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

   - FL Department of Health (Division of Medical Quality Assurance: Board of Pharmacy)
   - Agency for Health Care Administration (“ak-ah”) - created by Chapter 20, Florida Statutes as the chief health policy and planning entity for the state, administers Medicaid program, regulates hospital practice
   - “Hospitals must maintain current state licensure, but may choose to be Medicare certified and may chose to be accredited by The Joint Commission, American Osteopathic Association's Healthcare Facilities Accreditation Program or Det Norske Veritas. Accredited hospitals meeting Chapter 59A-3.253(3), Florida Administrative Code may be "deemed" to be in compliance with the licensure and certification requirements. Deemed hospitals are not scheduled for routine on-site licensure surveys. All hospitals are subject to periodic Life-Safety Code inspections.”
   - Drugs, devices and cosmetics program (Florida’s FDA) moves from Department of Health 10-1-10 to the Division of Business & Professional Regulation

   - Annual Inspection
     - Pharmacy permit inspection (FS chapter 465 and pharmacy rules 64B-16)
     - Wholesale license inspection (FS chapter 499 and drugs, devices and cosmetics rules 64F-12)
     - Hospital permit inspection
     - PRN complaint investigation (determines if founded or unfounded)

   b. Federal
      - Drug Enforcement Agency (DEA)
      - Environmental Protection Agency (EPA, State’s FDEP)
        - www.dep.state.fl.us
        - List of hazardous pharmaceuticals
        - Universal Pharmaceutical Waste regulations
2. Standards of Practice
   a. The Joint Commission – survey www.jointcommission.org
      • Standards
      • Sentinel event notices
      • National Patient Safety Goals
      • Perspectives Newsletter
      • FAQ (frequently asked questions) and Standards Interpretation
   b. American Society of Health-System Pharmacists www.ashp.org
      • Not surveyed unless accredited residency or technician training programs
      • Newslink subscription for members – weekly updates
      • Policy Positions, Practice Statements and Guidelines
HOSPITAL ACCREDITATION

WHY?

Medicare & Medicaid Payment – DEEMED STATUS by CMS

WHO?

1. Hospital Accreditation Program, The Joint Commission
3. Healthcare Facilities Accreditation Program by the American Osteopathic Association

Accrediting organization applies to CMS for “Deemed Status”

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:**

<table>
<thead>
<tr>
<th>Rx only</th>
<th>Vitamins</th>
<th>respiratory treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC</td>
<td>neutraceuticals</td>
<td>TPN</td>
</tr>
<tr>
<td>Samples</td>
<td>Vaccines</td>
<td>blood derivatives</td>
</tr>
<tr>
<td>Herbal remedies</td>
<td>radioactive meds</td>
<td>IV solutions</td>
</tr>
</tbody>
</table>

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: Periodic Performance Review (PPR)
- No longer using 1-5 scores or type 1 versus supplemental – changed to “full”, “partial”, or “non-compliant”
- No longer using a summary grid scores or preliminary report
- Changes in accreditation decisions (described in survey chapter)
- Complex organizations have one survey conducted and receive one report

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8.5
Medication Management Standards

Six critical processes:

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

Standards (Do not need to memorize)

Patient-Specific Information
Standard MM 01.01.01 Patient-specific information is readily accessible to those involved in the medication management system.
- Policy describes the minimum amount of information about the patient that is to be available to those involved in medication management. At a minimum, the information includes the following:
  - The patient’s age, sex, current medications, diagnoses, co morbidities, and concurrently occurring conditions, relevant laboratory values, allergies and past sensitivities
  - As appropriate, also includes information regarding weight and height, pregnancy and lactation status, other information required by the organization

Standard MM 01.01.03 High Alert and Hazardous Medications
- Identify high alert and hazardous drugs
  - ISMP has list of high alert medications
  - Sound-alike and Look alike medications
  - Chemotherapy
  - Narrow therapeutic index drugs
- Controlled substance loss is reported to the Director of Pharmacy and Chief Executive Officer

Selection And Procurement
Standard MM 02.01.01 The organization selects and procures medications.

<FORMULARY PROCESS>
- Written criteria for addition/deletion to formulary written by medical staff and others
- Criteria include the indication for use, effectiveness, risks (including propensity for adverse drug events, medication errors, drug interactions, abuse potential, and sentinel events), and costs.
- Formulary of drugs and strengths available for dispensing/administration is maintained and readily available (excludes samples)
- Drug concentrations are standardized
- Before using a new medication, processes and mechanisms are established to monitor patient response.
- Review formulary at least annually based on emerging safety and efficacy information.
Processes exist to approve and procure medications that are not on the formulary.
Processes exist to address medication shortages and outages. Substitution protocols are approved.
Disaster planning including process to replenish medications required during response and recovery phases of an emergency.

**Storage**

**Standard MM 03.01.01** Medications are properly and safely stored throughout the organization according to manufacturer recommendations and pharmacist instructions.
- Appropriate storage for stability, security, outdates quarantined (refrigerator checks)
- Labeled with contents, expiration date and any warnings
- Medications that are easy to confuse (for example, sound-alike and look-alike drugs or reagents and chemicals that may be mistaken for medications) are segregated
- Controlled substances are locked
- Follow manufacturer recommendations for storage, and if none, follow pharmacists’ instructions
- Medication storage areas are periodically inspected
- Under competent supervision
- Concentrated electrolytes (including but not limited to KCl, KPhos, NaCl >0.9%) are present in patient care areas only when necessary and precautions are used to prevent errors
- Ready to administer form

**Policy to address storage of meds from time of receipt to time of administration**
- After removal from ADM, cart or floorstock
- After pick-up from tube system or pharmacy
- At minimum policy includes
  - safe storage
  - safe handling
  - security
  - disposition including return to approved med storage area no later than the end of the individual’s shift

- Unauthorized individuals do not have access to medication storage
  - L&D and critical care units – considered secure if entry/exit are limited access
  - OR suite – secure if active, otherwise non-mobile carts are locked and mobile carts are placed in a locked room
  - Bedside meds – only for patient self-administration & med security is addressed
  - Mobile carts must be locked in a secure area

**Standard MM 03.01.03** Emergency medications and/or supplies, if any, are consistently available, controlled, and secure in the organization’s patient care areas.
- Determined by hospital leadership and members of medical staff
- Replaced as soon as possible

**Standard MM 03.01.05** A process is established to safely manage medications brought into the organization by patients or their families.
Includes the disposition, under what circumstances they can be used (see MM 03.01.05 if allowing self-administration)

Expectation that RPh approves medications that will be used AFTER visual inspection to determine its integrity

Notify physician and patient if medications are not authorized for use

Open liquid medications (including eye drops) should not be used in the hospital

**Ordering And Transcribing**

**Standard MM 04.01.01** Medication orders are clear and accurate. Policy describes specific types of medication orders that are acceptable

- There is a documented diagnosis, condition, or indication-for-use for each medication ordered.
- Prohibit use of resume orders
- Minimizes the use of verbal and telephone orders
- Requiring a verification read back process by the person taking the TO/VO
- Verbal orders are authenticated
- Periodically reviews/updates preprinted order sheets
- Define when weight-based dosing for pediatrics is required
- Physician order or hospital specific protocol for administration of flu and pneumococcal vaccines

Written policies address the following:

- The required elements of a complete medication order (drug name, dose or strength, route, frequency or rate) & key information is not missing on orders
- List of unacceptable abbreviations & they are not found in the patient’s chart
- Requirement for indication for use on a medication order
- Special precautions for ordering drugs with look-alike or sound-alike names
- Actions to take when medication orders are incomplete, illegible, or unclear
- Requirements and acceptability of the following types of orders:
  - As needed (PRN) orders
  - Standing orders
  - Automatic stop orders
  - Titrating orders
  - Taper orders
  - Range orders
  - Compounded drugs or drug mixture orders not commercially available
  - Medication-related device orders (for example, nebulizers and catheters)
  - Investigational medications
  - Herbal products orders
  - Discharge medication orders
### Preparing And Dispensing

**Standard MM 05.01.01** A pharmacist reviews the appropriateness of medication orders.

- Before dispensing, removal from floor stock, or removal from an automated system
- Exceptions:
  1. A Licensed Independent Practitioner (LIP) controls the ordering, preparation, and administration of the medication
  2. Urgent situations when the resulting delay would harm the patient
- Review all prescriptions for the following:
  - The appropriateness of the drug, dose, frequency, and route of administration
  - Therapeutic duplication
  - Real or potential allergies or sensitivities
  - Real or potential interactions between the prescription and other medications, food, and laboratory values
  - Other contraindications
  - Variation from organizational criteria for use
  - Other relevant medication-related issues or concerns
- Concerns, issues or questions are clarified with prescriber before dispensing
- If the pharmacy is not open 24/7 – define who is authorized to review orders in the absence of the pharmacist

**Standard MM 05.01.07** Medications are prepared safely.

- Pharmacy prepares all sterile medications, IV solutions except in emergencies or short stability.
- Use aseptic technique, laminar air flow hood or class 100 environment if not used within 24 hours
- Visual inspection of final product
- Radiopharmaceuticals prepared in-house are under the supervision of a trained pharmacist or physician

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**DO NOT USE Abbreviation**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Potential problem</th>
<th>Preferred term</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 U (for unit)</td>
<td>Mistaken as zero, four or cc</td>
<td>Write “unit”</td>
</tr>
<tr>
<td>2 IU (for international unit)</td>
<td>Mistaken as IV or ten</td>
<td>Write “international unit”</td>
</tr>
<tr>
<td>3 Q.D., Q.O.D., QD, qd, QOD, qod</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>4 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>5 MS, MSO₄, MgSO₄</td>
<td>Confused for each other</td>
<td>Write “morphine sulfate” or “magnesium sulfate”</td>
</tr>
</tbody>
</table>

Potential future prohibited abbreviations: Drug names are not abbreviated

<table>
<thead>
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<tbody>
<tr>
<td>&lt; or &gt; “less than or greater than”</td>
<td>μg “microgram”</td>
</tr>
<tr>
<td>cc “milliliter”</td>
<td>@ “at”</td>
</tr>
</tbody>
</table>
**Standard MM 05.01.09** Medications are appropriately labeled.
- Medications prepared but are not administered immediately must be appropriately labeled. Includes medications used on and off sterile field.
- Minimum labeling is in a standardized format
  - Drug name, strength, and amount (if not apparent from the container)
  - Expiration/beyond use date when not used within 24 hours
  - Expiration/beyond use time when expiration occurs in less than 24 hours
  - Date prepared and the diluent
- Pharmacy prepared also include:
  - Patient name and location
  - Directions for use and any applicable cautionary (e.g., “requires refrigeration,” “for IM use only”)

**Standard MM 05.01.11** Medications are dispensed safely.
- Quantities minimize diversion yet meet the patient’s needs.
- Dispensing & record keeping adheres to law, regulation, and standards of practice
- Medications are dispensed in a timely manner
- Most ready-to-administer forms available or prepackaged in unit dose (check what is available from manufacturer)
- Consistent use of dose packaging system or adequate to training to affected individuals/patients
- Define time frames for dispensing such as NOW and STAT

**Standard MM 05.01.13** The organization has a system for safely providing medications to meet patient needs when the pharmacy is closed.
- Trained designated prescribers and nurses are permitted access to approved medications (NOT entire pharmacy)
- Second check or other control process is in place to prevent errors
- FL law “charge nurse” & removal of a single dose
- Mechanism for pharmacist review as soon as possible
- Remote order processing or on call staff

**Standard MM 05.01.17** Medications dispensed by the organization are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration for safety reasons.

**Standard MM 05.01.19** Medications returned to the pharmacy are appropriately managed.
- Circumstances they may be reused
- Destruction processes

**Administering**

**Standard MM 06.01.01** Medications are safely and accurately administered.
• Policies and procedures define who may administer medications including qualifications (can include by drug or route)
• Prescriber notification process of ADEs
• Prior to administration patient is correctly identified using 2 individual identifiers – CANNOT use Room Number
• Verify medication is correct based on the medication order and product label
• Visually examine medication for expiration date and integrity
• Verify no contraindications
• Verify right time, right dose, right route
• Informs patient of potential ADEs
• Contacts prescriber with any concerns

**Standard MM 06.01.03** Self-administered medications are safely and accurately administered.
• Defined in policy including training, supervision and documentation requirements, and describe any restrictions
• Physician must write order or define in medical staff approved protocols
• Training includes why the medication was ordered, how to administer the med including the frequency, time, route and dose, potential side effects and monitoring
• Determine that the person administering is *competent* before being allowed to administer medications.
• Document administration in the medical record
• Address drug security (e.g., locked bedside table)

**Standard MM 06.01.05** Investigational medications are safely controlled and administered.
• Written process for reviewing, approving, supervising, and monitoring
• Accommodate the patient’s continued participation in the protocol
• When pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling, and distribution

**Monitoring**
**Standard MM 07.01.01** The effects of medication(s) on patients are monitored.
• Includes response and actual/potential problems
• Includes patient’s own perceptions about side effects, and perceived efficacy
• Monitor the patient’s response to the first dose(s) of a medication new to a patient while he or she is under the direct care of the organization.

**Standard MM 07.01.03** Policy addresses prescriber notification and reporting to organization wide performance improvement program for adverse drug events, significant drug reaction, medication incompatibilities or medication error.

**Evaluation**
**Standard MM 08.01.01** The organization evaluates the effectiveness of its medication
management system.
- Evaluate for risk points and identify areas to improve safety.
- Evaluates the literature for possible implementation of new technologies or successful practices
- Review internally generated reports to identify trends or issues

NATIONAL PATIENT SAFETY GOALS

Goal
01.01.01 Use at least two patient identifiers when providing care, treatment or services
  - cannot be room number
  - administering meds or blood products
  - collecting specimens & blood samples, when performing treatment or procedures
  - label specimens & blood samples in presence of patient

03.04.01 Label all medications, medication containers (for example, syringes, medicine cups, basins), or other solutions on and off the sterile field.
  - Label one medication/solution at a time
  - Discard any unlabeled medications
  - Minimum labeling requirements
    a. Medication name
    b. Strength and quantity
    c. Diluent and volume (if not apparent from the container)
    d. Preparation date
    e. Expiration date if not used within 24 hours and expiration time if expires < 24 hours

03.05.01 Reduce the likelihood of patient harm associated with the use of anticoagulation therapy.
  - Use protocols
  - Assess iNR prior to starting Coumadin
  - Use programmable pumps for heparin drips
  - Define minimum laboratory monitoring for anticoagulation therapies
  - Provide patient education

Goal 7 Reduce the risk of health care-associated infections.
07.01.01 Comply with current World Health Organization (WHO) Hand Hygiene Guidelines or Centers for Disease Control and Prevention (CDC) hand hygiene guidelines.
07.03.01 Implement evidence based practices to prevent health care associated infections due to multiple drug-resistant organizations (MRSA, CDI, VRE)
07.04.01 Implement best practices or evidence based guidelines to prevent central
07.05.01 Implement best practices for preventing surgical site infections

Goal 8 Accurately and completely reconcile medications across the continuum of care

There is a process for comparing the patient’s current medications with those ordered for the patient while under the care of the organization.

08.01.01 A complete list of the patient’s medications is communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization. The complete list of medications is also provided to the patient on discharge from the facility.

08.02.01 When a patient is transferred, the complete and reconciled list of medications is communicated to the next provider or service and the communication is documented.

08.03.01 When the patient leaves the organization, a complete and reconciled list is communicated to the next provider of service and the communication is documented.

08.04.01 In settings where medications are used minimally, or prescribed for short duration, modified medication reconciliation processes are performed.