3 in a special series of
5 risk assessment bulletins

JCAHO CMS AORN

Standards For Medication Labeling

What you need to know about JCAHO, CMS and AORN regulations and standards… and how to analyze the real cost of those injuries.

"11.4% of sentinel events are medication errors."[6]

Published as an industry service by Sandel Medical Industries, LLC

Regulations 1

JCAHO

Standard MM.4.30 Medications are appropriately labeled. *Element of Performance:* Any time one or more medications are prepared, but are not administered immediately, the medication container must be appropriately labeled. **1**

Standard MM.4.40 Medications are dispensed safely. *Element of Performance:* Dispensing adheres to law, regulation, licensure and professional standards of practice. **2**

AORN

AORN's Guidance Statement Regarding safe medication practices in the preoperative setting: "label all medications (medicine cups, syringes, basins) on the sterile field even if there is only one." **3**

CMS

Medicare Conditions of Participation (CoPs) Hospitals* must include preventive measures (in their Quality Assurance Performance Improvement program) that foster patient safety, such as reducing medical errors. CFR 482.21(c) **4**

Medicare Conditions of Participation (CoPs) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirement – CFR 482.12(c) CFR 482.23 **5**

***The term Hospital also refers to all types of medical facilities.**

Facts You Should Know 2

11.4% of sentinel events are medication errors. **6**

One of the major causes of medication errors is illegible or confusing handwriting. **7**

50% of medication errors reported to the FDA have naming, labeling and/or packaging issues associated with them. 60% of medication errors result in serious injury. There is a 10% overall mortality rate. **8**

Drug errors not only increase costs, but also significantly prolong hospital stays and increase the risk of death almost two-fold. **9**

Medication errors are one of the most common reasons for disciplining RNs. **10**

The single leading type of error is medication errors. Estimates range from 4% to 20% of all hospitalized patients encounter medication errors. **11**

Medication related errors could increase U.S. hospital costs by $2,000,000,000 (2 billion dollars). **12**

Benefits of Properly Labeling All Solutions and Medications

3

- Reduce the possibility of wrong medication administration.
- Improve communication between the entire O.R. team.
- Reduce the risk of litigation from adverse medication events.
- Improve patient safety.

Footnotes

1;2 JCAHO 2004 Standards. **3** AORN Guidance Statement: Safe Medication Practices in Perioperative Practice Settings. **4; 5** Medicare Conditions of Participation for Hospitals, CFR 482. **6** JCAHO Sentinel Events Statistics, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 6/24/03. **7** JCAHO Sentinel Events Statistics, (JCAHO) 9/02. **8** Medication Error Reporting: A Key Component to Improving Quality and Promoting Patient Safety American Society for Healthcare Risk Management (ASHRM) Annual Conference November 4, 2003. **9** Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. The Journal of the American Medical Association (JAMA) 1997; 277(4):301-6. **10** Texas Board of Nurse Examiners March 2001. **11** Leape LL (1994): Error in medicine. JAMA 272: 1851-1857 Lesar TS, (1997): Factors related to errors in medication prescribing. JAMA 277: 312-317. **12** To Err is Human, Building a Safer Health System, November 1999, Institute of Medicine.

Cost Analysis of Expenses Resulting From Medication Errors

Period Covered _____ to _____

Department Covered ☐ O.R. ☐ Other ☐ Facility-wide

Source of Information _____

# of Claims Reviewed _____

	Costs	Total Cost
1	Treatment	$
2	Diagnostic Testing Required	$
3	Drug Costs in Treating Patient	$
4	Increase in Hospital Stay	$
5	Staff Time in Performing Root Cause Analysis	$
6	Increase in Facility's Insurance Premium	$
7	Increase in Liability Reserves	$
8	Attorney Fees	$
9	Cost of Settlement	$
10	Other:	$
11		$
12		$
13		$
	Total Cost For The Period	$
	Cost of SMI product(s) to reduce/solve problem ($2.00-$4.00 per surgical procedure)	$
	Potential cost savings per year	$

Nurse inspired innovative product(s) to solve this issue are available from Sandel Medical Industries, LLC.

Correct Medication Labeling System™ Sandel Safety Marker™, SMI Medication Labels, Med Cup Flags, SMI Syringe Labels, SMI "No Spill" Med Cups

Prepared by _____

Title _____ **Date** _____

Make safety a line item in your budget.

Associated Websites

www.jcaho.org
Joint Commission on Accreditation of Healthcare Organizations

www.cms.hhs.gov/regulations
Centers for Medicare and Medicaid Services (regulations)

www.aorn.org
Association of Perioperative Registered Nurses

www.iom.org
Institute of Medicine

www.ashrm.gov
American Society for Healthcare Risk Managers

http://jama.ama-assn.org
The Journal of the American Medical Association

Partial List of Facilities Using Our Products

Kaiser Foundation Hospital South San Francisco, CA
Lutheran General Hospital Chicago, IL
St. Elizabeth Medical Center Edgewood, KY
LSU Medical Center-University Hospital Shreveport, LA
Boston Medical Center Boston, MA
Massachusetts General Hospital Boston, MA

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