

## **Draft ASHP Statement on the Role of the Medication Safety Leader\***

### **Position**

1 The American Society of Health-System Pharmacists (ASHP) believes that medication safety is a  
2 fundamental responsibility of all members of the profession of pharmacy. For a medication  
3 safety program to succeed, however, it is essential that there be a leader to set a vision and  
4 direction, identify opportunities for improvement, and lead implementation of error-prevention  
5 strategies. The medication safety leader's role includes responsibility for leadership, medication  
6 safety expertise, influencing practice change, research, and education. ASHP believes that  
7 because of their training, knowledge, skills, and abilities, pharmacists are especially well  
8 qualified to fill the roles and meet the responsibilities of the medication safety leader in  
9 hospitals and health systems, although physicians and nurses have also successfully served as  
10 medication safety leaders.

### **Background**

11 Hospital and health-system pharmacists have improved pharmacy systems over the past 60  
12 years to reduce the risk that medications could harm patients. Medication safety was at the  
13 heart of such historic innovations in pharmacy services as unit-dose systems, decentralized  
14 clinical pharmacy services, and intravenous admixture services. The crucial leadership role of  
15 pharmacists in medication safety has been summarized as follows:

16 Pharmacy leadership is the core of a successful medication safety program. Pharmacy  
17 leaders can play an enormously important role in performance improvement. They can

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18 be part of the senior leadership team’s DNA because their impact and view go far  
19 beyond the walls of the pharmacy.... Pharmacists can play an important role as leaders  
20 to reduce patient safety risks, optimize the safe function of medication management  
21 systems, and align pharmacy services with national initiatives that measure and reward  
22 quality performance.<sup>1</sup>

23 The landmark Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health*  
24 *System*<sup>2</sup> generated major patient safety initiatives by government agencies, regulatory and  
25 accrediting bodies, professional and organizational associations, and health care organizations.  
26 The ASHP 2015 Initiative<sup>3</sup> and The Joint Commission (TJC) National Patient Safety Goals  
27 (NPSGs)<sup>4</sup> are two examples of responses to that and subsequent IOM reports on medication  
28 and patient safety.

29 The medication safety leader (also referred to as a medication safety officer, medication  
30 safety manager, or medication safety coordinator, among other titles) is a clinical practitioner  
31 designated by an organization to serve as the authoritative expert in safe medication use.  
32 Traditionally, the medication safety leader has been a clinical pharmacist or manager within the  
33 department of pharmacy, although the position is sometimes filled by a nurse or physician. The  
34 medication safety leader often reports to the organization’s risk management department, its  
35 office of quality, or to a senior administrator (e.g., hospital vice president, chief medical officer,  
36 or chief executive officer), perhaps because of the belief that the medication safety leader may  
37 have more success if he or she reports outside of the department of pharmacy. Medication  
38 safety leadership may encompass a single hospital or a group of organizations (e.g., spanning a  
39 health system or at a corporate level of a larger organization). Regardless of organization size, it  
40 is critical that the fundamentals of medication safety are the central component of the  
41 medication safety leader’s job function. Although medication safety leaders may have other

42 responsibilities in smaller institutions, for example, medication safety should remain their core  
43 responsibility, and they must be strategically positioned and empowered to lead efforts to  
44 reduce the risks of medication use.

45 The characteristics of a medication safety leader include:

- 46 1. Clinical expertise and a broad understanding of health care systems and processes to  
47 facilitate accurate interpretation of clinical events.
- 48 2. Knowledge of and experience with all aspects of the medication-use system, including  
49 procurement, prescribing, transcribing, preparation, distribution, administration,  
50 documentation, and monitoring.
- 51 3. Three or more years of post-training practice experience.
- 52 4. Demonstrated leadership skills.
- 53 5. Excellent small and large group presentation skills.
- 54 6. Excellent verbal communication skills, especially the ability to communicate to all  
55 types of health care providers, as individuals as well as in small and large groups.
- 56 7. Excellent writing and editing skills.
- 57 8. Strong personal belief that resolving the problem of medication errors is a systems  
58 issue and not an individual health care provider issue.
- 59 9. Ability to function proactively rather than reactively.
- 60 10. Strong personal belief in the concept of a “Just Culture”<sup>5</sup> that enhances open  
61 participation in an organization’s medication error reporting system.
- 62 11. Understanding of concepts and application of safety principles, continuous quality  
63 improvement, and human factors engineering.
- 64 12. Appropriate assertiveness.
- 65 13. A passion for medication safety and improving patient outcomes.
- 66 14. Proven success in working with interdisciplinary teams and engaging diverse groups.
- 67 15. Strong personal belief in engaging patients as part of the health care team.
- 68 16. Eagerness to learn from events outside one’s own facility (e.g., through external  
69 sources of information) to apply learning about what went wrong in order to identify  
70 and remedy possible system weaknesses to prevent patient harm.<sup>6</sup>

71 The scope of a medication safety leader’s responsibilities reaches into every corner of the  
72 health care system and encompasses many roles, such as teacher, preceptor, mentor,  
73 detective, compliance officer, risk manager, engineer, accountant, statistician, computer  
74 analyst, and judge. A typical day may include attending safety rounds, precepting students,

75 writing policies, reviewing adverse drug reactions and medication error reports, developing  
76 error-prevention strategies, leading process improvement teams, implementing action items,  
77 reviewing smart pump libraries, assessing the safety of replacement drug products during drug  
78 shortages, orienting new professional staff, assisting with medication reconciliation, conducting  
79 tracers to ensure compliance with accreditation standards (e.g., TJC medication management  
80 standards and NPSGs), attending medical staff meetings, or educating the corporate board on  
81 the culture of safety. Most medication safety leaders quickly find themselves involved in many  
82 projects and committees as well as serving as the contact person when nursing, pharmacy, or  
83 medical staff have questions or problems. The medication safety leader needs a solid  
84 understanding of patient safety principles and must have the ability to prioritize work activities  
85 to have a positive impact on the safety of patient care. Formalized training in medication safety  
86 can be achieved through residency, fellowship, certificate programs, and other methods of  
87 continuing education. ASHP supports the expansion of pharmacy education and postgraduate  
88 residency training to include an emphasis on medication safety. For example, the ASHP  
89 Postgraduate Year 2 Pharmacy Residency in Medication-Use Safety is a year-long residency  
90 focusing specifically on obtaining skills for future leaders in medication safety.<sup>7</sup>

### **Responsibilities of Medication Safety Leaders**

91 Medication safety leaders must collaborate with all types of health care providers, support  
92 staff, and management, and consider all components of the medication-use process in order to  
93 improve medication safety. The medication safety leader's role includes responsibility for  
94 leadership, medication safety expertise, influencing practice change, research, and education.

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

- 96           1.     Develop a vision of an ideal safe medication-use system for the organization.
- 97           2.     Oversee the planning, creation, review, and refinement of a medication safety
- 98           plan.
- 99           3.     Proactively develop and lead implementation of error-prevention strategies based
- 100          on practice standards, literature review, medication safety tools, and analysis of
- 101          the organization's medication safety data.
- 102          4.     Participate in the planning, design, and implementation of the organization's
- 103          medication-use technology and automation systems.
- 104          5.     Build a culture of safety through education and communication across the entire
- 105          organization.

106           **Medication safety expertise.** In the role of medication safety expert, the medication

107 safety leader will:

- 108          1.     Serve as an authoritative resource on medication safety for the organization.
- 109          2.     Contribute the medication safety perspective for technology initiatives.
- 110          3.     Contribute the medication safety perspective to internal and external emergency
- 111          preparedness planning.
- 112          4.     Serve as an internal consultant to investigate medication safety events or issues
- 113          and develop recommendations for action.
- 114          6.     Be knowledgeable in the application and use of a variety of quality improvement
- 115          methodologies and tools (e.g., FOCUS-PDCA or Lean methodologies, root cause
- 116          analysis, failure mode and effects analysis).
- 117          7.     Collect, review, and analyze the organization's medication-use, medication error,
- 118          adverse drug reaction, and continuous quality improvement data (e.g., markers of
- 119          adverse drug events, smart pump event data, triggers and surveillance
- 120          information, and automated dispensing system and bedside barcode scanning
- 121          reports) and use appropriate data analysis techniques to identify needed
- 122          improvements and develop high-leverage error-reduction strategies.
- 123          8.     Predict and prepare to manage medication safety issues caused by potential or
- 124          actual drug product shortages and the use of replacement drug products.
- 125          9.     Maintain knowledge of trends and developments in the patient safety field
- 126          through continuous professional development; reading articles, journals, and
- 127          related material; attending appropriate seminars, conferences, or educational
- 128          programs; and utilization of information from the ISMP National Medication Error
- 129          Reporting Program, the FDA MedWatch program, and similar programs.
- 130          10.    Participate at a local and national level in patient safety and medication safety
- 131          organizations and initiatives.

132           **Influencing practice change.** To influence practice change, the medication safety leader

133 will:

- 134           1. Collaborate with other departments (e.g., pharmacy, risk management, and patient  
135           safety), hospital or health-system senior leadership, frontline staff, and nursing and  
136           medical staff leadership to identify and prioritize safety issues and develop risk-  
137           reduction strategies using the methods listed above to identify opportunities to  
138           improve medication safety.
- 139           2. Manage changes in the medication-use system to enhance medication safety, ensure  
140           that appropriate measures are taken to address and resolve medication safety issues,  
141           and see that hospital staff and faculty are supported in providing safe care for  
142           patients.
- 143           3. Work closely with others (e.g., the patient safety officer) to integrate medication  
144           safety into the overall strategic plan for patient safety and coordinate medication  
145           safety initiatives with organizational patient safety initiatives.
- 146           4. Participate in or lead multidisciplinary hospital and health-system committees  
147           concerned with medication errors, adverse drug events and reactions, near misses,  
148           policy review, safe medication use, new product review, and patient safety to identify  
149           risk points and prioritize system improvements to reduce the potential for medication  
150           error and patient harm.
- 151           5. Consult with and advise specific clinical teams and the hospital and health system  
152           generally on opportunities and strategies to improve patient care.
- 153           6. Encourage organization-wide medication error reporting through an established and  
154           accepted error reporting system that utilizes appropriate error detection methods  
155           (e.g., trigger tools).
- 156           7. Develop effective methods for spreading best medication-use practices throughout  
157           the organization.
- 158           8. Use continuous quality improvement principles to assess and report on the status of  
159           efforts to improve medication safety.

160           **Research and education.** To further research and education regarding medication

161 safety, the medication safety leader will:

- 162           1. Design and assist in the implementation of education and orientation programs in safe  
163           medication use, including:
  - 164           • development of competency assessment for staff tasks related to medication  
165           safety (e.g., use of smart pumps);
  - 166           • education of health care providers, other pertinent staff, and (as possible) patients  
167           to ensure they are competent in safe medication-use practices; and

- 168           • provision of effective ongoing programs and presentations related to safe  
169           medication use to diverse audiences (e.g., nursing, pharmacy, respiratory care,  
170           and medical staff).
- 171       2.   Share information about actual or potential medication errors or harm with safety  
172           organizations such as the Institute for Safe Medication Practices (ISMP), the FDA, drug  
173           or product manufacturers, and state error reporting programs.
- 174       3.   Conduct medication-use safety research and implement evidence-based practices for  
175           medication safety.
- 176       4.   Contribute to the literature on medication safety.
- 177       5.   Provide medication safety education to pharmacy colleagues, students, and residents,  
178           as well as other health care professionals.
- 179       6.   Integrate medication safety into orientation and training for all health care providers  
180           who participate in the medication-use process.

### Conclusion

181   ASHP believes that pharmacists, as experts on medication use, are especially well qualified to  
182   serve as medication safety leaders. Medication safety leaders articulate the vision and direction  
183   for improving the safety of the medication-use system to prevent harm to patients. The  
184   medication safety leader's role includes responsibility for leadership, medication safety  
185   expertise, influencing practice change, research, and education. Through analysis of the  
186   organization's medication safety data and literature review, the medication safety leader will  
187   lead development and implementation of proactive error-prevention strategies and build a  
188   culture of safety across the organization.

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### Suggested Readings

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### Web Resources

[www.ashp.org](http://www.ashp.org)

[www.ismp.org](http://www.ismp.org)

[www.safemedication.com](http://www.safemedication.com)

[www.asmsso.org](http://www.asmsso.org)

[www.ahrq.gov](http://www.ahrq.gov)

<http://www.fda.gov/cder/drugSafety.htm>

[www.ihi.org](http://www.ihi.org)

[http://www.jointcommission.org/standards\\_information/npsgs.aspx](http://www.jointcommission.org/standards_information/npsgs.aspx)

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[www.qualityforum.org](http://www.qualityforum.org)

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