

Overview of the Hospital Systems Policies and Procedures: What You Need to Know

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Disclosure Statement

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Objectives

- At the completion of this activity, the participant will be able to:
- Outline hospital policies and procedures for writing medication orders, administration of vaccines, use of standard orders and physician approved protocols
 - Understand policy and procedures for medication use, storage and safety in the hospital
 - Outline policy for routine and emergency use of drugs, as well as after hours dispensing and drug shortage management
 - Describe the record keeping and reporting required for medication use in a hospital setting

Policies and Procedures- Hospitals

- Medication Orders
- Patient name, drug name, strength, dosage form, route of administration, dose (in milligrams, grams, etc., preferably), frequency, indication (PRN's), # of doses for certain drugs (e.g., antibiotics, steroids)
 - PRN's for similar drugs, e.g. pain medications must differentiate between ones used for mild, moderate, and severe pain.
 - Documentation of effect from PRN's

803 Medication Administration Curriculum Section 8 © 2011 <http://www.pharmacy.ufl.edu/continuingeducation/curriculum/>

Medication Orders

- A medication order is written directions provided by a prescribing practitioner for a specific medication to be administered to an individual.
- The prescribing practitioner may also give a medication order verbally to a licensed person such as a pharmacist or a nurse.

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Medication Orders

- Who can write medication orders?
- How verbal orders are handled (put in writing immediately) and read back to provider (documented)
- When verbal orders must be signed by provider (within 24 hrs.)
- How medication orders are handled during computer downtime
- List unapproved abbreviations

805 Medication Administration Curriculum Section 8, 2011. <https://www.pharmacy.ufl.edu/continuing-education/medication-administration/>



Top 3 Joint Commission Medication Order Problem Areas

- Failure to clarify unclear, illegible, and incomplete orders- What's still on paper?
- Consistency in interpreting range orders
- Titration orders (anticoagulation, ICU blood pressure infusions)

Manual 7, The Joint Commission Medication Management Update for 2018. https://www.jointcommission.org/assets/Downloads/2018_Medications_Manual_Update.pdf



Assessment Question

1. What has the Joint Commission identified as a problem area related to medication orders?
 - a. Range orders
 - b. Titration orders
 - c. Failure to clarify orders
 - d. All the above



Assessment Question

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Administration of Vaccines

- Health care providers who administer vaccines covered by the National Vaccine Injury Compensation Program (VICP) are required under the National Childhood Vaccine Injury Act to ensure that the permanent medical record of the recipient (or a permanent office log or file) indicates
 - Date of vaccine administration
 - Vaccine manufacturer
 - Vaccine lot number
 - Name, address, and title of the person administering the vaccine
- In addition, the provider is required to record the edition date of the VIS distributed and the date those materials were provided.
- Vaccine Adverse Event Reporting System (VAERS)



Centers for Disease Control and Prevention. <https://www.cdc.gov/vaccines/imz/downloads/nchv-vaccines.html>

Standard Orders

- Standard orders are a set of orders entered by a physician for every patient scheduled to receive a particular procedure or treatment, or to be admitted for a particular condition. Standardized order sets include, but are not limited to, "standing orders"

Article in Safe Medication Practices. <http://www.smp.org/standards/standard-orders.html>

Standard Orders

Well-designed **standard order sets**—both electronic and paper formats—have the potential to:

- Integrate and coordinate care by communicating best practices through multiple disciplines, levels of care, and services
- Modify practice through evidence-based care
- Reduce variation and unintentional oversight through standardized formatting and clear presentation of orders
- Enhance workflow with pertinent instructions that are easily understood, intuitively organized, and suitable for direct application to current information-management systems
- Reduce the potential for medication errors through integrated safety alerts and reminders
- Reduce unnecessary calls to physicians for clarifications and questions about orders

Article for Safe Medication Practices. <https://www.smp.org/standardized-orders>

Physician Approved Protocols

- A protocol is a step by step statement of a procedure routinely used in the care of individual patients to assure that the intended effect is reliably achieved.
- It requires the patient to meet certain clinical criteria, and there must be an order to initiate the protocol.
- Protocols are considered to be a predetermined set of orders that define appropriate interventions for a specific medical condition or intervention.

Southeast Hospital Policy Order Sets, Paperwork, Standing Orders, Standardized Protocols. <https://www.seohp.org/medication-pharmacy-education/medication-safety/standardized-orders>

Protocols, Standard Orders, and Order Sets

- Approved by the P&T
- Evidence-based using authoritative guidelines
- Examples: Anticoagulation, pneumonia, insulin

Southeast Hospital Policy Order Sets, Paperwork, Standing Orders, Standardized Protocols. <https://www.seohp.org/medication-pharmacy-education/medication-safety/standardized-orders>

Differentiating Order Sets, Protocols, and Standing Orders

- An order set is a list of individually selectable interventions or orders that the practitioner may choose from – AMI, CHF, Pneumonia, Total Knee Replacement
- A protocol requires the patient to meet certain clinical criteria, but there must be an order to initiate the protocol – Heparin protocol
- A standing order is an order that may be initiated without an initial order by the physicians or LIP by the nurse if the patient meets certain criteria. - ACLS , RRT, IV Start pre-op...

Module 7: The Joint Commission Medication Management Update for 2018 <https://www.jointcommission.org/2018-07-07/medmgt-updates-2018/>



Traditional and Unit Dose Systems

- Traditional
 - Pharmacy profile is used to batch a 24-hour supply of medications referred to as a "cart fill"
 - Organized by patient in a bin or envelope
 - Daily "cart exchange" when the new medications are delivered and unused medications are returned to the pharmacy
 - Throughout the day as new orders are written doses are dispensed from the pharmacy (i.e., first doses)

Module 11: Drug Distribution Systems <https://www.jointcommission.org/2018-07-07/medmgt-updates-2018/>



Traditional and Unit Dose Systems

- Unit-dose
 - Centralized- all doses sent to floor in individualized packages with the ordered dose in the package. Sent from central pharmacy.
 - Decentralized- all doses sent to floor in individualized packages with the ordered dose in the package. Sent from satellite pharmacies.

Module 11: Drug Distribution Systems <https://www.jointcommission.org/2018-07-07/medmgt-updates-2018/>



Automated Medication Systems

- Automated dispensing cabinets- prefilled with unit-dose medications.
- Machines are connected to pharmacy computer system to allow dispensing once order is verified.

Orlando 31 Drug Distribution Systems <http://www.pharmacyeducation.com/continuing-education/2019/04/01/orlando-31-drug-distribution-systems>

Automated Medication Systems



Orlando 31 Drug Distribution Systems <http://www.pharmacyeducation.com/continuing-education/2019/04/01/orlando-31-drug-distribution-systems>

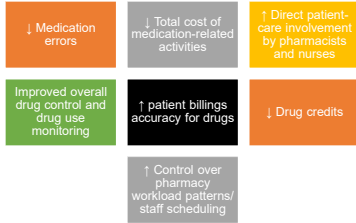
Medication Systems

- Policies and Procedures should address the following principles:
 - Patient Safety
 - Organizational efficiency and economy
 - Effective utilization of professional resources

American Society of Hospital Pharmacists. (2007). *Management of unit-dose drug distribution*. Am J Hosp Pharm, 166: 48-53.

Medication Systems

• A unit dose system combined with automated dispensing cabinets is in use in approximately 80% of hospitals



American Society of Hospital Pharmacists. ADP statement on unit dose drug distribution. Am J Hosp Pharm. 1989; 44:2346.

Medication Systems (results continued from previous slide)

- Improved overall drug control and drug use monitoring.
- More accurate patient billings for drugs.
- The elimination or minimization of drug credits.
- Greater control by the pharmacist over pharmacy workload patterns and staff scheduling.

American Society of Hospital Pharmacists. ADP statement on unit dose drug distribution. Am J Hosp Pharm. 1989; 44:2346.

Storage and Safety Essentials

- Medication Storage and Preparation Areas: There shall be suitable facilities to enable the receipt, storage, and preparation of medications under proper conditions of:
 - sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety throughout the hospital.
- Compounding Areas: There shall be suitable facilities to enable the compounding, preparation, and labeling of sterile and nonsterile products
 - Including hazardous drug products, in accordance with established quality-assurance procedures. The work environment should promote orderliness and efficiency and minimize the potential for medication errors and contamination of products.

American Society of Hospital Pharmacists. ADP guidelines minimum standard for pharmacies in hospitals. Am J Health-Syst Pharm. 2013; 70:1019-20.

Storage and Safety Essentials

- Joint Commission
 - Dating of open injectables- properly – SDVs vs MDVs; "date opened vs date expired"
 - Storing medications in patient care areas (including automated dispensing cabinets) in MDVs if single dose dosage forms exist
 - Medications left unattended or in areas not considered to be secure
 - Operating rooms not in use, but with unlocked medications, after hours
 - Review these items monthly as a part of your unit inspections

Manual J, The Joint Commission Medication Management Update for 2018. <https://www.jointcommission.org/standards/updates/2018/medication-management/>



Routine Medication Use

- Therapeutic appropriateness of the patient's medication regimen.
- Therapeutic duplication or omissions in the patient's medication regimen.
- The appropriateness of the dose of the medication, as well as the route, method, and frequency of administration of the medication.

American Society of Health-System Pharmacists. ASHP guidelines: minimum standard for pharmacies in hospitals. Am J Health-Syst Pharm. 2013; 70:1019-30.



Routine Medication Use

- Patient adherence to the prescribed medication regimen.
- Medication–medication, medication–food, medication–dietary supplement, medication–laboratory test, and medication–disease interactions.
- Adverse drug reactions and other undesired effects.
- Patient medication allergies and sensitivities

American Society of Health-System Pharmacists. ASHP guidelines: minimum standard for pharmacies in hospitals. Am J Health-Syst Pharm. 2013; 70:1019-30.



Routine Medication Use

- Clinical and pharmacokinetic laboratory data to evaluate the efficacy and safety of medication therapy and to anticipate toxicity and adverse effects.
- Physical signs and clinical symptoms relevant to the patient's medication therapy.
- Assessment of the effectiveness of the patient's medication therapy

American Society of Health-System Pharmacists. ASHP guidelines minimum standard for pharmacies in hospitals. Am J Health-Syst Pharm. 2012; 70:1019-20.



Emergency Medication Use

- Joint Commission requires a policy that defines requirements for monitoring overrides
 - Override review process should assess
 - Urgency of situation or presence of LIP "at bedside"
 - Trends
 - Medications
 - Time of day
 - Users of override process
 - Presence of a medication order
 - Barcode scanning of medications removed



Miner, J. The Joint Commission Medication Management Update for 2016. <https://www.jointcommission.org/2016/01/20/2016-joint-commission-medication-management-update/>



Other Joint Commission Issues

- Emergency medications are readily accessible
- Determination of contents
- Process for ensuring availability
- Replenishment
- Separate packaging of pediatric from adult medications in combined cart
- Ready to administer dosage forms

Miner, J. The Joint Commission Medication Management Update for 2016. <https://www.jointcommission.org/2016/01/20/2016-joint-commission-medication-management-update/>



When is Pharmacist Order Review not required?

- Prospective medication order review is a standard of care except in 3 situations:
 - Emergency situation,
 - If a delay in administration would harm the patient
 - If a licensed independent practitioner is present to oversee the ordering, preparation, and administration of the medication.

American Society of Health-System Pharmacists. ASHP guidelines on emergency medicine pharmacist services. Am J Health-Syst Pharm. 2011;68(4):46.



After Hours Dispensing

- Models
 - RN managed with on-call pharmacist
 - Tele-pharmacy with on-call pharmacist
 - Pharmacy open 24/7

Kane, CA. After-Hours Pharmacy Service Models in U.S. Hospitals. Clinical Pharmacy Assistant. 2011 <http://www.pharmacyassistant.com/2011/02/02/after-hours-pharmacy/>



Case Study

- A patient is admitted to the med-surg unit of the hospital with CAP. Among the orders written by the admitting physician is an order for fluvastatin 40 mg each night at bedtime.
- Fluvastatin is currently on shortage and unavailable in the hospital.
- The pharmacist who verifies the admission orders does not note that the product is unavailable, so the physician is not contacted, and no therapeutic interchange is made.



Case Study

- Nurses on the unit, unable to find the drug in the ADC or patient specific drawer document the fluvastatin as "not given, not available" for 72 hours.
- A clinical pharmacist who is working on the med-surg unit is reviewing the patient for antimicrobial stewardship and discovers the medication variance.
- The physician is contacted, and the order is changed to another HMG-CoA Reductase Inhibitor.

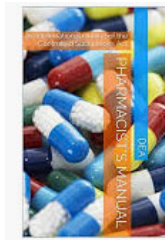
Drug Shortage Management

- Strategies:
 - Inventory system should be designed to detect subminimum inventory levels
 - Pharmacy staff should monitor reliable sources of information regarding drug product shortages (e.g., the ASHP and FDA drug shortages web resource centers).
 - The pharmacy should develop strategies for identifying alternative therapies, working with suppliers, collaborating with physicians and other health care providers
 - Conducting an awareness campaign in the event of a drug product shortage.

American Society of Health-System Pharmacists. ASHP guidelines: minimum standard for pharmacies in hospitals. Am J Health-Syst Pharm. 2013; 70:1619-30.

Controlled Substances

- Drug Enforcement Administration, Office of Diversion Control, has developed a guide to assist pharmacists in their understanding of the Federal Controlled Substances Act and its implementing regulations
- Download a copy of "Pharmacists' Manual" and keep it for reference



Leonhart, MN, Rannazzisi, JT, Caverly, MW. An Informational Outline of the Controlled Substances Act. 2010. <https://www.deadiversion.usdoj.gov/pub/manual/pharm2/index.html>

Records

- The records which must be maintained by a pharmacy include:
 - Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
 - Power of Attorney authorization to sign order forms
 - Receipts and/or invoices for schedules II, III, IV, and V controlled substances
 - All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business

United States Department of Justice, Pharmacist's Manual An Informational Outline of the Controlled Substances Act 2010 <http://www.deadiversion.org/pdf/4/400/40001main.pdf>



Records

- The records which must be maintained by a pharmacy include:
 - Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
 - Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
 - Reports of Theft or Loss (DEA Form 106), if applicable
 - Registrant Record of Controlled Substances Destroyed (DEA Form 41), if applicable

United States Department of Justice, Pharmacist's Manual An Informational Outline of the Controlled Substances Act 2010 <http://www.deadiversion.org/pdf/4/400/40001main.pdf>



Records

- The records which must be maintained by a pharmacy include:
 - Records of transfers of controlled substances between pharmacies
 - DEA registration certificate

United States Department of Justice, Pharmacist's Manual An Informational Outline of the Controlled Substances Act 2010 <http://www.deadiversion.org/pdf/4/400/40001main.pdf>



Alcohol Inventory

- Treat alcohol as a drug.
- Buy in single use containers.
- Treat as an III-V drug.

Title 21 Code of Federal Regulations, Part 1304-Records and Reports of Registrants. <https://www.fda.gov/oc/ohrt/21-cfr-1304-11204>

Recalls

- Notices from wholesalers or manufacturers with lot #s
- Document on notices that search of inventory was done. Include when and by whom.
- If any recalled medicine found, follow instructions on notice.



Recalls.gov. Recalls.gov. <https://www.recalls.gov/>

Medication-Use Evaluation

- Steps of the MUE Process:
 - Establish organizational authority for the MUE process and identify responsible individuals and groups.
 - Develop screening mechanisms (indicators) for comprehensive surveillance of the medication-use system.

American Society of Health-System Pharmacists. ASHP guidelines on medication-use evaluation. Am J Health-Syst Pharm. 1996; 53:1053-6.

Medication Use Evaluation

• Steps of the MUE Process

- Set priorities for in-depth analysis of important aspects of medication use.
- Inform health care professionals (and others as necessary) in the practice setting(s) about the objectives and expected benefits of the MUE process.

American Society of Health-System Pharmacists. ADAP guidelines on medication-use evaluation. Am J Health-Syst Pharm. 1996; 53:1653-5.



Medication Use Evaluation

• Steps of the MUE Process

- Establish criteria, guidelines, treatment protocols, and standards of care for specific medications and medication-use processes. These should be based on sound scientific evidence from the medical and pharmaceutical literature.
- Educate health care professionals to promote the use of criteria, guidelines, treatment protocols, and standards of care.

American Society of Health-System Pharmacists. ADAP guidelines on medication-use evaluation. Am J Health-Syst Pharm. 1996; 53:1653-5.



Medication Use Evaluation

• Steps of the MUE Process

- Establish mechanisms for timely communication among health care professionals.
- Initiate the use of MUE criteria, guidelines, treatment protocols, and standards of care in the medication-use process.
- Collect data and evaluate care.
- Develop and implement plans for improvement of the medication-use process based on MUE findings (if indicated)

American Society of Health-System Pharmacists. ADAP guidelines on medication-use evaluation. Am J Health-Syst Pharm. 1996; 53:1653-5.



Medication Use Evaluation

• Steps of the MUE Process

- Assess the effectiveness of actions taken, and document improvements.
- Incorporate improvements into criteria, guidelines, treatment protocols, and standards of care, when indicated.
- Repeat the cycle of planning, evaluating, and taking action for ongoing improvement in medication-use processes.
- Regularly assess the effectiveness of the MUE process itself and make needed improvements.

American Society of Health-System Pharmacists. ASHP guidelines on medication-use evaluation. Am J Health-Syst Pharm. 1996; 53:1652-5.

Medication Use Evaluation

- Medication-Use Evaluation conclusions are reported to the P&T Committee

American Society of Health-System Pharmacists. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. Am J Health-Syst Pharm. 2008; 65:1272-83.

Medication Errors

• Recommended reading:



To Err is Human
 Building a Safer Health System
 Institute of Medicine (IOM) Committee on Quality of Health Care in America. Editors: Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson.
 Washington (DC): National Academies Press (US); 2000.
 ISBN-10: 0-309-06837-1
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Medication Errors

- Collection of errors including those that do not reach the patient
- Analysis for patterns to drive interventions that improve safety
- Reports to P&T Committee



American Society of Health-System Pharmacists. The ASHP Dispenser Guide to The Pharmacist's role in Quality Improvement. <https://www.ashp.org/medication-management/quality-improvement/quality-improvement/medication-management>

Medication Errors

- As you develop your policy incorporate "Just Culture."
- "Just Culture" is a model that is used in industries, including healthcare, to improve the way system safety and staff accountability relate to each other.

Bylaws: PG Doc. And culture a foundation for sustained accountability and patient safety. October 2 2015 15/04/05-06

Statistical Reports obtained from Drug Wholesaler

- Your wholesaler will have analytics technology available that may feature:
 - Data integration that connects purchasing and price changes
 - Clear insights to drive purchasing decisions and budget forecasting
 - Simple reporting that saves time and communicates with senior executives
 - Trend analysis for individual pharmacies and across health system facilities
 - Interactive graphing to easily visualize trends
 - Daily updates that capture key insights

McKesson Drug Spend Analysis. McKesson. <https://www.mckesson.com/Pharmacy-Management/Drug-Spend-Analysis>

Benefits Derived from these analytics

- Improve drug cost containment
- Increase product mix awareness
- Increase data management
- Increase operational efficiencies
- Decrease drug waste
- Strengthen inventory control

Mission: Drug Spend Analysis. Mission: <https://www.mission.com/PharmacyManagement/Drug-Spend-Analysis/>



Drug Charges

- Pharmacy revenue cycle includes:
 - pharmacy purchasing data,
 - dispensing transactions,
 - charge description master (CDM),
 - pharmacy charges,
 - patient billing

Details: Documentation, coding, charging, and billing for medications identifying rates and internal and local areas. Association of Healthcare Internal Auditors. <https://www.aiaaudit.com/industry/healthcare/charge-master/>



Drug Charges. Key Questions to Consider.

- What is the process for charging patient accounts?
 - Are patient accounts automatically billed when drugs are dispensed or upon administration?
 - Do charges need to be manually entered into patient accounts based on the Medication Administration Record (MAR)?
 - What types of adjustments can be made to the charges?
 - If compounding is completed, how are compounded drugs documented and charged?

Details: Documentation, coding, charging, and billing for medications identifying rates and internal and local areas. Association of Healthcare Internal Auditors. <https://www.aiaaudit.com/industry/healthcare/charge-master/>



Drug Charges. Key Questions to Consider.

- How are unused medications returned or disposed/wasted, documented, and credited to the patient account and inventory?
- How is waste documented and billed in certain situations?
- How are variances identified between medications purchased and medications billed?

Details: Documentation, coding, charging, and billing for medications identifying rates and interest and focus area: Association of Healthcare Internal Auditors
<https://www.aiaa.com/2018/02/28/Documentation-Coding-Charging-and-Billing-for-Medications-Identifying-Rates-and-Interest-and-Focus-Area-Association-of-Healthcare-Internal-Auditors/>



Drug Charges. Key Questions to Consider.

- Is the CDM reviewed on a periodic basis and can it be modified only by appropriate personnel?
- How is pharmaceutical pricing determined? Is pricing information accurate?
- What is the pricing methodology for specialty drugs?

Details: Documentation, coding, charging, and billing for medications identifying rates and interest and focus area: Association of Healthcare Internal Auditors
<https://www.aiaa.com/2018/02/28/Documentation-Coding-Charging-and-Billing-for-Medications-Identifying-Rates-and-Interest-and-Focus-Area-Association-of-Healthcare-Internal-Auditors/>



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- <https://www.ismp.org/guidelines/standard-order-sets>
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- <http://www.niha.com/media/476876/EDU-1736-PPT-Mansur-Joint-Commission-Update-2018.pdf>
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