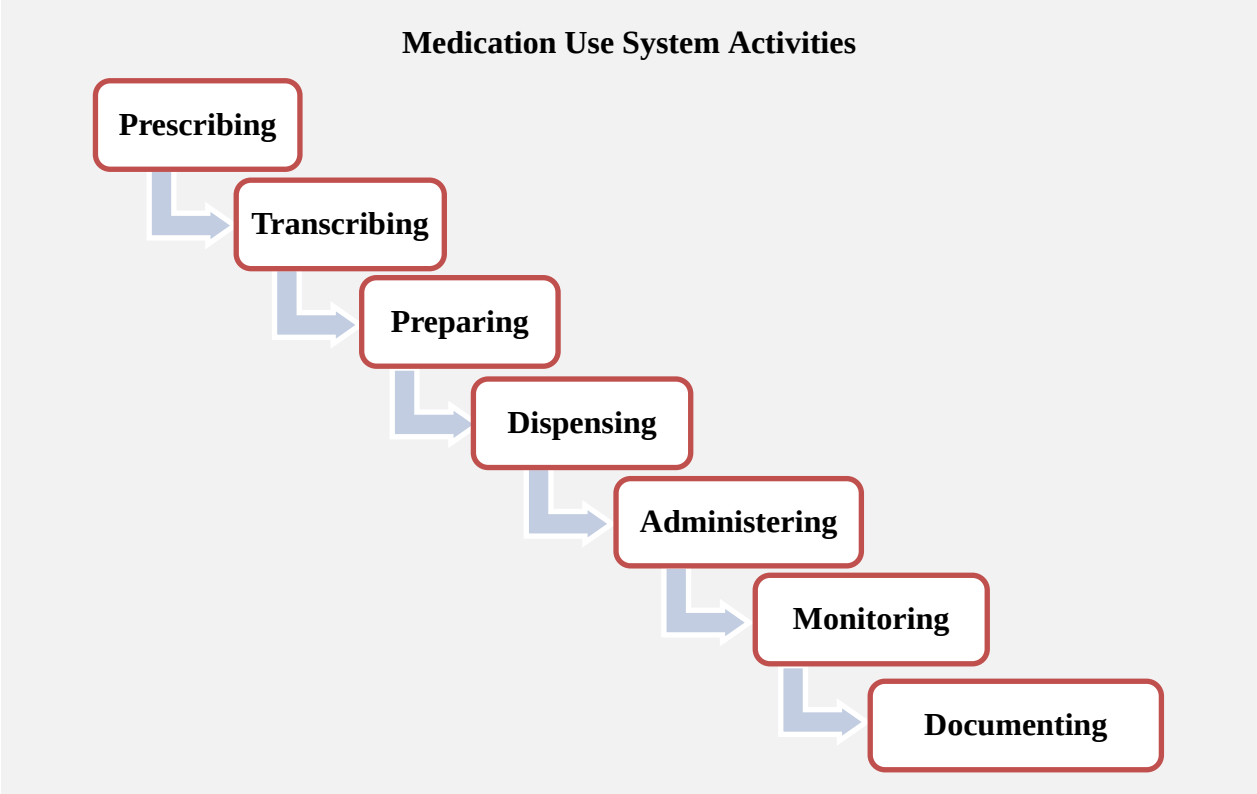
FGI *Guidelines* Update #2 September 26, 2013

# Medication Safety Zones

Eileen B. Malone, RN, MSN, MS, EDAC

The use of medication is the most common treatment intervention that patients receive in most health care environments. From prescriptions written and dispensed in the outpatient setting to complicated medication regimens for the sickest tertiary medical center patients, medication therapy is the central pillar of most treatment plans. Medication use systems involve complex processes (depicted in the diagram below) that take place across multiple organizations and departments in a variety of locations. To help promote accurate medication use in health care settings, the Health Guidelines Revision Committee adopted new physical environment requirements for inclusion in the Facility Guidelines Institute's 2014 standards.




After publication of the 2010 edition of the FGI *Guidelines for Design and Construction of Health Care Facilities*, the U.S. Pharmacopeial Convention (USP), a non-governmental public standards-setting authority for prescription and other health care products manufactured or sold in the United States, added an important chapter to its *National Formulary*: <Chapter 1066> "Physical Environments that Promote Safe Medication Use" (USP-NF, 2010). The chapter provides physical environment standards that support accurate medication use in any practice

setting, including the patient's home, and improve the performance of individuals who function in medication use systems. The standards, which are based on evidence and expert opinion, begin with definition of the physical locations where medication processes occur—medication safety zones—followed by design standards that respond to environmental conditions known to affect the rate of medication errors: illumination, interruptions and distractions, sound and noise, and organization of the work space (USP-NF, 2010; Grissinger, 2012).

These USP-defined standards were used to create new requirements for planning, design, and construction of medication safety zones in the 2014 FGI *Guidelines*.

## Medication Safety and the Patient Protection and Affordable Care Act

Studies have shown that medication errors—defined as any mistakes that occur in the medication use process, regardless of whether an injury occurs or a potential injury is present—are among the most common medical errors (Bates et al., 1995), causing more than 7,000 deaths each year in a review of death certificates (Institute of Medicine, 1999). Medication complications account for 19 percent of all medical errors, with injury in 4 to 6 percent of patients (Leape et al., 1991; ESCIM, 2009). The Joint Commission (2012) reports that medication errors stubbornly remain in the top 10 of voluntarily reported sentinel events. In fact, one study found that the prevalence of medication errors in 36 facilities was 19 percent (605 of 3,216 medication doses were in error), with 7 percent judged to be potential adverse drug events (Barker et al., 2002). These mistakes are costly to patients and the health care system alike, with preventable medication errors estimated to cost approximately $16.4 billion per year in hospitals and $4.2 billion per year in outpatient settings (National Priorities Partnership, 2010).

**What is a medication safety zone?**

A medication safety zone is a "critical area where medications are prescribed, orders are entered into a computer or transcribed onto paper documents, or medications are prepared or administered" (*U.S. Pharmacopeia and National Formulary*, 2010). It can be a medication preparation room or an area in a patient room or other patient care area as well as a self-contained medication dispensing unit, an automated medication-dispensing station, or another system the authority having jurisdiction has approved to serve as a medication safety zone.

The 2010 Patient Protection and Affordable Care Act is driving a fundamental shift from care reimbursement based on volume to reimbursement based on quality care improvement, with the goal of controlling health care costs. Reducing adverse drug events (ADE), of which medication errors are a component, is one of the nine hospital-acquired condition focus areas targeted in the Center for Medicare & Medicaid Services' Partnership for Patients program. Approximately 50 percent of the estimated 1.9 million annual ADEs are thought to be preventable, and the program's goal is to eliminate 830,000 ADEs by the end of 2013 (CMS, 2013). CMS's Hospital Value-Based Purchasing program will link Medicare and Medicaid reimbursement rates to facility success in reducing hospital-acquired conditions like medication errors.

## Medication Safety Zones and the 2014 FGI *Guidelines*

Medication safety planning, design, and construction requirements and supporting appendix language are found throughout the 2014 *Guidelines for Design and Construction of Hospitals*

*and Outpatient Facilities* as summarized in the table below. These new medication safety zone requirements are based on USP-NF (2010), OSHA (2001), and NIOSH (1998) standards.

During the planning phase of a design and construction project, those with legal responsibility for operating the health care facility (the governing body, often the owner) will identify medication safety zones as part of an overall safety risk assessment. A medication safety zone is a room or an area in a room where a medication use system activity occurs. Once the medication

**Summary of New 2014 *Guidelines* Medication Safety Zone Requirements**

| ***Guidelines* Location** | **Medication Safety Zone Requirements** |
|---|---|
| **CHAPTER 1.1: PLANNING, DESIGN, CONSTRUCTION, AND COMMISSIONING** | |
| Medication safety portion of safety risk assessment (Section 1.2-5.3) | - Medication safety risk assessment is a component of the new safety risk assessment, which is designed to improve patient and caregiver safety. See FGI *Guidelines* Update #1: *Designing for Safety*.<br>- Requires the governing body to identify the medication safety zones in a project as a component of the safety risk assessment report |
| **PART 2: HOSPITALS** | |
| Chapter 2.1: Common Elements for Hospitals (Section 2.1-2.6.6) | - Provides design requirements for medication safety zones, based on USP-NF standards:<br>• Location to minimize distractions and interruptions<br>• Work space organization, including consideration of personnel and medication safety technology and equipment impacts on design<br>• Sound and noise attenuation by meeting the criteria in Table 1.2-4 (Minimum Design Room Sound Absorption Coefficients), Table 1.2-2 (Maximum Design Criteria for Noise in Interior Spaces Caused by HVAC and Other Building Systems), and Table 1.2-6 (Design Criteria for Minimum Sound Isolation Performance Between Enclosed Rooms).<br>• Task-specific lighting levels found in USP-NF, Chapter 1066<br>- Includes reference to requirements for sharps containers, including placement, in medication safety zones based on OSHA (2001) and NIOSH (1998) standards and guidance. |
| Chapters 2.2–2.7 (All hospital types) | - Medication safety zone requirements are addressed for each of the different types of hospitals.<br>- Sends the reader back to Section 2.1-2.6.6 for the medication safety zone requirements detailed in the Common Elements chapter. |
| **PART 3: OUTPATIENT FACILITIES** | |
| Chapter 3.1: Common Elements for Outpatient Facilities (Section 3.1-3.6.6) | - Provides design requirements for medication safety zones, based on USP-NF standards as described above for Part 2.<br>- Includes sharps container reference as described above for Part 2. |
| Chapters 3.2–3.14 (Specific types of outpatient facilities) | -Medication safety zone requirements are addressed for each of the different types of outpatient facilities.<br>- Sends the reader back to Section 3.1-3.6.6 for the medication safety zone requirements detailed in the Common Elements chapter. |

safety zones have been identified, the project team will design these locations following the requirements found in *Guidelines* sections 2.1-2.6.6 (for hospitals) or 3.1-3.6.6 (for outpatient facilities). Adherence to these new requirements is not expected to significantly increase the amount of time or other resources necessary to design and build a project. However, it is expected the requirements will generate an informed discussion about the impact of the built environment on medication use system processes and patient safety.

**Medication Distribution Locations in Residential Care Facilities**

The approach to medication safety in the new *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities* (published for the first time in 2014) differs somewhat from that in the 2014 FGI *Guidelines for Hospitals and Outpatient Facilities* because medication is often *not* the most common treatment intervention for long-term residents. However, the new standard includes requirements for medication room design and a medication error component to the safety risk assessment (Section 1.2-3.5). It is suggested that the assessment of medication error risk for a nursing home, hospice, or other project identify medication distribution and storage locations as well as design features to mitigate risk based on the needs of the care population and the nature and scope of planned medication system use.

### Needle-Stick Injuries and Staff Safety

Needle-stick injuries represent one of the most common occupational hazards for hospital-based health care workers, with an estimated 385,000 needle-sticks per year—an average of 1,000 sharps-related injuries per day (Panlilo et al., 2004). The scope of the problem is no doubt larger because this figure does not include other health care delivery locations, such as long-term care facilities, home-based care, and private medical offices. Multiple surveys of health care workers reveal that 50 percent or more do not report occupational sharps injuries (CDC, 2008). Approximately 80 percent of accidental exposures to blood occurs during these injuries (OSHA, 2013), resulting in the documented transmission of more than 20 pathogens, including hepatitis B and C viruses and HIV (CDC, 2008). Excluding the cost of actually treating a worker who contracts a disease, the direct costs associated with occupational treatment and follow-up can range from $71 to close to $5,000 per worker depending on the care required (CDC, 2008). This does not take into account the financial costs associated with time lost from work because of post-exposure treatment complications and the anxiety and fear after a needle-stick injury.

National Surveillance System for Healthcare Workers data (CDC, 2011) reveals that the majority of needle-stick injuries occur on inpatient units (40 percent) followed by the operating room (25 percent). Circumstances associated with hollow-bore needle injuries that may be shaped by environmental variables, such as the location and placement of sharps containers, include the following (CDC, 2008):

- In transit to disposal – 4 percent
- During sharps disposal – 12 percent
- Collision with a worker or sharp – 10 percent

Section 1910.1030 (d)(4)(iii)(A)(2)(i) of the OSHA Bloodborne Pathogen standard (OSHA, 2001) requires that containers for contaminated sharps be "located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found." This

standard underpins the 2014 *Guideline*s requirement for a sharps container in medication safety zones where sharps are used. The ability to see the opening at the top of a sharps container is important for a health care worker to avoid inadvertent injury when disposing of a used needle. NIOSH (1998) provides an ergonomically ideal formula for determining the height of sharps containers, which accommodates 95 percent of the adult female population, as described in appendix section A2.1-2.6.6.2 (v); a reference to the NIOSH formula is provided for designers and planners in the *Guidelines* appendix.

### Expected Outcomes of New Medication Safety Requirements

The physical environment shapes all health care delivery, including those episodes of care when mistakes are made, like medication errors and staff needle-stick incidents. The 2014 *Guideline*s provides a framework for a predesign safety risk assessment and minimum design requirements (with supporting appendix language) to guide design and construction of medication safety zones across the continuum of care with the goal of supporting safe medication use systems. The health care facility team offers important evidence-based design solutions to help eliminate medication errors. We have an opportunity to create safe environments that reduce patient and staff harm and contribute positively to a health care organization's bottom-line.

### References


Barker, K., E. Flynn, G. Pepper, D. W. Bates, and R. L. Mikeal (2002). "Medication errors observed in 36 health care facilities." *Archives of Internal Medicine* 162 (16): 1897-1903.

Bates, D. W., D. J. Cullen, N. Laird, L. A. Petersen, S. D. Small, D. Servi, G. Laffel, B. J. Sweitzer, B. F. Shea, R. Hallisey et al. (1995). "Incidence of adverse drug events and potential adverse drug events: Implications for prevention." ADE Prevention Study Group. *JAMA* 274 (1): 29.

Centers for Disease Control and Prevention (CDC) – Department of Health and Human Services (2008). *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Program*. www.cdc.gov/sharpssafety/pdf/sharpsworkbook_2008.pdf

———(2011). "The National Surveillance System for Healthcare Workers (NaSH): Summary Report for Blood and Body Fluid Exposure Data Collected from Participating Healthcare Facilities (June 1995 through December 2007)." www.cdc.gov/nhsn/PDFs/NaSH/NaSH-Report-6-2011.pdf

Centers for Medicare & Medicaid Services (CMS) – Department of Health and Human Services (2013). Partnership for Patients Adverse Drug Events Resources page (list of resources on preventing adverse drug events). http://partnershipforpatients.cms.gov/p4p_resources/tsp-adversedrugevents/tooladversedrugeventsade.html

Grissinger, M. (2012). "Physical Environments That Promote Safe Medication Use." *Pharmacy &Therapeutics* 37 (7): 377-78. www.ncbi.nlm.nih.gov/pmc/articles/PMC3411211/

Institute of Medicine (1999). *To Err Is Human: Building a Safer Health System*. Washington, D.C.: National Academies Press.

The Joint Commission (2012). *Summary data of sentinel events reviewed by The Joint Commission*. www.jointcommission.org/assets/1/18/Summary_2Q_2012.pdf

Leape, L.L., T. A.Brennan, N. Laird, A. G. Lawthers et al. (1991). "The nature of adverse events in hospitalized patients: Results of the Harvard Medical Practice Study II." *New England Journal of Medicine* 324: 377-84.

National Institute for Occupational Safety and Health (NIOSH) – Department of Health and Human Services (1998). *Selecting, Evaluating, and Using Sharps Disposal Containers*, 97-111. www.cdc.gov/niosh/docs/97-111/pdfs/97-111.pdf

National Priorities Partnership – convened by the National Quality Forum (2010). Compact Action Brief: "Preventing Medication Errors: A $21 Billion Opportunity." Washington, D.C.: National Priorities Partnership and National Quality Forum, December. www.psnet.ahrq.gov/resource.aspx?resourceID=20529

Occupational Safety & Health Administration – Department of Labor (2001). 29 CFR 1910:1030 Bloodborne Pathogens, (d)(4)(iii)(A)(2)(i) "Contaminated Sharps Discarding and Containment." https://www.osha.gov/needlesticks/needlesticks-regtxtrev.html

——— (2013). How to Prevent Needlestick Injuries: Answers to Some Important Questions (Web publication) https://www.osha.gov/Publications/OSHA3161/osha3161.html

Panlilio, A. L., J. G.Orelien, P. U.Srivastava, J. Jagger, R. D. Cohn, D. M. Carco; NaSH Surveillance Group; the EPINet Data Sharing Network (2004). "Estimate of the annual number of per-cutaneous injuries among hospital-based healthcare workers in the United States, 1997-1998." *Infection Control & Hospital Epidemiology* 25 (7): 556-62.

Research Group on Quality Improvement of the European Society of Intensive Care Medicine (ESICM) Sentinel Events Evaluation (SEE) Study Investigators [A. Valentin, M. Capuzzo, B. Guidet, R. Moreno, B. Metnitz, P. Bauer, P. Metnitz] (2009). "Errors in administration of parenteral drugs in intensive care units: multinational prospective study." *British Medical Journal* 338, b814. www.ncbi.nlm.nih.gov/pmc/articles/PMC2659290/

The United States Pharmacopeia–National Formulary (USP–NF) (2010). <Chapter1066> *Physical environments that promote safe medication use*. Revision Bulletin, Official October 1, 2010. www.usp.org/sites/default/files/usp_pdf/EN/USPNF/gc1066PhysicalEnvironments.pdf

## About the Author

Eileen B. Malone, RN, MSN, MS, EDAC, senior partner at Mercury Healthcare Consulting, LLC, in Alexandria, Va., is a member of the 2014 Health Guidelines Revision Committee.

## Reprint Permission