effective public

415 medication safety program is the Drug Enforcement Agency's (DEA) Prescription Take Back Day that

416 teaches the public how to safely dispose of unused medication to prevent unintentional medication use or

417 poisonings. Between 2018 and October 2023, the program collected 8,950 tons of medications through its

418 twice-yearly events.[71]

419

420 Alternative Strategies

421 An alternative strategy is continued passive surveillance of dispensing errors. Instead of taking the best

422 practices proactive approach to error prevention[55], this strategy takes a reactive approach that fails to

423 address preventive measures and blames pharmacy staff without any root cause analysis of the

424 contribution of the pharmacy system. This approach thwarts efforts to prevent dispensing errors and their

425 associated patient harm.

426

427 Increasing medication safety training sessions and continuing education programs for pharmacy staff may

428 be proposed as sufficient for addressing error concerns. However, limited educational sessions are often

429 insufficient to address system-mediated medication safety.[72] To be effective, personnel training needs to

430 be one component of a comprehensive safety strategy that builds on a culture of safety.

431

432 Human errors may lead to a desire to rely totally on technology (e.g., robots, AI-driven assessments and

433 counseling) to prevent dispensing errors. While technology does lower rates of some types of errors[43],

434 those requiring complex decision-making based on knowledge and experiential skills may not be reliably

435 prevented with today's AI capabilities.

436

437 **XI. Action Steps to Implement Evidence-Based Strategies**

	Evidence-Based Strategy		**Action Steps**
1	To increase research and practice-based analysis to	1	CDC, AHRQ and the Health Resources and Service Administration (HRSA) in partnership with researchers and

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, APHA calls upon:		medication safety stakeholders, to 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 healthcare 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.
	2.	Secretary of Health and Human Services (HHS) to: Direct federal health agencies to develop and implement a system for collective reporting of dispensing errors.
	3	AHRQ to: 1. 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. 2. Build upon its current work related to pharmacy safety to assist outpatient pharmacies in using data to effectively support CQI efforts. 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, healthcare payers, and consumer advocates. 3. Examine the effectiveness of PSOs in supporting CQI efforts within pharmacies. 4. Support researcher access to de-identified PSO data.
	4	Congress to request the HHS Office of Inspector General to assess outpatient pharmacies' CQI programs and their impact on dispensing errors and patient safety.

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2	To strengthen the culture of safety within community pharmacies, APHA calls upon:	1	Outpatient pharmacies and their corporate owners to: 1. Create a culture of safety that guides pharmacy dispensing activities. 2. Establish medication safety leadership positions to promote a culture of safety from top management to the individual pharmacy level. 3. Provide intentional training and ongoing education to all pharmacy staff regarding prescription dispensing error prevention, detection and mitigation with emphasis on team contributions to CQI. 4. Appropriately staff and resource pharmacies to ensure adequate time for prescription review, patient counseling, and meaningful involvement in CQI initiatives. 5. Collaborate with prescribers, other health professionals, community advocates, patients, and caregivers to ensure dispensing safety policies and practices are responsive to community needs.
		2	OHSA to partner with national and state pharmacy associations to educate pharmacists and pharmacy technicians about their rights to safe working environments and lawfully organize.
		3	ONC to conduct and/or fund research on the impact of CQI program requirements on outpatient pharmacy staff health and safety.
		4	ONC to 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 non-commercial, patient-centered communications. Partners in this effort should include outpatient pharmacy corporations, healthcare systems, health professionals, health informatics experts, health information exchanges, and consumer advocates.
		5	The FDA, ISMP, outpatient pharmacies, health professional associations, and consumer advocacy groups to 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	To incentivize healthcare payers, patients/caregivers and the general public to hold pharmacies accountable for dispensing safety, APHA calls upon:	1	State boards of pharmacy to require and enforce regulations that: 1. Prohibit pharmacy policies, practices and workplace conditions that contribute to dispensing errors. 2. Require outpatient pharmacy CQI initiatives related to dispensing errors. 3. Mandate the provision and documentation of oral patient counseling for every prescription dispensed. 4. Hold outpatient pharmacies and their corporate owners accountable for consistently following laws and regulations intended to prevent dispensing errors.
		2	CMS, in partnership with national accreditation organizations, pharmacies, pharmacy professional associations, and consumer advocates to develop Conditions of Participation and Conditions for Coverage that outpatient pharmacies must meet in order to begin and continue participation in the Medicare and Medicaid programs.
		3	Private and public healthcare payers to work with AHRQ, outpatient pharmacies, pharmacy professional associations, medication safety experts and health information specialists to develop a standardized data-driven approach to holistically evaluate pharmacies based on their culture of safety.
		4	Shareholders to call for publicly-traded pharmacy corporations to include information related to their outpatient pharmacy dispensing safety practices in their annual corporate reports.

438

439 **XII. Opposing Arguments**

440 <u>Dispensing safety data should be confidential and proprietary</u>

441 Dispensing error reporting may raise concerns that public sharing of patient and pharmacist personal

442 identifying information within error data may violate patient confidentiality laws and thus dampen error

443 reporting efforts. For this reason, release of de-identified data only is encouraged with an emphasis on its

444 educational use for error prevention.[16] As businesses concerned about their public image and subject to

445 shareholder concerns about liability, pharmacy corporations may argue that even de-identified aggregate

446 dispensing error data are proprietary and should not be publicly available. However, state boards of

447 pharmacy have a duty and healthcare payers and the public have a vested interest in being able to review

448 and assess prescription safety information.[55]

449

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

451 Another opposing argument is that prescription dispensing errors are a result of staffing shortages

452 exacerbated by the COVID-19 pandemic.[73] Some may state that as the impact of the pandemic

453 subsides, pharmacy workplace issues will resolve and workloads will decline. However, responsibilities

454 related to COVID testing and immunizations remain. Staffing shortages were problematic prior to the

455 pandemic.[33]

456

457 Errors should be addressed by a focus on individual workers

458 Some may suggest that individuals, not systems, are the cause of prescription errors.[74] Pharmacists are

459 liable for the errors they cause, but this viewpoint ignores the prevailing view that individual sanctions for

460 human errors discourage error reporting and a systems approach to assessing and improving safety is

461 more effective in preventing recurrent errors.[55,74]

462

463 Safety regulations and accountability may lead to unintended negative consequences

464 Two unintended negative consequences of promoting CQI initiatives may occur. CQI initiatives

465 themselves may add to pharmacy staff responsibilities and, if staff resources are not increased, will

466 contribute to errors by further overwhelming the system.[75] Pharmacy corporations may decide the costs

467 of safety changes are too high and exit the market, thus limiting public access to pharmacies and

468 increasing workloads for remaining pharmacy staff. They may also adopt dispensing models that

469 complicate external accountability for safety. It may be difficult to prevent such reactions, but the benefits

470 of improving prescription safety and preventing patient harm supports the Action Steps presented.

471

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