CHAPTER 8

Hospital Accreditation
HOSPITAL PHARMACY OVERVIEW

“Consultant of Record” for the permit is responsible for all medication use in the facility.

Director of Pharmacy – usual hospital title for pharmacist in charge.

Depending on organization complexity and size daily activities include pharmacist and administrative responsibilities.

Major Influences

1. Regulatory Authority

   a. State of Florida

      i. Florida Department of Health, Division of Medical Quality Assurance, Board of Pharmacy (FS chapter 465 and 893; FAC 64B-16)
      ii. Florida Agency for Health Care Administration (AHCA) - created by Chapter 20, Florida Statutes as the chief health policy and planning entity for the state, administers Medicaid program, regulates hospital practice. The hospital must be inspected for compliance with the Conditions of Participation as directed by the Centers for Medicare and Medicaid Services.
      iii. Drugs, devices and cosmetics program (Florida’s FDA) moves from Department of Health to the Division of Business & Professional Regulation (64F-12 to 61N-1)
      iv. Annual inspection
         1. Pharmacy permit inspection; every other year inspection with good history of inspections
         2. Wholesale license inspection (FS chapter 499 and drugs, devices and cosmetics rules 61N-1)
         3. Hospital permit inspection
      v. PRN complaint investigation (founded or unfounded)

   b. Federal

      i. Drug Enforcement Agency (DEA)
      ii. Environmental Protection Agency (EPA, State’s FDEP)
         1. www.dep.state.fl.us
         2. List of hazardous pharmaceuticals
         3. Universal Pharmaceutical Waste regulations
         4. Pharmaceutical waste guidance
         5. RCRA 101 compliance assistance
iii. OSHA – occupational safety  www.osha.gov

2. Standards of Practice

a. The Joint Commission  www.jointcommission.org
   i. Minimum standards
   ii. Sentinel event notices
      1. First published in 1998 due to fatal errors involving intravenous administration of concentrated potassium chloride
      2. Recent medication-related notices include risks associated with misuse of injectable vials, use of opioid analgesics in hospitals, and anticoagulation error prevention
   iii. National Patient Safety Goals
   iv. Perspectives Newsletter
   v. FAQ (frequently asked questions) and Standards Interpretation

b. American Society of Health-System Pharmacists  www.ashp.org
   i. Best Practices
   ii. Not surveyed unless accredited residency or technician training programs
   iii. Newslink subscription for members – weekly updates
   iv. Policy Positions, Practice Statements and Guidelines

   i. Best Practices
   ii. Subscription bi-weekly “Medication Safety Alerts”
   iii. Self-assessment tools (e.g. implementation of automated dispensing cabinets)
   iv. Consultant surveys
HOSPITAL ACCREDITATION

Hospitals must be accredited by the Department of Health and Human Services (DHHS) to participate in and receive payment through Medicare and Medicaid Programs (CMS).

Accrediting organization applies to CMS for “Deemed Status”

More than one choice:

1. Hospital Accreditation Program, The Joint Commission
3. Healthcare Facilities Accreditation Program by the American Osteopathic Association
4. Center for Improvement in Healthcare Quality (CIHQ)

History of The Joint Commission

1917 American College of Surgeons formed a voluntary accreditation process
1951 Joint Commission on Accreditation of Healthcare Organizations (JCAHO) formed by name as a voluntary accreditation body
2007 Name change from JCAHO to The Joint Commission

CMS validates Joint Commission surveys by conducting their own survey on a random number of hospitals (so accredited Hospitals may still have a federal survey).

(Deemed status options are available for Joint Commission accredited Ambulatory Surgery Centers, Home Health Agencies, Hospice organizations, Critical Access Hospitals, Acute Care Hospitals, Clinical Laboratories and Medicare + Choice HMOs and PPOs – NOT NURSING HOMES)

THE JOINT COMMISSION General Survey Categories – MAY HAVE ONE OR MORE SURVEY DEPENDING ON COMPLEXITY OF THE HOSPITAL

- Hospitals
- Ambulatory Care
- Assisted Living
- Behavioral Health Care
- Health Care Networks
- Home Health Care
- Long Term Care
- Office Based Surgery
- Pathology and Clinical Laboratory Services
- Preferred Provider Organizations
- Critical Access Hospitals
Organization of the Hospital Standards - CHAPTER TITLES (Standard Prefix)

- Medication Management (MM)
- Performance Improvement (PI)
- Leadership (LD)
- Environment of Care (EC)
- Human Resources (HR)
- Information Management (IM)
- Infection Prevention and Control (IC)
- Medical Staff (MS)
- Nursing (NR)
- Rights and Responsibilities of the Individual (RI)
- Provision of Care (PC)
- Record of Care (RC)
- Emergency Management (EM)
- Life Safety (LS)
- Transplant Safety (TS)
- Waived Testing (WT)

Medication definition includes:

- Rx only (legend drugs)
- Vitamins
- Respiratory treatments
- OTC
- Neutraceuticals
- TPN
- Samples
- Vaccines
- Blood derivatives
- Herbal remedies
- Radiopharmaceuticals
- IV solutions

Medication does NOT include: enteral nutrition, oxygen or other medical gasses.

Standard format

- Numbering (such as MM.01.01)
- Standard (description of the required performance)
- Rationale for standard (background and expectations)
- Elements of performance (compliance required)

Survey process and scoring

- Self assessment required: Focused Standard Assessment (FSA) – “R” Standards (MM=16)
- Scoring is “full”, “partial”, or “non-compliant”
- Complex organizations have one survey conducted and receive one report

Must be in compliance with the standards to obtain and maintain The JOINT COMMISSION Accreditation
Medication Management Standards

Six critical processes:

- Selection and procurement
- Preparing and dispensing
- Storage
- Administration
- Ordering and transcribing
- Monitoring

The Joint Commission does NOT dictate how or by what system drugs are distributed in the hospital.

Standard: MM.01.01.01 The hospital plans its medication management processes.

EP1 The organization has a written policy that describes that the following information about the patient is accessible to licensed independent practitioners and staff who participate in the management of the patient’s medications: Age, Sex, Diagnoses, Allergies, Sensitivities, Current medications, Height and weight (when necessary), Pregnancy and lactation information (when necessary), Laboratory results (when necessary). Any additional information required by the organization

EP2 The hospital implements its policy to make information about the patient accessible to licensed independent practitioners and staff who participate in the management of the patient’s medications.

Note 1: This element of performance does not apply in emergency situations.

Standard: MM.01.01.03 The hospital safely manages high-alert and hazardous medications.

EP1 The hospital identifies, in writing, its high-alert and hazardous medications.

Footnote *: For a list of high-alert medications, see http://www.ismp.org. For a list of hazardous medications, see http://www.cdc.gov/niosh/docs/2012-150/.

EP2 The hospital has a process for managing high-alert and hazardous medications.

EP3 The hospital implements its process for managing high-alert and hazardous medications.

EP5 For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital reports abuses and losses of controlled substances, in accordance with law and regulation, to the individual responsible for the pharmacy department or service and, as appropriate, to the chief executive.

Standard: MM.01.02.01 The hospital addresses the safe use of look-alike/sound-alike medications.

EP1 The hospital develops a list of look-alike/sound-alike medications it stores, dispenses, or administers.


EP2 The hospital takes action to prevent errors involving the interchange of the medications on its list of look-alike/sound-alike medications.

EP3 The hospital annually reviews and, as necessary, revises its list of look-alike/sound-alike medications.

Note: This element of performance is also applicable to sample medications.
Standard: MM.02.01.01 The hospital selects and procures medications.

EP1 Members of the medical staff, licensed independent practitioners, pharmacists, and staff involved in ordering, dispensing, administering, and/or monitoring the effects of medications develop written criteria for determining which medications are available for dispensing or administering to patients.

EP2 The hospital develops and approves criteria for selecting medications, which, at a minimum, include the following: indications for use, effectiveness, drug interactions, potential for errors and abuse, adverse drug events, sentinel event advisories, population(s) served (for example, pediatrics, geriatrics), other risks, costs.

EP3 Before using a medication new to the hospital, the hospital determines a method to monitor the response of the patient.

EP4 The hospital maintains a formulary, including medication strength and dosage.

EP5 The hospital makes its formulary readily available to those involved in medication management.

EP6 The hospital standardizes and limits the number of drug concentrations available to meet patient care needs.

EP7 The hospital has a process to select, approve, and procure medications that are not on its formulary.

EP8 The hospital implements the process to select, approve, and procure medications that are not on its formulary.

EP9 Medications designated as available for dispensing or administration are reviewed at least annually based on emerging safety and efficacy information.

EP10 The hospital has a process to communicate medication shortages and outages to licensed independent practitioners and staff who participate in medication management.

EP11 The hospital implements its process to communicate medication shortages and outages to licensed independent practitioners and staff who participate in medication management.

EP12 The hospital develops and approves written medication substitution protocols to be used in the event of a medication shortage or outage.

EP13 The hospital implements its approved medication substitution protocols.

EP14 The hospital has a process to communicate to licensed independent practitioners and staff who participate in medication management about the medication substitution protocols for shortages or outages.

EP15 The hospital implements its process to communicate to licensed independent practitioners and staff who participate in medication management about the medication substitution protocols for shortages and outages.

Standard: MM.03.01.01 The hospital safely stores medications.

EP2 The hospital stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.

Note: This element of performance is also applicable to sample medications.

EP3 The hospital stores all medications and biologicals, including controlled (scheduled) medications, in a secured area to prevent diversion, and locked when necessary, in accordance with law and regulation.


EP4 The hospital has a written policy addressing the control of medication between receipt by an individual health care provider and administration of the medication, including safe storage, handling, security, disposition, and return to storage.

EP5 The hospital implements its policy addressing the control of medication between receipt by an individual health care provider and its administration.
EP6 The hospital prevents unauthorized individuals from obtaining medications in accordance with its policy and law and regulation.
EP7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.
EP8 The hospital removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration.
EP9 The hospital keeps concentrated electrolytes present in patient care areas only when patient safety necessitates their immediate use, and precautions are used to prevent inadvertent administration.
EP10 Medications in patient care areas are available in the most ready-to-administer forms commercially available or, if feasible, in unit doses that have been repackaged by the pharmacy or a licensed repacker.
EP18 The hospital periodically inspects all medication storage areas.
EP19 For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital has a pharmacy directed by a registered pharmacist or a supervised drug storage area, in accordance with law and regulation.
EP24 For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital maintains records of the receipt and disposition of radiopharmaceuticals.

**Standard: MM.03.01.03** The hospital safely manages emergency medications.

EP1 Hospital leaders, in conjunction with members of the medical staff and licensed independent practitioners, decide which emergency medications and their associated supplies will be readily accessible in patient care areas based on the population served.
EP2 Emergency medications and their associated supplies are readily accessible in patient care areas.
EP3 Whenever possible, emergency medications are available in unit-dose, age-specific, and ready-to-administer forms.
EP6 When emergency medications or supplies are used, the hospital replaces them as soon as possible to maintain a full stock.

**Standard: MM.03.01.05** The hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners.

EP1 The hospital defines when medications brought into the hospital by patients, their families, or licensed independent practitioners can be administered.
EP2 Before use or administration of a medication brought into the hospital by a patient, his or her family, or a licensed independent practitioner, the hospital identifies the medication and visually evaluates the medication’s integrity.
EP3 The hospital informs the prescriber and patient if the medications brought into the hospital by patients, their families, or licensed independent practitioners are not permitted.

**Standard: MM.04.01.01** Medication orders are clear and accurate.

EP1 The hospital has a written policy that identifies the specific types of medication orders that it deems acceptable for use.
Note: There are several different types of medication orders. Medication orders commonly used include the following: as needed (PRN) orders, standing orders, automatic stop orders, titrating orders, taper orders, range orders, orders for compounded drugs or drug mixtures not commercially available, orders for medication-related devices (for example, nebulizers, catheters), orders for investigational medication, orders
for herbal products, orders for medications at discharge or transfer.
EP2 The hospital has a written policy that defines the following: The required elements of a complete medication order.
EP3 The hospital has a written policy that defines the following: When indication for use is required on a medication order.
EP4 The hospital has a written policy that defines the following: The precautions for ordering medications with look-alike or sound-alike names.
EP5 The hospital has a written policy that defines the following: Actions to take when medication orders are incomplete, illegible, or unclear.
EP6 The hospital minimizes the use of verbal and telephone medication orders.
EP7 The hospital reviews and updates preprinted order sheets, within time frames it identifies or sooner if necessary, based on current evidence and practice.
EP8 The hospital prohibits summary (blanket) orders to resume previous medications.
EP9 A diagnosis, condition, or indication for use exists for each medication ordered.
Note: This information can be anywhere in the medical record and need not be on the order itself. For example, it might be part of the medical history.
EP10 The hospital defines, in writing, the circumstances for which weight-based dosing is required for pediatric populations.
EP13 The hospital implements its policies for medication orders.
EP14 The hospital requires an order from a doctor of medicine or osteopathy or, as permitted by law and regulation, a hospital-specific protocol(s) approved by a doctor of medicine or osteopathy to administer influenza and pneumococcal vaccines.
EP15 For hospitals that use Joint Commission accreditation for deemed status purposes: Processes for the use of preprinted and electronic standing orders, order sets, and protocols for medication orders include the following:
- Review and approval of standing orders and protocols by the medical staff and the hospital’s nursing and pharmacy leadership
- Evaluation of established standing orders and protocols for consistency with nationally recognized and evidence-based guidelines
- Regular review of such standing orders and protocols by the medical staff and the hospital’s nursing and pharmacy leadership to determine the continuing usefulness and safety of the standing orders and protocols
- Dating, timing, and authenticating of standing orders and protocols by the ordering practitioner or another practitioner responsible for the patient’s care in accordance with professional standards of practice; law and regulation; hospital policies; and medical staff bylaws, rules, and regulations.

<table>
<thead>
<tr>
<th>DO NOT USE Abbreviation</th>
<th>Potential problem</th>
<th>Preferred term</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 IU (for unit)</td>
<td>Mistaken as zero, four or cc</td>
<td>Write “unit”</td>
</tr>
<tr>
<td>2 Q.D., Q.O.D., QD, qd, QOD, god</td>
<td>Mistaken for each other. The period can be mistaken for “i” &amp; “O” for “I”</td>
<td>Write “daily” and “every other day”</td>
</tr>
<tr>
<td>3 Trailing zero (X.0 mg) &amp; lack of leading zero (.X mg)</td>
<td>Decimal point is displaced</td>
<td>Never write zero by itself after a decimal point (X mg) and always use a zero before a decimal point (0.X mg)</td>
</tr>
<tr>
<td>4 MS, MSO₄, MgSO₄</td>
<td>Confused for each other</td>
<td>Write “morphine sulfate” or “magnesium sulfate”</td>
</tr>
</tbody>
</table>
**Standard: MM.05.01.01** A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital.

**EP1** Before dispensing or removing medications from floor stock or from an automated storage and distribution device, a pharmacist reviews all medication orders or prescriptions unless a licensed independent practitioner controls the ordering, preparation, and administration of the medication or when a delay would harm the patient in an urgent situation (including sudden changes in a patient’s clinical status), in accordance with law and regulation.

EP2 When an on-site pharmacy is not open 24 hours a day, 7 days a week, a health care professional determined to be qualified by the hospital reviews the medication order in the pharmacist’s absence.

EP3 When an on-site pharmacy is not open 24 hours a day, 7 days a week, a pharmacist conducts a retrospective review of all medication orders during this period as soon as a pharmacist is available or the pharmacy opens.

EP4 All medication orders are reviewed for the following: Patient allergies or potential sensitivities.

**EP5** All medication orders are reviewed for the following: Existing or potential interactions between the medication ordered and food and medications the patient is currently taking.

**EP6** All medication orders are reviewed for the following: The appropriateness of the medication, dose, frequency, and route of administration.

**EP7** All medication orders are reviewed for the following: Current or potential impact as indicated by laboratory values.

EP8 All medication orders are reviewed for the following: Therapeutic duplication.

EP9 All medication orders are reviewed for the following: Other contraindications.

EP11 After the medication order has been reviewed, all concerns, issues, or questions are clarified with the individual prescriber before dispensing.

**Standard: MM.05.01.07** The hospital safely prepares medications.

**EP1** A pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product’s stability is short.

EP2 Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.

EP3 During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity.

EP4 The hospital uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.

EP5 For hospitals that use Joint Commission accreditation for deemed status purposes: Medications are prepared and administered in accordance with the orders of a licensed independent practitioner or other practitioner responsible for the patient’s care, and in accordance with hospital policies; medical staff bylaws, rules, and regulations; and law and regulation.

EP6 For hospitals that use Joint Commission accreditation for deemed status purposes: In-house preparation of radiopharmaceuticals is done by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathy.
Standard: **MM.05.01.09** Medications are labeled.

EP1 Medication containers are labeled whenever medications are prepared but not immediately administered.

Note 1: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.

EP2 Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.

EP3 All medications prepared in the hospital are correctly labeled with the following: Medication name, strength, and amount (if not apparent from the container).

EP4 All medications prepared in the hospital are correctly labeled with the following: Expiration date when not used within 24 hours.

EP5 All medications prepared in the hospital are correctly labeled with the following: Expiration time when expiration occurs in less than 24 hours.

EP6 All medications prepared in the hospital are correctly labeled with the following: The date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.

EP7 When preparing individualized medications for multiple patients, the label also includes the following: The patient's name.

EP8 When preparing individualized medications for multiple patients, the label also includes the following: The location where the medication is to be delivered. Note: The location is not to be used as a patient identifier during administration of a medication.

EP9 When preparing individualized medications for multiple patients, the label also includes the following: Directions for use and applicable accessory and cautionary instructions.

EP10 When an individualized medication(s) is prepared by someone other than the person administering the medication, the label includes the following: The patient's name.

EP11 When an individualized medication(s) is prepared by someone other than the person administering the medication, the label includes the following: The location where the medication is to be delivered. Note: The location is not to be used as a patient identifier during administration of a medication.

EP12 When an individualized medication(s) is prepared by someone other than the person administering the medication, the label includes the following: Directions for use and applicable accessory and cautionary instructions.

Standard: **MM.05.01.11** The hospital safely dispenses medications.

EP1 The hospital dispenses quantities of medications that are consistent with patient needs.

EP2 The hospital dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice.

EP3 The hospital dispenses medications within time frames it defines to meet patient needs.

EP4 Medications are dispensed in the most ready-to-administer forms commercially available and, if feasible, in unit doses that have been repackaged by the pharmacy or licensed repackager.

Standard: **MM.05.01.13** The hospital safely obtains medications when the pharmacy is closed.

EP1 The hospital has a process for providing medications to meet patient needs when the pharmacy is closed.

EP2 When non-pharmacist health care professionals are allowed by law or regulation to obtain medications after the pharmacy is closed, the following occurs: Medications available are limited to those approved by
the hospital.
EP3 When non-pharmacist health care professionals are allowed by law or regulation to obtain medications after the pharmacy is closed, the following occurs: The hospital stores and secures the medications approved for use outside of the pharmacy.
EP4 When non-pharmacist health care professionals are allowed by law or regulation to obtain medications after the pharmacy is closed, the following occurs: Only trained, designated prescribers and nurses are permitted access to approved medications.
EP5 When non-pharmacist health care professionals are allowed by law or regulation to obtain medications after the pharmacy is closed, the following occurs: Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system such as bar coding) are in place to prevent medication retrieval errors.
EP6 When non-pharmacist health care professionals are allowed by law or regulation to obtain medications after the pharmacy is closed, the following occurs: The hospital arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provide medications beyond those accessible to non-pharmacy staff.
EP7 The hospital implements its process for providing medications to meet patient needs when the pharmacy is closed.

**Standard: MM.05.01.17** The hospital follows a process to retrieve recalled or discontinued medications.

EP1 The hospital has a written policy describing how it will retrieve and handle medications within the hospital that are recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA).
EP2 The hospital implements its policy on retrieving and handling medications when they are recalled or discontinued for safety reasons.
EP3 When a medication is recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA), the hospital notifies the prescribers and those who dispense or administer the medication.
EP4 When required by law and regulation or hospital policy, the hospital informs patients that their medication has been recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA).

**Standard: MM.05.01.19** The hospital safely manages returned medications.

EP1 The hospital determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the hospital.
EP2 When the hospital accepts unused, expired, or returned medications, it has a process for returning medications to the pharmacy’s control that includes procedures for preventing diversion.
Note: This element of performance is also applicable to sample medications.
EP3 The hospital determines if and when outside sources are used for destruction of medications.
Note: This element of performance is also applicable to sample medications.
EP4 The hospital implements its process for managing unused, expired, or returned medications.
**Standard: MM.06.01.01** The hospital safely administers medications.

EP1 The hospital defines, in writing, licensed independent practitioners and the clinical staff disciplines that are authorized to administer medication, with or without supervision, in accordance with law and regulation.
EP2 Only authorized licensed independent practitioners and clinical staff administer medications.
Note: This does not prohibit self-administration of medications by patients, when indicated.
EP3 Before administration, the individual administering the medication does the following: Verifies that the medication selected matches the medication order and product label.
EP4 Before administration, the individual administering the medication does the following: Visually inspect the medication for particulates, discoloration, or other loss of integrity.
EP5 Before administration, the individual administering the medication does the following: Verifies that the medication has not expired.
EP6 Before administration, the individual administering the medication does the following: Verifies that no contraindications exist.
EP7 Before administration, the individual administering the medication does the following: Verifies that the medication is being administered at the proper time, in the prescribed dose, and by the correct route.
EP8 Before administration, the individual administering the medication does the following: Discusses any unresolved concerns about the medication with the patient’s licensed independent practitioner, prescriber (if different from the licensed independent practitioner), and/or staff involved with the patient’s care, treatment, and services.
EP9 Before administering a new medication, the patient or family is informed about any potential clinically significant adverse drug reactions or other concerns regarding administration of a new medication.

**Standard: MM.06.01.03** Self-administered medications are administered safely and accurately.
Note: The term self-administered medication(s) may refer to medications administered by a family member.

EP1 If self-administration of medications is allowed, written processes that address training, supervision, and documentation guide the safe and accurate self-administration of medications or the administration of medications by a family member.
EP2 The hospital implements its written processes for medication self-administration or medication administration.
EP3 The hospital educates patients and families involved in self-administration about the following: Medication name, type, and reason for use.
EP4 The hospital educates patients and families involved in self-administration about the following: How to administer medication, including process, time, frequency, route, and dose.
EP5 The hospital educates patients and families involved in self-administration about the following: Anticipated actions and potential side effects of the medication administered.
EP6 The hospital educates patients and families involved in self-administration about the following: Monitoring the effects of the medication.
EP7 The hospital determines that the patient or the family member who administers the medication is competent at medication administration before allowing him or her to administer medications.
**Standard: MM.06.01.05** The hospital safely manages investigational medications.

EP1 The hospital has a written process addressing the use of investigational medications that includes review, approval, supervision, and monitoring.

EP2 The hospital's written process for the use of investigational medications specifies that the pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications.

EP3 The written process for the use of investigational medications specifies that when a patient is involved in an investigational protocol that is independent of the hospital, the hospital evaluates and, if no contraindication exists, accommodates the patient’s continued participation in the protocol.

EP4 The hospital implements its processes for the use of investigational medications.

**Standard: MM.07.01.03** The hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

EP1 The hospital has a written process to respond to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

EP2 The hospital has a written process addressing prescriber notification in the event of an adverse drug event, significant adverse drug reaction, or medication error.

EP3 The hospital complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

EP5 The hospital implements its process for responding to adverse drug events, significant adverse drug reactions, and medication errors.

EP6 For hospitals that use Joint Commission accreditation for deemed status purposes: Medication administration errors, adverse drug reactions, and medication incompatibilities as defined by the hospital are immediately reported to the attending physician or clinical psychologist and as appropriate to the organization wide quality assessment and performance improvement program.

**Standard: MM.08.01.01** The hospital evaluates the effectiveness of its medication management system.

EP1 The hospital collects data on the performance of its medication management system.

EP2 The hospital analyzes data on its medication management system.

Note: This element of performance is also applicable to sample medications.

EP3 The hospital compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management system.

Note: This element of performance is also applicable to sample medications.

EP4 The hospital reviews the literature and other external sources for new technologies and best practices.

EP5 Based on analysis of its data, as well as review of the literature for new technologies and best practices, the hospital identifies opportunities for improvement in its medication management system.

EP6 The hospital takes action on improvement opportunities identified as priorities for its medication management system.

Note: This element of performance is also applicable to sample medications.

EP7 The hospital evaluates its actions to confirm that they resulted in improvements for its medication management system.

EP8 The hospital takes additional action when planned improvements for its medication management processes are either not achieved or not sustained.
NATIONAL PATIENT SAFETY GOALS (NPSG)

NPSG.03.04.01 Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.
Note: Medication containers include syringes, medicine cups, and basins.

EP1 In perioperative and other procedural settings both on and off the sterile field, label medications and solutions that are not immediately administered. This applies even if there is only one medication being used.
Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.
EP2 In perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container.
EP3 In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following:
- Medication or solution name
- Strength
- Amount of medication or solution containing medication (if not apparent from the container)
- Diluent name and volume (if not apparent from the container)
- Expiration date when not used within 24 hours
- Expiration time when expiration occurs in less than 24 hours
Note: The date and time are not necessary for short procedures, as defined by the hospital.
EP4 Verify all medication or solution labels both verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it.
EP5 Label each medication or solution as soon as it is prepared, unless it is immediately administered.
Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.
EP6 Immediately discard any medication or solution found unlabeled.
EP7 Remove all labeled containers on the sterile field and discard their contents at the conclusion of the procedure.
Note: This does not apply to multiuse vials that are handled according to infection control practices.
EP8 All medications and solutions both on and off the sterile field and their labels are reviewed by entering and exiting staff responsible for the management of medications.
NPSG.03.05.01 Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

Note: This requirement applies only to hospitals that provide anticoagulant therapy and/or long-term anticoagulation prophylaxis (for example, atrial fibrillation) where the clinical expectation is that the patient’s laboratory values for coagulation will remain outside normal values. This requirement does not apply to routine situations in which short-term prophylactic anticoagulation is used for venous thrombo-embolism prevention (for example, related to procedures or hospitalization) and the clinical expectation is that the patient’s laboratory values for coagulation will remain within, or close to, normal values.

EP1 Use only oral unit-dose products, prefilled syringes, or premixed infusion bags when these types of products are available.

Note: For pediatric patients, prefilled syringe products should be used only if specifically designed for children.

EP2 Use approved protocols for the initiation and maintenance of anticoagulant therapy.

EP3 Before starting a patient on warfarin, assess the patient’s baseline coagulation status; for all patients receiving warfarin therapy, use a current International Normalized Ratio (INR) to adjust this therapy. The baseline status and current INR are documented in the medical record.

Note: The patient’s baseline coagulation status can be assessed in a number of ways, including through a laboratory test or by identifying risk factors such as age, weight, bleeding tendency, and genetic factors.

EP4 Use authoritative resources to manage potential food and drug interactions for patients receiving warfarin.

EP5 When heparin is administered intravenously and continuously, use programmable pumps in order to provide consistent and accurate dosing.

EP6 A written policy addresses baseline and ongoing laboratory tests that are required for anticoagulants.

EP7 Provide education regarding anticoagulant therapy to prescribers, staff, patients, and families.

Patient/family education includes the following:
- The importance of follow-up monitoring
- Compliance
- Drug-food interactions
- The potential for adverse drug reactions and interactions

EP8 Evaluate anticoagulation safety practices, take action to improve practices, and measure the effectiveness of those actions in a time frame determined by the organization.
NPSG.03.06.01 Maintain and communicate accurate patient medication information.

EP1 Obtain information on the medications the patient is currently taking when he or she is admitted to the hospital or is seen in an outpatient setting. This information is documented in a list or other format that is useful to those who manage medications.

Note 1: Current medications include those taken at scheduled times and those taken on an as-needed basis. See the Glossary for a definition of medications.

Note 2: It is often difficult to obtain complete information on current medications from a patient. A good faith effort to obtain this information from the patient and/or other sources will be considered as meeting the intent of the EP.

EP2 Define the types of medication information to be collected in non–24-hour settings and different patient circumstances.

Note 1: Examples of non–24-hour settings include the emergency department, primary care, outpatient radiology, ambulatory surgery, and diagnostic settings.

Note 2: Examples of medication information that may be collected include name, dose, route, frequency, and purpose.

EP3 Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies.

Note: Discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the hospital, does the comparison. (See also HR.01.06.01, EP 1)

EP4 Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose).

Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.

EP5 Explain the importance of managing medication information to the patient when he or she is discharged from the hospital or at the end of an outpatient encounter.

Note: Examples include instructing the patient to give a list to his or her primary care physician; to update the information when medications are discontinued, doses are changed, or new medications (including over-the-counter products) are added; and to carry medication information at all times in the event of emergency situations. (For information on patient education on medications, refer to Standards MM.06.01.03, PC.02.03.01, and PC.04.01.05.)
### Standards Manual Content

#### Accreditation Requirements

- Accreditation Participation Requirements (APR)
- Environment of Care (EC)
- Emergency Management (EM)
- Human Resources (HR)
- Infection Prevention and Control (IC)
- Information Management (IM)
- Leadership (LD)
- Life Safety (LS)
- Medication Management (MM)
- Medical Staff (MS)
- National Patient Safety Goals (NPSG)
- Nursing (NR)
- Provision of Care, Treatment, and Services (PC)
- Performance Improvement (PI)
- Record of Care, Treatment, and Services (RTS)

#### Accreditation

- January 1, 2015
- August 25, 2014
- July 2, 2014

#### View By:

- All Standards

#### Filters Applied:

- Organization Profile

#### Chapter Overview

- Score Only
- Ep Attributes
- Both

#### Cross Program Scoring

#### ID Elements of Performance (EPs)

- **1**
  - The hospital identifies, in writing, its high-alert and hazardous medications. *(See also EC.02.02.01, EF 8)*
  - Note: This element of performance is also applicable to sample medications.
  - Footnote: *For a list of high-alert medications, see [http://www.fda.gov](http://www.fda.gov). For a list of hazardous medications, see [http://www.cdc.gov/niosh/docs/2012-150/](http://www.cdc.gov/niosh/docs/2012-150/).

#### Final Score Date: 05/29/2013

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