1   **DRAFT ASHP Statement on the Role of the Medication Safety Leader**

2   **Position**

3   The American Society of Health-System Pharmacists (ASHP) believes that medication safety is a

4   fundamental and shared responsibility of the pharmacy workforce and all healthcare

5   professionals. Medication safety programs require engagement of the entire healthcare team,

6   as well as innovative leadership to set a vision and direction, identify opportunities to improve

7   the medication-use system, and lead implementation of error-prevention strategies across all

8   practice settings. The medication safety leader plays a key role in driving initiatives focused on

9   patient safety, providing medication safety expertise, and influencing practice change, research,

10   and education. ASHP believes that because of their training, knowledge of the medication-use

11   process, integration within healthcare teams, close patient interaction, and proven leadership

12   in this field, pharmacists are uniquely qualified to serve as the medication safety leader in

13   hospitals and health systems.

14

15   **Background**

16   Over the past 60 years, hospital and health-system pharmacies have reduced the risk of

17   medication harm. Medication safety was the basis of several historic innovations in pharmacy

18   services (e.g., unit-dose systems, decentralized clinical pharmacy services, therapeutic drug

19   monitoring, medication reconciliation, and sterile compounding of intravenous medications).

20   The fundamental leadership role of pharmacists in medication safety has been summarized as

21   follows:

22

23   Pharmacy leadership is the core of a successful medication safety program. Pharmacy

24   leaders can play an enormously important role in performance improvement. They can

25   be part of the senior leadership team's DNA because their impact and view go far

26   beyond the walls of the pharmacy. Pharmacists can play an important role as leaders to

27   reduce patient safety risks, optimize the safe function of medication management

28   systems, and align pharmacy services with national initiatives that measure and reward

29   quality performance.[1]

30

31   The landmark Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health*

32   *System,*[2] generated major patient safety initiatives by government agencies, regulatory and

33   accrediting bodies, professional and organizational associations, and health care organizations.

34   The Joint Commission National Patient Safety Goals (NPSGs)[3] is an example of a response to the

35   original IOM report. The Practice Advancement Initiative (PAI)[4] and the National Quality Forum

36   (NQF) Safe Practice 18: Pharmacist Leadership Structures and Systems[5] incorporate medication

37   safety principles to ensure optimal patient safety and outcomes.

38   The medication safety leader (also referred to as a medication safety officer, medication

39   safety manager, or medication safety coordinator, among other titles) is a clinical practitioner

40   designated by an organization to serve as the authoritative expert in safe medication use. An

41   effective medication-safety leader must embody a set of essential characteristics that will

42   enable them to influence change, drive system improvement, and promote safety across the

43   entire medication-use process (Table 1). Traditionally, the medication safety leader has been a

44   clinical pharmacist or manager within the department of pharmacy, although the position is

45   sometimes filled by a nurse or physician. The medication safety leader may report to the

46   organization's pharmacy, risk-management, or quality departments, or to senior

47   administration. The medication safety leader should be positioned on the organizational chart

48   where it will best enhance his or her "ability to affect change and advocate that the position

49   remains targeted on medication safety."[6] Medication safety leadership may encompass a single

50   hospital or a group of organizations (e.g., spanning a health system or at a corporate level of a

51   larger organization). Regardless of organization size, it is critical that the fundamentals of

52   medication safety are the central component of the medication safety leader's job function.

53   Although medication safety leaders may have other responsibilities, medication safety should

54   remain a core responsibility, they should have training in medication safety and quality

55   improvement, and they must be strategically positioned and empowered to lead efforts to

56   reduce the risks of medication use.

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Table 1. Characteristics of a Medication Safety Leader	
Education, Training, and Professional Development	• Completed post-graduate specialized training (e.g., medication safety residency or fellowship, related certificate or certification) or three or more years of health-system practice experience. • Maintains continuous professional development focused on new developments in safety and quality improvement concepts.
Clinical and Medication-Use System Expertise	• Knowledge of and experience with all aspects of the medication-use system, including procurement, prescribing, transcribing, preparation, distribution, administration, documentation, and monitoring. • Strong understanding of the facility's internal systems and processes developed through firsthand experience, observations, medication-use evaluations, interviews, and data analysis for the spectrum of patient populations treated in their organization (e.g., pediatric, geriatric, cardiac, oncology). • Clinical expertise and a broad understanding of health care systems and processes to facilitate accurate interpretation of clinical events. • Proactive drive to learn from external safety events and ability to learned insights to strengthen system vulnerabilities to prevent patient harm.
Systems-Focused Quality Improvement and Data Driven Decision Making Expertise	• Demonstrates mastery in applying of safety principles, continuous quality improvement methods, and human factors engineering, and high-reliability principles. • Strong analytical acumen and an understanding of statistics, population data, and risk-prioritization concepts to inform sound safety decisions. • Proficiency in performance-improvement methodology and tools, including root cause analysis (RCA), failure mode and effects analysis (FMEA), cause-and-effect diagramming, process-flow mapping, and methods for monitoring projects and measuring the progress of performance-improvement initiatives. • Ability to trend and leverage data related to the medication use process to proactively identify and improve system vulnerabilities.
Safety Mindset, Values, and Professional Philosophy	• Commitment to just-culture[7] principles, fostering transparency, inclusive participation of all health care professionals, and a learning-focused environment within the organization's medication error reporting system. • A passion for medication safety and improving patient outcomes. • Values and actively promotes meaningful patient engagement as an essential as part of the health care team.

Table 1. Characteristics of a Medication Safety Leader	
Leadership, Influence, and Change Management	• Demonstrates transformational leadership skills. • Demonstrates a system-focus approach to adverse drug events, advocates for system-level solutions, and applies just culture principles to all event reviews. • Functions proactively rather than reactively. • Demonstrates appropriate assertiveness- knowing when to ask and how firmly to advocate based on the issue at hand, the organizational landscape, and shifting priorities. • Successfully engages with diverse groups - interdisciplinary clinical teams, health-system leaders, supportive staff, and patient-family advocates.
Communication and Collaboration Skills	• Communicates with exceptional clarity- verbally and in writing, with flexibility to tailor and edit message to the audience and communication medium. Demonstrates strong presentation skills that are tailored to diverse audiences of healthcare professionals and patients.

59

60 The scope of a medication safety leader's responsibilities reaches every corner of the health

61 care system and encompasses many roles: educator, preceptor, mentor, detective, compliance

62 officer, risk manager, engineer, accountant, statistician, computer analyst, and counselor. A

63 typical day may include activities related to medication safety surveillance, system-level quality

64 improvement, and providing medication safety-related education (Table 2). Most medication

65 safety leaders quickly find themselves involved in many projects and committees as well as

66 serving as the contact person when nursing, pharmacy, or medical staff have questions or

67 problems. The medication safety leader must understand patient safety principles and prioritize

68 work activities to positively impact the safety of patient care. The medication safety leader

69 should strive to acquire additional skills crucial to success, such as presentation and

70 communication skills, as well as expertise in process-improvement methodologies such as Six

71 Sigma and Lean. Formalized training in medication safety can be achieved through residency,

72 fellowship, and certificate programs and other methods of continuing education. ASHP

73 supports the expansion of pharmacy education and postgraduate residency training to include

74 an emphasis on medication safety.[9]

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Table 2. Proposed Daily Activities of a Medication Safety Leader			
Medication Safety Surveillance	**Systems-Level Quality Improvement**	**Education, Training, and Professional Development**	**Leadership**
• Attend safety rounds and/or clinical staff meetings • Investigate and respond to adverse drug event reports • Conduct tracers to ensure compliance with accreditation standards and best practices • Assess the safety during drug shortages	• Lead process improvement teams • Evaluate trends medication safety data by applying analytic frameworks (i.e., dashboards) • Develop and implement error- prevention strategies • Design and optimize the medication reconciliation process	• Precept pharmacy students and residents • Provide medication safety and just culture education to new clinical staff and existing staff and leaders across the system • Develop education for staff related to system improvement framework	• Lead medication safety committee, workgroup meetings, and/or technology governance groups (i.e., automated medication dispensing systems, smart infusion pump) • Report medication safety data to health system leaders • Develop policies and procedures related to safe medication use

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79 **Responsibilities of Medication Safety Leaders**

80 Medication safety leaders must collaborate with all types of health care professionals, support

81 staff, management, and patient-family advocates, while considering all components of the

82 medication-use process in all settings of healthcare (e.g., acute care, ambulatory care, infusion

83 centers, community pharmacies, drug distribution centers) to improve medication safety. The

84 medication safety leader is responsible for medication safety leadership and expertise that

85 influence practice change, research, and education.

86

87 *Leadership.* To provide leadership, the medication safety leader will:

88   1. Provide accountable, strategic, health-system-level stewardship of the medication-use

89   process by serving as a chair of the medication safety committee, steering the

90   medication safety team, and operating as the organization's expert leader for

91   medication use-related processes and regulatory/accreditation requirements.

92   2. Develop and communicate a vision of an ideal, high-reliability medication-use process

93   that informs organizational strategy and medication safety priorities.

94   3. Ensure medication management and patient safety are embedded in organizational

95   quality and outcomes initiatives, championing high-reliability principles in system and

96   process design.

97   4. Lead the development, implementation, and continuous refinement of the

98   organization's medication safety program, ensuring alignment with regulations,

99   accreditation standards, best practices and emerging guidelines.

100   5. Design and implement proactive error-prevention strategies using internal data trends,

101   external medication safety risk reports, professional practice standards and guidelines,

102   and best practices and evidence-based recommendations from patient safety

103   organizations(e.g., ISMP, ECRI, ASHP, etc.).

104   6. Ensure the medication-safety team has timely access to informatics data and advanced

105   analytics, including emerging technologies such as AI, by coordinating with

106   organizational data owners.

107   7. Lead the planning, implementation, and optimization of the organization's medication

108   error reporting platform and medication-use technologies, including automation,

109   smart infusion pumps, and clinical decision support software.

110   8. Foster a culture of psychological safety and shared responsibility for medication safety

111   across the health system through transformational leadership, by eliminating barriers

112   for voluntary reporting, and by advocating caregiver support through the

113   implementation of a second victim/care-for-the-caregiver program.

114   9. Advance safety science literacy across the health-systems by guiding leaders and

115   clinicians in process improvement methodology, high reliability principles, and human

116   factor engineering learning.

117   10. Collaborate with technology vendors through bidirectional feedback, advisory panels,

118   and optimized partnerships to improve clinical usability of informatics and safety

119   systems.

120

121   *Expertise.* In the role of medication safety expert, the medication safety leader will:

122   1. Serve as the organization's authoritative resource on medication safety, providing

123   expert guidance for clinical teams, medication-use process owners, and in

124 organizational strategic planning.

125 2. Provide the medication safety perspective in technology initiatives that directly or

126 indirectly affect the medication-use process, ensuring safe design, implementation,

127 and optimization.

128 3. Contribute medication safety expertise to internal and external emergency-

129 preparedness planning, including contingency workflows to support safe medication

130 use when information systems are inaccessible.

131 4. Act as a an internal consultant by investigating medication safety events or concerns,

132 conducting retrospective and proactive analyses, and developing actionable

133 recommendations to reduce risk and prevent event reoccurrence.

134 5. Ensure compliance with state and federal regulatory and accreditation requirements

135 relating to medication safety, including medication management standards and

136 National Patient Safety Goals (NPSGs).

137 6. Apply quality-improvement and human-factors methodologies (e.g., find a problem,

138 organize a team, clarify the problem, understand the problem, select an intervention

139 [FOCUS], Plan-Do-Check-Act [PDCA], Lean, root cause analysis [RCA], and failure mode

140 and effects analysis [FMEA], etc.) to evaluate processes, identify vulnerabilities, and

141 guide system level improvements.

142 7. Collect, review, and analyze the organization's medication-use process data including

143 voluntarily reported adverse drug events, adverse drug event surveillance data (e.g.,

144 triggers, clinical data trends including those using emerging analytics technology, etc.)

145 and medication-related technology data (e.g., alert override reports, smart pump

146 events or compliance reports, automated dispensing system reports, compounding

147 technology reports, etc.)

148 8. Use data-driven insights to identify improvement opportunities and pro-actively

149 develop high-leverage, error-reduction strategies.

150 9. Anticipate and manage medication safety risks caused by potential or actual drug

151 product shortages, including evaluating replacement drug products and coordinating

152 safe practices across the health system (e.g., acute care, ambulatory care, etc.).

153   10. Maintain and advance professional expertise by staying current with trends in patient
154   and medication safety, engaging in continuous professional development, and
155   participating in local and national safety organizations to share and adopt best
156   practices.

157

158   ***Practice Transformation.*** To influence practice change, the medication safety leader will:

159   1. Foster a culture of safety and shared accountability by collaborating with health-
160   system leadership, human resources, clinicians, and patient-family advocates embed
161   high reliability principles in practice and establish a just, psychologically safe
162   environment committed to continuous learning.

163   2. Partner with departments across the health-system (e.g., pharmacy, risk management,
164   patient safety, clinical teams, ambulatory care centers, etc.), to identify, prioritize, and
165   address medication safety issues using data-informed, evidence-based risk-reduction
166   strategies.

167   3. Expand medication-safety engagement across all care settings (e.g., ambulatory,
168   primary care, infusion centers, home care, etc.) through collaborative partnerships,
169   data-driven insights, and shared decision-making with the frontline teams.

170   4. Manage improvements made to the medication-use system, resolve medication safety
171   issues, and ensure frontline clinicians are supported in delivering safe care for patients
172   (e.g., optimization of clinical decision support tools).

173   5. Integrate medication safety into the organization's strategic patient safety plan by
174   working closely with senior leaders (e.g., patient safety officer, chief medical officer,
175   etc.) to align medication safety initiatives with broader system priorities.

176   6. Lead or participate in multidisciplinary committees where adverse drug events,
177   medication-use policy, formulary management, and patient safety are addressed to
178   identify risk points and prioritize system improvements to reduce the potential for
179   medication error and patient harm.

180   7. Promote robust medication error reporting (internal and external) and the use of data
181   analytics frameworks, i.e., dashboards including ones leveraging emerging

182   technologies (artificial intelligence, trigger tools) to analyze. Report identified

183   organizational trends to key committees (medication safety committee, pharmacy and

184   therapeutics committee, etc.).

185   8. Develop and disseminate best practices for safe medication-use principles across the

186   health-system confirming effective spread and adaptation.

187   9. Apply continuous quality-improvement principles to plan, address, assess and ensure

188   sustainment of improvement efforts.

189

190   **Research and Education.** To further provide medication safety research and education to staff,

191 the medication safety leader will:

192   1. Design and assist in the implementation of educational and orientation programs in safe

193   medication by:

194   • Leading and periodically refining the provision of effective ongoing programs and

195   presentations related to safe medication use to diverse audiences (e.g., nursing,

196   pharmacy, respiratory care, and medical staff).

197   • Developing and providing competency assessments to staff for tasks related to

198   medication safety (e.g., use of smart pumps and automated medication

199   dispensing systems);

200   • Disseminating educational resources to health care providers, other pertinent

201   staff, and patients to ensure they are competent in safe medication-use

202   practices; and

203   2. Integrate medication safety into orientation and training for all health care providers

204   who participate in the medication-use process.

205   3. Provide medication safety education to pharmacy colleagues, students, and residents,

206   as well as other health care professionals across the health-system.

207   4. Share information about actual or potential medication errors or harm with safety

208   organizations such as ISMP, FDA, drug or product manufacturers, and state error

209   reporting programs.

210   5. Conduct medication-use safety research through well-designed, externally validated

211   studies and implement evidence-based practices for medication safety.

212   6.   Publish findings, case studies, and best practices in peer-reviewed journals and

213   professional forums to advance the field of medication safety.

214

215   **Conclusion**

216   ASHP believes that pharmacists, as medication use experts, are uniquely qualified to serve as

217   medication safety leaders. Medication safety leaders articulate the vision and direction for

218   improving the safety of the medication-use system to prevent patient harm. The medication

219   safety leader's role includes responsibility for leadership through direction and prioritization,

220   medication safety expertise, staff engagement, influencing practice change, research, and

221   education. By analyzing both the organization's medication safety data and relevant external

222   sources, the medication safety leader will lead development and implementation of proactive,

223   error-prevention strategies that build a culture of safety across the organization.

224

225   **Web Resources**

226   • Agency for Healthcare Research and Quality (AHRQ): www.ahrq.gov

227   • American Society for Healthcare Risk Management (ASHRM): http://www.ashrm.org

228   American Society of Health-System Pharmacists (ASHP): http://www.ashp.org

229   • Anesthesia Patient Safety Foundation (APSF): www.apsf.org

230   • Center for Disease Control and Prevention (CDC): www.cdc.gov

231   • Consumer Medication Safety: www.consumermedsafety.org

232   • Emergency Care Research Institute (ECRI): www.ecri.org

233   • FDA Med Watch: www.access.fda.gov/scripts/medwatch/medwatch/medwatch-

234   online.htm

235   • Institute for Healthcare Improvement (IHI): www.ihi.org

236   • Institute for Safe Medication Practices (ISMP): www.ismp.org

237   • International Center for Health Outcomes and Innovation Research (InCHOIR):

238   www.mers-tm.org

239   • Medication Safety Officers Society (MSOS): www.medsafetyofficer.org

240   • National Coordinating Council for Medication Error Reporting and Prevention

241   (NCCMERP): www.nccmerp.org

242   • National Patient Safety Foundation (NPSF): www.psnet.ahrq.gov/issue/national-patient-

243   safety-foundation

244   • National Quality Forum: www.qualityforum.org

245   • Patient for Patient Safety (PFPS) US: www.pfps.us

246   • Patient Safety Authority: www.patientsafety.pa.gov

247   • Patient Safety Movement Foundation: www.psmf.org

248   • SafeMedication.com: www.safemedication.com

249   • The Joint Commission (TJC) National Patient Safety Goals:

250   www.jointcommission.org/standards_information/npsgs.aspx

251   • The Just Culture Community: www.justculture.org

252   • The Leapfrog Group: www.leapfroggroup.org

253   • U.S. Pharmacopeia (USP): www.usp.org

254   • World Health Organization (WHO): www.who.int/en

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256   **Additional Readings**

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321 Additional Information

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