TJC Medication Standards 2014

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Speaker

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Learning Objectives

1. Recall TJC’s definition of what constitutes a medication.
2. Review hospital requirements for self-administered medications.
3. Describe problematic medication management standards for hospitals.
4. Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
5. Evaluate compliance requirements and penalties.
TJC MM Standards

- Understanding and implementing the Joint Commission’s Medication standards continue to be a challenge for some hospitals
- These standards are very important from a patient safety perspective
- The medication management standards are often scored as noncompliant during the hospital surveys
- There are 3 top problematic standards in the Medication Management (MM) chapter and one in the National Patient Safety Goals (NPSG)

Top Problematic Standards for Hospitals

- Three of the Medication Management (MM) and 1 NPSG standards are problematic for hospitals
- MM.03.01.01 The hospital safely stores medications.
- MM.04.01.01 Medication orders are clear and accurate.
- MM.05.01.01 Pharmacist reviews appropriateness of all medications dispensed in the hospital
- NPSG.03.04.01 Label all medications, containers, and other solutions on and off the sterile field

Sample Medications 2014

- TJC standards apply to sample medications effective July 1, 2014
- Many hospitals quit providing sample medications years ago because of legal and regulatory issues
- TJC said they are not endorsing the use of sample medications
- Rather they have had many questions and have now determined which standards will apply to sample medications
- Rare instance it is used for inpatient but if so all the MM standards apply
Safe MM System Addresses 8 Areas

- Planning
- Selection and procurement
- Storage
- Ordering
- Preparing and dispensing
- Administration
- Monitoring
- Evaluation
20 Standards in MM Chapter

Chapter Outline:

I. Planning
   A. Medication Planning (MM-01.01.01, MM-01.01.03) (MM-01.01.05 is not applicable to hospitals)
   B. Look-Alike/Sound-Alike Medications (MM-01.02.01)
II. Selection and Procurement (MM-02.01.01)
III. Storage (MM-03.01.01, MM-03.01.03, MM-03.01.05)
IV. Ordering and Transferring (MM-04.01.01)
V. Preparing and Dispensing (MM-05.01.01, MM-05.01.07, MM-05.01.09, MM-05.01.11, MM-05.01.13, MM-05.01.17, MM-05.01.18) (MM-05.01.13 is not applicable to hospitals)
VI. Administration (MM-06.01.01, MM-06.01.03, MM-06.01.05)
VII. Monitoring (MM-07.01.03) (MM-07.01.05 is not applicable to hospitals)
VIII. Evaluation (MM-08.01.01)

Goal of the MM Chapter

- To provide a framework for an effective and safe medication management (MM) system
- Manage high-alert and hazardous medications
- Select, procure, and storing medications
- Manage emergency medications
- Controlling medications brought into the hospital by patients, families, or LIPs
- Managing medication orders
- Preparing, labeling and dispensing medications

Goal of MM Chapter

- Administering medications
- Retrieving recalled or discontinued medications
- Managing investigational medications
- Monitoring patients’ reactions to medications
- Responding to real or potential adverse drug events, adverse drug reactions, and medication errors
  - CMS, Tag 508, requires definition of medication errors, ADR, and drug incompatibility and must include near miss in the definition
Resources NPSG

- Some overlap of medication management standards and National Patient Safety Goals (NPSGs)
- Introduction to the NPSGs and Elements of Performance
- Labeling of Medications under NPSG.03.04.01 and reducing harm from anticoagulants under NPSG
- Medication reconciliation has five EPs under NPSG.03.06.01

Labeling of Medications NPSG.03.04.01

- Revised July 1, 2011 and 5 EPs
- Obtain information from the patient on the medication he or she is currently taking
- Define the types of medication information to be collected in non-24 hours settings such as ED, radiology, ambulatory surgery etc.
- Compare medication taken with those ordered to be sure you are not missing any
- Provide patient with written information on medication when discharged and explain importance of managing medication information
Medication Management FAQs

- TJC has a section called Standards FAQs
- Not called JCAHO anymore
- Will call TJC
- There are 9 FAQs under Medication Management (MM)
- Updated periodically
Safe Injection Practices

- TJC has FAQ on multidose vials
- This is part of the safe injection practices
- Safe injection practices is being hit hard by both TJC and CMS
- CDC has ten standards on this such as one needle, one syringe for every patient
- CMS has a revised worksheet on infection control which contains a section on this and memo on this
- Free memo summarizes and hospitals should have P&P and staff on safe injection practices

Safe Injection Practices

- [Image of EMPSF Emergency Medicine Patient Safety Foundation]

The Centers for Disease Control and Prevention (CDC) says there are 2.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 80,000 deaths occur as a result. Infection prevention and control is an important issue in today’s healthcare environment. It is important to communicate with organizations like the Joint Commission (TJC), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Centers for Disease Control and Prevention (CDC) about these standards in the chapter on Infection Control (Chapter 10: The Safe Use of Medications) of the EMPSF Emergency Medicine Patient Safety Foundation (EMPSF) guidebook.

CMS 3rd Revised Worksheet Safe Injections

- [Image of CMS 3rd Revised Worksheet Safe Injections]
Sample Medication FAQ

Medication Management (CAHN / Hospitals)

Sample Medications

1. What issues must our organization consider relating to sample medications?

   A. The following issues:
      • Patient specific medication information must be available in formulary (MM 01.01.01)
      • Medication administration cannot be made up (MM 01.01.01)
      •Medication orders or prescriptions are clear and accurate (MM 01.01.02)
      • The patient record contains information that there is no other adverse reactions (MM 01.01.02)
      • Medications are needed (MM 01.01.02)

Medication Management Chapter

- This chapter is important
- Every nurse, physician, and pharmacist should know what is in this section
- MM is one of the 14 priority focus areas
- There is a medication management tracer
- Will look at medication labels and medication process during tracers
- Tracer includes patients on high risk medications
Definition of Medication

For the purposes of these standards, medication includes (found in glossary):

- Product designated by FDA as a drug
- Prescription medications and sample medications
- Herbal remedies, vitamins, and nutriceuticals (nutritional supplements)
- Over-the-counter drugs
- Vaccines and diagnostic and contrast agents (radioactive meds)
- Respiratory therapy treatments and parenteral nutrition

Definition of Medication

- Blood derivatives
- IV solution plain, with electrolytes and or drugs
- The pharmacy does not have to control all of these things
- However, the MM standards still apply
- Lab may handle blood derivatives so make sure they know the standards
- Nuclear med department may handle radioactive material

Definition Does NOT Include:

- Enteral nutrition- as these as food products
- Oxygen
- Medical gases
Eight Sections of MM Chapter

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

Planning MM.01.01.01

- **Standard**: Hospital plans its MM process
- **Rationale** addresses issues that MM is a complicated area
- MM involves many people to manage quality and safety
  - Such as physicians, ward clerk, pharmacist techs, nurses etc.
  - Each part has to be planned to ensure safety and quality is maintained
- There are two EPs

Planning MM.01.01.01 EP1

- EP1 P&P is required to make sure information is accessible for those who need to use it;
  - Age, sex, and diagnoses
  - Allergies and sensitivities
  - Current medications
  - Height and weight when necessary
    - Recommend weigh children in kg for only
  - Pregnancy and lactation when necessary
  - Lab results when indicated
  - Any additional information required by hospital
Planning

- EP2- The hospital implements its policy and procedure (P&P) so that the information is available to those who need to use it like LIP and staff
- This EP does not apply in an emergency situation when time does not permit like a code
- This is talking about the minimal amount of information that would have to be available to those in the MM process including the pharmacist

So What’s in Your Policy?

Patient Specific Information

- Major cause of error is lack of information
- Need lab for patients on Heparin and Coumadin, Dig level for patient on Lanoxin, weight for pediatric patient (use Kg only), BUN and creatinine on elderly patient when prescribing certain antibiotics
- Need to create an accurate medication history and current list of medication
- Medication reconciliation as part of NPSG
High Alert Medication  MM.01.01.03

- **Standard:** Hospital needs to safely manage both high alert and hazardous medications
- **Rationale:** High alert medications are those that account for a large number of medication errors and sentinel events
  - ISMP has a list of high alert medications
  - IHI has how to guide to prevent harm from high alert medications
  - Four elements of performance

Hazardous Medications

- **Hazardous Medications** are those that studies in animals or humans indicate that exposure to them have the potential for causing
  - Cancer
  - Developmental or reproductive toxicity
  - Harm to organ
- NIOSH has a list of hazardous medications
  - Including resources on hazardous exposure in health care

NIOSH Hazardous Drugs

[NIOSH Hazardous Drugs](https://www.cdc.gov/niosh/topics/hazdrug/)
NIOSH Hazardous Drugs


NIOSH Hazardous Drugs List

- Previous update was Dec 2010
- Updated in 2012 (FR June 27, 2012) and proposed changes in 2014
- NIOSH reviewed 70 new drugs that received FDA approval
- NIOSH reviewed 180 drug that received new special warnings (usually black box warnings)
- Found 26 of these that were added to the list
- Removed 15 drugs that are no longer available in the ED

List of Hazardous Drugs in Healthcare
NIOSH List of Hazardous Drugs

Proposed Additions and Deletions to the NIOSH Hazardous Drug List 2014

High Risk Meds 01.01.03

- EP1 Define your list high alert medicines and hazardous medications in writing
  - EC.02.02.01 EP 8 Hospital minimizes risks associated with disposing of hazardous medications
- EP2 Define a process for managing high alert and hazardous drugs
- MM.03.01.01 EP 9 Concentrated electrolytes are only in patient care units where necessary and precautions are taken
High Risk Medications

- Hospital needs to develop its own list of high risk or high alert drugs and hazardous medications
  - KCl, Concentrated NaCl over 0.9%, Chemo, Insulin, paralytic agents, etc.
- Examples include medications not FDA approved, investigational drugs, new ones, controlled substances, LASA, ones with narrow therapeutic range such as Coumadin, Theophylline, and Digoxin.

High Risk Meds MM.01.01.03

- EP3 Implement your process for high alert and hazardous medications
  - EC.02.02.01 EP1 Hospital maintains current inventory of hazardous material and waste that is uses, stores, or generated
  - Inventory only materials required by law
  - EC.02.02.01 EP8 Hospital minimizes risk with disposing of hazardous materials
  - Do you do double checks or bar coding?

CMS High Risk Drugs

- Do performance evaluation of pharmacist include for high risk activities such as compounding hazardous medications (CMS 492)
- CMS requires system to minimize ADE in high risk medications (CMS Tag 500)
- CMS says high risk drugs are
  - Includes investigational drugs, controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications and look-alike/sound-alike medications and those new to the market or new to the hospital.
CDC Drugs Considered Hazardous


High Risk Meds  MM.01.01.03

- EP5 Hospital must report abuses and losses of controlled substances to pharmacy department and, as appropriate, to the CEO (DS)
  - This for hospitals that use TJC for deemed status so it is most hospitals except VA and Shiners
  - This is a CMS CoP requirement for hospitals
  - CMS also requires a high risk policy in the hospital CoPs (490)

How to Comply

- Include in getting, storing, transcribing, preparing etc.
  - Such as two nurses will check before giving chemo, insulin, or Heparin, chemo certified nurses only
  - Tell you to more frequently monitor BP if on this drug
  - Example, separate storage and different label (flashing lights) for paralytic drugs
  - Separate insulin and mark well and have two nurses check dose, bottle, and order
Policy on High Alert Medications

- Have a policy on high alert meds,
- Digoxin IV, Heparin, adrenergic agonists, concentrated electrolytes and chemo have highest risk of injury (ISMP)
- Insulin, Opiates and Narcotics, injectible KCL, Heparin, and NaCl over 0.9% were most commonly ones involved in error
- CMS amends CoPs and is focusing on safe use of opioids

Policy on High Alert Medications

- If select insulin have vials in different bins or sections of box
- Use tall man lettering such as NovaLog and NovaLIN
- High alert may include; Epidural infusions, Fentanyl, Heparin over 1000 units, insulin, Lidocaine with Epi vials, neuromuscular blockers, PCA, TPN, moderate sedation, anesthetic agents (propofol), and adrenergic agonists (phenylephrine)
LASA Drugs MM.01.02.01

- **Standard:** The hospital addresses the safe use of look-alike/sound-alike (LASA) medications
  
  - It is a much bigger problem according to recent research so USP has database hospitals can check for LASA drugs
  
  - 8th Annual MedMaRX report issued in 2008 shows problems with 3,170 drug pair names which is doubled number since 2004
  
  - Oxycontin confused with oxycodone
  
  - Cerebyx confused with celebrex
EP1 The hospital develops a list of LASA medications it stores, dispenses, or administers

- ISMP publishes a list of LASA drugs at www.ismp.org
LASA Drugs   MM.01.02.01

- EP2 The hospital takes action to prevent errors involving the interchange of the medications on its list of LASA medications
- EP3 The hospital annually reviews and, as necessary, revises its list of LASA medications
  - So in your policy include precautions for LASA medications

LASA Drugs   MM.01.02.01

- Heparin mix up
- Bottles looked alike
- Bottles were stored next to each other
- Red warning labels should be placed on neuromuscular blockers

Compliance  LASA Drugs

- CPOE helps to prevent illegible handwriting
- Implement storage processes in the pharmacy and other facility medication storage areas that physically separate or differentiate products with similar names
- Use proven technologies like Robotic Fills and Bar Code Medication Administration (BCMA)
- Include a purpose on all prescriptions
- Provide education to facility on products that have been confused
- Tall man lettering in software and labeling
How to Comply LASA Drugs

- Implement read backs and spell backs
- Track medication errors caused by LASA and identify most frequent medications
- Make sure patients get counseled by pharmacist and use correct pronunciation for the new drugs
- Include a line on prescription pads on indication for the drug and discuss if indication does not match what patient expects to see

Selection and Procurement MM.02.01.01

**Standard:** The hospital needs to select and obtain medications

This means that the medications available for dispensing are selected, listed and procured based on criteria

- This is the first step in the medication process
- You need to figure out what medications you need and how to get them to your hospital
- There are 15 EPs

July 1, 2012 Change  MM 02.01.01  EP2

- Added to list under EP 2 Population served such as pediatrics or geriatrics
Select and Procure Medications 02.01.01

- EP1 Develop written criteria for determining which medications are available for dispensing or administration
- This must be developed with input from medical staff, LIPs, pharmacist, and staff
- EP2 The written criteria should include indications for use, effectiveness, drug interactions, ADE, possibility of medication error or other risk, abuse potential, sentinel event advisories, population served (such as kids and geriatric patients) and cost
  - MM.05.01.01 EP 10 Medications are reviewed if variation from the hospital’s indications for use

Medication New to Hospital

- EP3 A process must be established to monitor patient response when a new drug is used
  - Talking about when a new medicine is made available to your hospital and placed on the formulary
  - How it is monitored such as INR for Coumadin or patient on Metformin having CT with contrast with history of severe renal failure when these drugs first came out
  - FAQ that says before you add medication to your formulary, be sure staff and LIPs are trained on the effects of the medication and the monitoring requirements
  - Hospital must have access to appropriate lab or diagnostic test to monitor effectiveness

New Medications Added to the Formulary

- When drugs are added how do you educate staff about the new drug and when lab or other tests may be needed to monitor the drug (FAQ)?
- Do staff document this process?
- CMS in hospital CoP also has first dose rule and new medication added
Formulary

- EP4 The hospital maintains a formulary and this must contain the dosages and strengths
  - Formulary may be your list of what is available in your hospital but must have strength and dose (FAQ)
  - Sample medications are not required to be on your list
- EP5 Formulary is available to those involved in medication management

Formulary

- The formulary is synonymous with the list of medications available for use in the hospital so staff will know what is available
- Lots of questions on this standard such as if you need a lab test to monitor the effects of the drug, like a WBC, or other diagnostic testing, make sure you can do this before the drug is included in your formulary
- TJC has FAQ that states the formulary should be a resource for prescribers and staff to know which products, strengths and dosage forms are available
Standardized Concentrations  MM.02.01.01

- EP6 Hospital standardizes and limits the number of drug concentrations to meet the patient’s need
  - For example use unit dose, premixed IV products and don’t send gallon bottles as floor stock anymore
  - If Lidocaine will get 2 grams in 500 cc IV and no other concentration is available

KCl Piggybacks   FAQ

- No concentrated electrolytes in patient care areas such as concentrated KCl or solution over 0.9% NaCl
- FAQ: Can have 100ml bags of KCl with this in it but not 20 or 40 mEq vials
KCl Piggybacks

Can have 100ml bags of KCL with this in it but not 20 or 40 mEq vials

Standardize Concentration and Rule of 6

- Standardize and limit the number of IV concentrations
  - Like only get 20,000 units of Heparin in 1000cc
- Rule of 6 violates this which is common practice in pediatrics that allows a nurse to quickly approximate dose of a vasopressors agent by using a factor of six to adjust concentration of the drug while keeping the rate constant-significant risk of error

Broselow-Luten Pediatric Tape

- Make sure you have one of the newer ones or you will be cited
- Make sure staff know how to use it correctly
- There is a 24 pages long study packet for the correct use of the Broselow Pediatric emergency tape available at no charge at http://dukehealth1.org/deps/Study_Packet_v2_0_rev_may2006.pdf
- Place on flat surface, red end of tape is even with top of patient’s head, remember red to head, stop free hand at bottom of patient’s heel (not toes)
- Free hand indicate weight in kg and the patient’s color zone
Medications Not on the Formulary

- **EP7** Hospital has a process to select, approve, and get the medications that are **not** on the formulary
  - With medication reconciliation process have seen increase in this
  - Need process and mini approval process for these non formulary drugs like certain minor ones pharmacist can decide or go to the department director
  - This standard applies to sample medication (SM)

Medications Not on the Formulary

- **EP8** Hospital implements their process to select, approve, and procure medications **not** on their formulary
  - For example, patient takes Allegra for allergies and hospital substitutes a drug that contains something the patient is allergic to
  - Applies to sample medications (SM)
  - There is a policy and staff knows how to follow it like meds locked in patient room, counted, and nurse opens and gives patient one and documents it
Annual Review of Formulary Drugs

- EP9 Review yearly the list of medications that are on the formulary and available to be dispensed or administered
- This is done to look at emerging safety and efficacy information
- Is the drug in the class not as safe based on new information and rethink if this drug should be in your formulary as FDA continually to publish new warnings

Drug Shortage Management

- EP10 Need a process to communicate shortages and outages to LIP and staff who participate in MM
- EP 11 Hospital implements this process for shortages and outages
- EP12 Hospital develops and approves written protocols to be used if shortage or out of drug
- Shortage has become a significant problem lately including shortages of cardiovascular drugs, anesthetic and central nervous system drugs and anti-infective drugs

Medications Substitution Policies/Shortages

- EP13 Hospital implements approved medication substitution protocols
- EP14 Hospital has a process to communicate about medication substitution for shortages or outages
- EP15 Hospital implements the process to communicate shortages and outages
- ASHSP found shortages lead to medication errors and significant issue lately
Medications Shortages

- FDA has a website on current shortages and can sign up to get this information sent via email
- FDA drug shortage program designated by Center for Drug Evaluation and Research (CDER) Center Director
- FDA also has list of drugs to be discontinued
- Sign up to get email notification at www.fda.gov/cder/drug/shortages/default.htm

Sign Up To Get Drug Shortage Information

Drug Shortage Manual

Table of Contents

Preface

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Attachment A

Attachment B


ASHSP Drug Shortage Website

- American Society of Health System Pharmacist has website on current shortages and drugs no longer available
- Has other resources such as articles and news on drug shortages
- Has two articles on understanding and managing drug product shortages which you can use to help draft this required P&P
- http://www.ashp.org/shortages

www.ashp.org/shortages
www.ashp.org/s_ashp/docs/files/BP07/Procure_Gdl_Shortages.pdf


ASHP Guidelines on Managing Drug Product Shortages

Purpose

Drug shortages occur when there is insufficient availability of a drug product. This can be caused by issues such as production delays, supply chain disruptions, or demand exceeding supply. The purpose of this guideline is to provide clear and actionable steps for pharmacists to manage drug shortages effectively.

Strategies

1. Forecasting: Regularly review current and future demand trends to anticipate potential shortages.
2. Collaboration: Work closely with suppliers to maintain consistent supply levels.
3. Diversified Sources: Maintain a list of alternative suppliers to ensure a consistent supply of essential medications.

Implementation

Pharmacists should implement these strategies to ensure the timely and effective management of drug product shortages. By following these guidelines, pharmacists can better manage the challenges posed by drug shortages, ensuring patient safety and optimal health care delivery.
Storage of Medications MM.03.01.01

- Standard The hospital must safely store medications.
- Rationale This is important to maintain the drug’s integrity, minimize diversion, reduce errors and to ensure medications are available when they are needed.
- There are 19 EPs but only 11 apply to hospitals.
- FAQ states do not have to temperate logs for refrigerators and freezers however.

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Storage of Medications MM.03.01.01

- EP2 Medications must be stored according to the manufacturers instructions and if none according to a pharmacist’s instructions.
  - Refrigerated, keep out of light, room temperature etc.
- EP3 Drugs, biologicals and controlled scheduled drugs are stored to prevent diversion and locked as necessary and as required by law.
  - Schedules drugs are Schedule II-V of the Comprehensive Drug Abuse Prevention and Control Act.
- CMS made changes in the hospital CoP.

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Refrigerator Logs

- Medication Management (CAHPS / Hospitals)
- Medication Refrigeration Temperature Logs
  - Updated November 21, 2006
  - A. Joint Commission does not specifically require temperature logs for refrigerators and freezers used for medication storage. Standard MM.03.01.01, EP2 requires that medications be stored according to manufacturers recommendations. Additionally, CMS requires that organization desic ces and implement processes to maintain and monitor equipment performance. If your organization chooses to use temperature monitoring to achieve this, the monitoring method must track temperature in an ongoing manner. To indicate whether or not internal temperature has deviated from the required range for all drugs stored. In addition, the organization should have a validated process for handling disconnection of medication from a refrigerator or freezer which has deviated from the recommended temperature range.
Storage of Medications  P&P

- EP4- A written policy is needed to address control of medication across the continuum
  - Such as receipt of drug, administration of the medication including safe storage, handling, and return to storage
- EP5  Hospital implements its policy addressing the control of medications between receipt by the provider and its administration (SM)

Storage of Medications MM.03.01.01

- EP6 UnAUTHORIZED individuals are prevented from obtaining medications in accordance with policy and law (SM)
- EP7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings (SM)
  - Multidose vials expires 28 days after opening so label bottle with expiration date
  - TJC has FAQ on multi-dose vials

ASC Quality Coll Toolkit Safe Injections

Safe Injection Practices Toolkit

For notes on this toolkit may only be used for internal improvement and education others. May not be used for commercial purposes. Safe injection practices are related to how one instills patient safety and provider protection. Navigating the landscape of patient care, and a role can be played in the patient to gain when safe injection practices are not used.

The ASC Quality Collaboration has assembled a variety of resources and information that may be used to supplement your current processes for evidence-based injection practices. The Toolkit’s Safe Injection Practices Toolkit includes three essential resources:

- Safe Injection Practices: What DOH Employees Are Looking For
- Infection Prevention and Infection Control
- Injection Practice Policy and Procedure Template

The PHNNDRO Safe Injection Practices contains both essential resources and a broader array of materials, including:

- Assessment Tools
- Implementation Guides
- Training Materials
- Monitoring Tools
- Workplace Protocols

http://ascquality.org/SafeInjectionPractice'sToolkit.cfm
**CMS Memo on Safe Injection Practices**

- All entries into a SDV for purposes of repackaging must be completed with 6 hours of the initial puncture in pharmacy following USP guidelines.
- Only exception of when SDV can be used on multiple patients.
- Otherwise using a single dose vial on multiple patients is a violation of CDC standards.
- CMS will cite hospital under the hospital CoP infection control standards since must provide sanitary environment.
  - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.

**Bottom line is you can not use a single dose vial on multiple patients.**

**CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines.**

**SDV typically lack an antimicrobial preservative.**

Once the vial is entered the contents can support the growth of microorganisms.

The vials must have a beyond use date (BUD) and storage conditions on the label.
TJC FAQ on Multi-dose Vials

If the manufacturer’s original expiration date is shorter than the revised expiration date then the shorter date must be used. Also, if directly in question as compartment the multi-dose vials should be discarded regardless of the date.

Labeling the multi-dose vial with the date applied will not meet the requirements.

Q. Do vials need to follow the 28-day rule?

Currently, vials are not required to follow this requirement. The CDC Communication Program states that each dose is to be discarded per the manufacturer’s expiration date. The Joint Commission is adopting the approval of all vaccines (whether or not the CDC or state immunization program or purchased by health facilities) with the understanding that the vaccines are stored and handled appropriately (temperature maintained, frequency of temperature checks, etc.). Following the guidelines provided in the package insert is very expected see a result of the vaccine.

The CDC has excellent resources regarding the use, storage, and handling of vaccines.

Where can I find additional information on safe medication practices for multi-dose vials?

The Safe Injection Practices Coalition has developed the One and Only Campaign (www.oneandonlycampaign.org) to improve health campaigns led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC). It aims to improve awareness among patients and healthcare providers about suboptimal injection practices.

The website for this campaign provides useful resources for staff and patients.

One and Only Campaign

www.oneandonlycampaign.org

About the Campaign

Safe Injection Practices

Precaution Information

Contact Us

About the Campaign

Only Once

Safe Injection Practices are key to reducing patient harm, increasing patient safety, decreasing bacterial transmission, and improving immunization rates. This campaign aims to promote safe injection practices and reduce the risk of complications. The campaign provides valuable resources to help healthcare providers improve their practice.
Not All Vials Are Created Equal

Safe Injection Practices Memo

Identify Risks for Transmitting Infections

- Hospital and ASC in Colorado where surgery tech with Hepatitis C infection steals Fentanyl and replaces it with used syringes of saline infecting 17 patients as of December 11, 2009 and 5,970 patients tested (total 36 for 3 facilities)
- Kristen Diane Parker in 2010 gets 30 years for drug theft and needle swap scheme
- Worked at Denver’s Rose Medical Center and Colorado Springs’ Audubon Surgery Center

1 www.krdo.com/Global/link.asp?L=399119
Pleads Guilty

- 34 yo pleads guilty
- He pleads guilty to 16 federal drug charges
- He worked as cardiac tech and former lab tech in 18 hospitals in 7 states
- 46 patient confirmed with his strain of Hepatitis C
  - 32 in New Hampshire, 7 in Maryland, 6 in Kansas, and 1 in Pennsylvania
- Stole fentanyl and replaced it with saline and used dirty needle
  - Stealing drugs since 2002 and pleads guilty Aug 2013
Remove Expire Drugs/ Concentrated Lytes

- EP8 All expired, damaged, or contaminated medications are removed (SM)
  - These should be stored separately from medications available for administration
- EP9 Concentrated electrolytes are kept in patient care areas only when patient safety necessitates their immediate use
  - Precautions are used to prevent inadvertent administration

Storage of Medications MM.03.01.01

- EP10 Medication should be in the most ready to administer forms that are commercially available (SM)
  - In unit doses that have repackaged by the pharmacist or licensed repackager
  - Anticoagulants use see NPSG.03.05.01
- EP18 Hospital inspects medication storage areas periodically

Supervise Drug Storage Areas

- EP19- Must have a director of pharmacy by a registered pharmacist or a supervised drug storage area (DS)
  - This must in accordance with law and regulation
  - This is for hospitals that used TJC for deemed status
  - This is a CMS CoP requirement
  - Applies to sample medication (SM)
Storage of Medications MM.03.01.01

- EP 24 The hospital maintains records of the receipt and disposition of radiopharmaceuticals
- Effective July 2, 2014

- This is a common problematic standard for hospitals
- Should stock only approved medication that are on your formulary
- Exception is medications brought to hospital by the patient which is MM.03.01.05
- Store medication under appropriate circumstances such as refrigerate or keep out of light
- No medications lying on ledge of the dumb waiter or shelf of tube system in hallways

Storage of Medications

- Make sure the hospital’s P&P contains all the elements required by this standard and by the CMS CoP policy requirements
- Schedule II-IV medications must be locked
- Should do hazard vulnerability analysis (HVA) on the location of all carts and places where medications are stored including crash carts
- Make sure medicine carts are locked in OB for stat C-sections
Storage Issues

- Have monthly inspections and all expired, damaged, or contaminated medications are removed
- Medications that are easy to confuse should be separated, like sound alike or look alike drugs (LASA) Celebrex and Celexia since many go alphabetically
- Be sure to separate insulin and mark it with tall man lettering so similar names are not confusing

TJC FAQ on Anesthesia Cart

ASHP Guidelines on the Safe Use of Automated Medication Storage and Distribution Devices
Medications in the OR ASA Position


Emergency Medications MM.03.01.03

- Standard Hospital needs to safely manage emergency medications
- Rationale Emergency medications must be treated with the same care for safety as in other non-emergency settings
- Hospital needs to decide which medications and supplies are needed
- Hospital needs to plan how it will address patient emergencies

Emergency Medications 03.01.03

- EP1 Hospital leadership and MS and LIPs decide which emergency medications will be accessible based on the population served
- EP2 Emergency medications and supplies are readily accessible in patient care areas
  - Often referred to as the crash cart standard
  - Crash carts can be locked with plastic lock, under constant surveillance, or with real lock based on HVA
  - Schedule II-V must be locked
Emergency Cart Security FAQ Oct 2013

- Medicine must be stored in secure manner to prevent tampering, theft or diversion
- Balance security with need to have drugs and supplies readily available
- Padlocks are discouraged and don’t want to create a barrier
- Do a risk assessment to make decisions
- In ED permissible to use breakaway lock since staffed 24 hours as long as process in place to monitor the integrity of the breakaway lock

Crash Cart Security

- PC.03.01.01 EP 8 Need resuscitation equipment when doing operative, high risk procedures, or moderate sedation since can lose protective reflexes
- Many consider the ACLS changes to ensure emergency drugs on their crash carts and recommendations from organizations like ENA and ACEP (www.acep.org and www.ena.org)
- American Academy of Pediatrics, Committee on Pediatric Emergency Medicine has list of recommendations (www.aap.org)
AAP Policy

AMERICAN ACADEMY OF PEDIATRICS
American Academy of Pediatrics, Committee on Pediatric Emergency Medicine and American College of Emergency Physicians, Pediatric Committee

Care of Children in the Emergency Department: Guidelines for Preparedness

ABSTRACT: Children requiring emergency care have unique and special needs. This is especially true in times of war and terrorist attacks. For these reasons, there is a variety of unique considerations for the care of children in the emergency department. It is important to provide emergency care in children that are not in medical emergencies. In the emergency department, it is necessary to have the appropriate equipment, drugs, and personnel available to treat children. In the field, it is essential that the care provider have the appropriate personnel and equipment. This requires the appropriate training of all emergency health care personnel to safely treat children. This guideline describes the emergency department's role in providing appropriate pediatric care in times of emergency.

Emergency Medications 03.01.03

- EP3 Emergency medications need to be available in unit dose, age specific, and ready to administer forms
  - Remember pediatric doses previously discussed
  - Emergency ACLS drugs like Atropine or EPI should be in its ready to use injectible form during a code

Perspective Pediatric Doses on Crash Cart

CLARIFICATION: Pediatric Emergency Medications and Immediate Threat to Life

The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor." The word "shift" should be changed to the word "minor."
Restock Crash Carts

- EP6 Hospital replaces emergency medications or supplies when they are used to maintain a full stock
- Careful when replacing crash carts as to make sure medications are secure
- Don't want surveyor to find crash cart not restocked after it was used
- Some of the larger ED are putting pharmacist on staff in the ED
- Make sure top of crash cart is not dusty

ASHP Pharmacist in the ED

ASHP Statement on Pharmacy Services to the Emergency Department

Pharmacists' involvement in the ED has been documented to improve patient care, reduce medication errors, and increase patient satisfaction. Pharmacist involvement in the ED also enhances the education of medical and paramedic students.

Pharmacy Services to the ED

ASHP statement on pharmacy services to the ED

ED Pharmacist Research Center AHRQ

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**MM.03.01.01 Effective July 2, 2014**

- EP 24 The hospital maintains records for the receipt and disposition of radiopharmaceuticals
  - For hospitals with deemed status
  - Also note a change in the federal law effective July 11, 2014
- Allow in-house preparation of radiopharmaceuticals by trained nuclear medicine technicians in hospitals on off hours without a physician or a pharmacist being present
  - Removed the wording of direct supervision but still under their supervision

**Medications Brought In MM.03.01.05**

- **Standard** Hospital safely controls medications brought in by patients, families, or LIPs
- **Rationale** The hospital needs to control medications brought in to protect the safety and quality of care
  - Also when medication reconciliation is done and hospital does not carry like vitamins and OTC
  - Patient may be allergic to the drug in substitutions
Medications from Home
- There are a number of reasons for allowing patients to bring in medications especially with the medication reconciliation process as may not have a non-formulary drug or herbal agent
- Another valid reasons for allowing includes avoiding interruption of medications or lack of alternatives
- May be used for observation patients since Medicare does not pay for their oral drugs
- All 3 EPs apply to sample medication

Medications Brought In 03.01.05
- EP1 Hospital defines when medications are brought in by patients, families, or LIPs can be administered
- EP2 Hospital identifies all medication brought in prior its use and the medication needs to be visually evaluated to determine the medication’s integrity
  - Example are medications in the correct bottle with all same type of pills, not outdated, and labeled?

Medications Brought In 03.01.05
- EP3 Hospital needs to inform patients, families, and LIPs when medications are not permitted
  - So develop your process is to safety manage medications brought from home
  - Signed form by patient, counted by staff, locked in drawer, physician order, integrity of bottle, medications clearly labeled by a pharmacist, medication in original bottle, medication not outdated, no state law prohibitions etc.
Medication Brought in by LIP 03.01.05

- The policy must address the safety and use of the medication acquired by a practitioner from sources other than the organization for use in patient care
- Will you allow this and what is your policy and be sure physicians and LIP know what your P&P is
- For example, Botox is brought in by patient to be given for migraine headaches by neurologist in the outpatient department

Medication Orders MM.04.01.01

- Standard- Medication orders have to be clear and accurate
- There are 14 EPs but only 12 apply to hospitals
- EP1 Hospital has to have a written policy to include specific types of medication orders that are acceptable
  - As needed (PRN) orders, automated stop orders
  - Standing orders
    - A pre-written medication order and specific instructions from the LIP to administer a medication to a person in clearly defined circumstances

Medication Orders MM.04.01.01

- Written policy to include the following
  - Titrating and range orders
  - Orders for compounded drugs or drug mixtures not commercially available
  - Orders for medication related devices (nebulizers, catheters)
  - Orders for investigational medications or herbal agents
  - Orders for medication at discharge or transfer
Medication Orders P&P

- EP2 Policy needs to include elements of a complete medication order
  - Drug, dose, frequency, route, etc.
- EP3 Policy on medication use needs to include indication for use and when it is required
  - What is the diagnosis or condition for each drug unless obvious such as antibiotic for pneumonia patient
  - Can be on med reconciliation form, H&P or other place in chart so can tell why patient takes that med

TJC FAQ on Indication for Use

- TJC FAQ on Indication for Use

LASA

- EP4 Policy need to includes precautions for LASA medications
  - It is a much bigger problem according to recent research so USP has database hospitals can check for LASA drugs
  - 8th Annual MedMaRX report issued in 2008 shows problems with 3,170 drug pair names which is doubled number since 2004
  - Discussed previously
Incomplete or Illegible Orders

- EP5 Policy needs to include actions to take when medication orders are incomplete, illegible or unclear
  - Nurse contacts ordering practitioner when this occurs
  - Consider adding clarification information in nurses notes and on order sheet
  - Lasix order clarified with Dr. Smith 4/25/00 1100 and is 20 mg PO once a day
  - Asked during medication management tracer

Verbal Orders

- EP6 Hospital minimizes the use of verbal and telephone orders for medications
  - Big issue with both CMS and TJC
  - No verbal orders if standing in the nursing station absent a code or emergency
  - Limited to situations like orders needed and doctor at home or in office
  - Remember to make sure all verbal orders are written down, read back, signed off, dated and timed

Indication for the Medication

- There is documented diagnosis, condition, or indication for each med ordered,
  - Consider new form- why do you take Pepcid-is it to prevent stress ulcer?
  - May be in history and physical or admission orders or on medication reconciliation form,
  - Why is the patient getting this drug?
  - Okay if clear such as antibiotic for pneumonia,
Preprinted Order Sheets
- EP7 Hospital reviews and updates preprinted orders within time frame identified or sooner if based on current or new evidence
  - Consider adding review date to preprinted orders
  - May sure is drafted based on evidenced based medicine
  - Remember CMS Cop to have practitioner sign this is page 3 of 3 and to initial any additions or deletions and June 7, 2013 Changes see EP15
  - CMS says protocols must be approved by the MS and entered as an order in the chart
    - Tag 405, 405, 450 and 457

Resume Previous Medications
- EP8 Hospital prohibits summary (blanket) orders to resume previous medications
  - So physician cannot writing an admitting order that says “Resume all home meds” or “Resume preop drugs” after surgery
- EP9 Each medication ordered need a diagnosis, condition or indication for use
  - Can be in history and not on the order itself

Medication Orders
- EP10 Define in writing when weight based dosing is required for pediatric patients (SM)
  - Only use kg for children
- EP13 Hospital implements its policies for medication orders
- EP14 Hospital requires a physician approved protocol to administer flu and Pneumovac or order
Standing Orders 2013

- EP 15 Preprinted Orders, Electronic Standing Orders, Order Sets, and Protocols for Medication Include the following: (DS)
- To comply with CMS CoP Changes
- Must be reviewed and approved by MS (MEC) in conjunction with nursing and pharmacy
- Evaluate to make sure consistent with evidence-based guidelines and nationally recognized standards

Standing Orders 2013

- Must regularly review standing orders and protocols to make sure they are current, useful, and safe
  - This must be approved by the Medical Staff (such as MEC) in coordination with nursing and pharmacy
  - Standing orders and protocols have to still be signed off, dated and times by the ordering practitioner or practitioner responsible for the care of the patient
  - In accordance with hospital P&P, MS by-laws or Rules and Regulations and law
  - Make sure order is placed in chart so it can be signed off
Medical Homes EHR Prescribing

- EP 21 The primary care medical home uses an electronic prescribing process
- This standard applies only to hospitals that elect the TJC primary care medical home option

Pharmacist Review MM.05.01.01

- **Standard:** A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital
  - There are 11 EPs but only 10 apply to hospitals
  - This has been a problematic standard for hospitals and source of frequent questions
  - All prescriptions or medication orders are reviewed for appropriateness by the pharmacist before the **first dose** is given for safety reasons
Pharmacist Review before First Dose

- EP1 Pharmacist reviews all medication orders or prescriptions prior to dispensing or removing medications from the floor stock
- Exception is made if LIP controls the ordering, preparation and administration (such as in radiology, endoscopy, or the ED)
- Radiology service must define, through protocol or policy, the role of the LIP to directly supervise the patient during and after IV contrast is administered in case of a patient emergency
  - Author suggest you make it a policy in light of CMS protocol IG

ACR Manual on Contrast Media

Version 9


CMS hospital CoP Tag 500

Necessary to prevent backup in the ED

ED must have LIP available in the unit who is available for immediate intervention should patient have an ADE
LIP Order in the ED Exception

- If the patient is still in the ED and a bed is not going to be available for 12 hours and patient needs their daily medication, there is time to have the pharmacist do a review of their medication before giving them their daily medications.
- Example is patient is admitted to the medical unit for pneumonia and nurse can not just go to the automated dispensing unit and get meds until pharmacy has reviewed the list.

Pharmacy Closed

- EP2- If the pharmacy is not open 24 hours a day then a healthcare professional determined to be qualified reviews the medication order in the pharmacist absence.
  - Many hospitals have the nurse supervisor access the night cabinet and then reviews with RN who will give.
  - Many hospitals provide additional medication training to the supervisor who has to pull drugs from the night cabinet and consider bar coding.
  - Some hospitals fax the medication order to a pharmacist as part of tele-pharmacy process.

Pharmacist Retrospective Review

- EP3- The pharmacist conducts a retrospective review of all medication orders during this period as soon as a pharmacist is available or the pharmacy opens.
  - The nurse supervisor or physician should only pull the drugs that are needed during the time there is no pharmacist.
  - The pharmacist needs to review all the drugs that were given from the night cabinet when they come in that morning.
Review Medications First Dose Rule

- EP4-9 The following is a list of things that the pharmacist needs to review before the first dose is given;
  - Allergies or potential sensitivities
  - Existing or potential interactions between the medication ordered and food and
  - Medications the patient is currently taking

First Dose Review by Pharmacist

- EP4-9 The following is a list of things that the pharmacist needs to review before the first dose is given (Continued);
  - Appropriateness of the medication, dose, frequency, and route of administration
  - Current or potential impact as indicated by laboratory values
  - Therapeutic duplication and other contraindications

Clarify Any Unclear Orders

- EP11- Concerns, issues, or questions are clarified with the individual prescriber before dispensing
  - This issue is discussed during medication management tracer so make sure staff know what to do if order is unclear or illegible
  - Should document clarification in the medical record and CMS CoP standard
Safe Preparation of Medication MM.05.01.07

- **Standard-** The hospital safely prepares medications
- **EP1** A pharmacist or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparation
  - An exception would be in an urgent situation where a delay could harm the patient
  - Remember the USP 797 standards where piggybacks and IVs need to be made under laminar hood etc.
  - Must follow any specific state law

Separate Area to Prepare Medications

- **EP2-** Staff need to use clean or sterile technique and maintain a clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications
  - Separate medication room or something that is mounted to wall and folds down like a Wallaroo
  - CMS requirement also
Inspect Medication & USP 797

- EP3 Staff visually inspect the medication for particulates, discoloration, or other loss of integrity during preparation
- 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

Need Order for Medication 2013

- EP5 Need an order for medications (DS)
  - Medications are prepared in accordance with an order and in accordance with P&P, MS R/R and by-laws and regulations
  - CMS CoP states need an order for any drug or biological, updated June 7, 2013 in Tag 405 (2014 changes on medications & opioid use) and 406
  - May use protocols for emergency situations such as ED nurse starts IV on patient thought to be a MI patient after approval by MEC
  - Nurse needs to enter the order in the order sheet and have physician or LIP sign the order

Radiopharmaceuticals

- EP6 In-house preparation of radiopharmaceuticals is done by, or under the supervision of an appropriately trained registered pharmacist or doctor (DS)
  - This is a requirement under the CMS CoP for hospitals but proposes to change in 2014
  - July 11, 2014 change that allows radiology tech to do on off hours without a physician or pharmacist present
Radiopharmaceuticals CMS

- In nuclear medicine radioactive substances are used to diagnose and treat disease
  - The medical imaging use radioactive isotopes (radionuclides) to locate organs or cellular receptors
  - The radiopharmaceuticals are taken IV or orally
  - An example is a myocardial perfusion scan or pulmonary ventilation and perfusion (V/Q) scan
- CMS revised the nuclear medicine CoP to remove the requirement from "direct supervision" from the in-house preparation supervision requirement

**Direct supervision** meant that the pharmacist or physician had to be physically located inside the hospital and immediately available during the preparation of the radiopharmaceutical

- This was extremely burdensome on off hours
- The rule adopted the proposed changes to revise to supervision instead of direct supervision so appropriately trained staff can prepare in-house pharmaceuticals under the oversight of a registered pharmacist or physician

This means that now on off hours, such as evenings and weekends, a pharmacist or MD/DO does not have to be present to do nuclear medicine tests

- CMS received information that there is minimal in-house preparation required for radiopharmaceuticals
- Many are batch prepared by the manufacturer
- This was based on the recommendation of the Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Radiopharmaceuticals CMS

- Hospitals need to have a P&P on supervision of nuclear medicine personnel and in-house preparation
- CMS said they expect hospitals to follow the Society of Nuclear Medicine and Molecular Imaging recommendations on this issue
- This includes emergency performance of diagnostic procedures such as CAD, pulmonary emboli, stroke, and testicular torsion
- All comments were supportive of this change

ACR PRACTICE GUIDELINE FOR THE USE OF INTRAVASCULAR CONTRAST MEDIA

PURPOSE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not intended to be a prescription of practice and are not intended to be used to establish a legal standard of care. For these reasons, and those set forth below, the American College of Radiology retains ultimate control of these guidelines in situations in which clinical decision of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in medical judgment in light of all the circumstances present. Thus, an approach that differs from the guidelines, meeting other, can never reasonably apply that the approach is better than the standard of care.

In the future, a reasonable practitioner may reasonably judge a course of action different from that set forth in the guidelines. As the reasonable judgment of the practitioner, each course of action is evaluated by the condition of the patient, limitations on available resources, or advances in knowledge or technology.

Therefore, it should be recognized that adherence to these guidelines will not ensure an optimal diagnosis or an optimal treatment. All but should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, evidence, resources, and the needs of the patient in delivering efficient and cost-effective care. The sole purpose of these guidelines is to assist practitioners in delivering the best care.

1. INTRODUCTION

This guideline has been developed to provide the safe and effective administration of intravascular contrast media used in angiography studies.

Intravascular contrast media are used in a wide variety of imaging studies. The majority of intravascular contrast-enhanced imaging studies (arterial and venous contrast media, PET and functional MRI) may be used for diagnostic purposes (CT, MR angiography, and topography).

IV Contrast

- April 2007 changed the requirement that pharmacist had to do a retrospective review of all ED drugs within 48 hours but still requires IV contrast protocol or P&P
- A hospital’s radiology department will be allowed to define, through a policy or protocol, the role of LIP’s in the direct supervision of patients during and after administration of IV contrast media
- If radiologist not present when IV contrast is given, ED physician would be present to administer to ED patient
- FAQ discusses medication administered under an LIP and states pharmacist may want to later assess risk points by randomly sampling and reviewing the LIP orders
IV Contrast

- Hospitals should refer to the American College of Radiology practice guidelines for the use of intravascular contrast media
- Also a number of guidelines for contrast in pediatric patients and contrast for MRI
- Exception for oral and rectal contrast media see August 2006 edition of The Joint Commission Perspectives.

ACR Contrast Manual


Safe Preparation of Medications

- Suggest use premixed when available as safer than mixing up on the floor
- Suggest do not add drugs to Buritol or bags when pharmacist on duty
- Pharmacist needs to prepare piggybacks when on duty unless short half life or urgent need
Labeling of Medications  MM.05.01.09

- **Standard** All medications must be labeled
- **Rationale** It has been a long standing standard of practice that all medications must be labeled as is required by law and regulation
- A standardized method of labeling can promote medication safety
- 12 EPs
- Labels for medications are discussed under NPSG.03.04.01

Labeling of Medications  MM.05.01.09

- **EP1** A medication must be labeled when prepared if not immediately given (SM)
  - Exception is nurse in ED prepares Phenergan 12.5 mg to be given IV and immediately goes to the bedside and administers it slowly over 3 minutes
  - There is no break in the process and prepared and administered by the same person
- **EP2** Information on the label is displayed in standardized format

Medication Labels Must Contain

- **EP3 to EP6** The medication label must contain:
  - Medication name, strength, and amount
  - Expiration date when not used within 24 hours
  - Expiration time when expiration occurs in less than 24 hours
  - The date prepared and the diluent for all compounded
  - Intravenous admixtures and parenteral nutrition formulas
    - Plain IVs do not need a label
**Labeling of Medications**

- EP7 to EP9  Label must contain the following when preparing individualized medications for **multiple patients**
  - Patient's name
  - The location where the medication is to be delivered
    - Location not used as identifier during administration
  - Directions for use and applicable accessory and cautionary instructions
    - Such as keep out of light, refrigerate, give over 2 minutes, dilute in 5 ml 0.9% NaCl
  - Same as when pharmacist prepares for the nurse

- EP10 to EP12  When preparing individualized medication by someone other than the person administering (pharmacist prepares for nurse) the label must include:
  - The patient's name
  - The location where the medication is to be delivered
  - Directions for use and applicable accessory and cautionary instructions

**Dispensing Medications MM.05.01.11**

- **Standard:** The hospital safely dispenses medications
- EP1  Quantities dispensed are consistent with patient needs
  - Hospital does not want to dispense large numbers of medication unnecessarily as could lead to diversion
Dispensing Medications

- EP2 Medications are dispensed in accordance with professional standards of care and records maintained in accordance with law and regulation (SM)
  - Include anti-diversion strategies
  - There are many standards such as those set out by professional organizations like ASHSP, ISMP, APIC, IHI, FDA, and USP
  - There are many state regulations like those from the state pharmacy board
  - There are many federal laws/ regulations such as the USP 797

Dispensing Medications

- EP3 Hospital dispenses within time frames it defines to meet the patient needs
  - If physician orders medication stat what is the time frame to administer it to patient such as 20 minutes
  - If physician orders medication ASAP what is the hospital's time frame such as 2 hours

Dispensing Medications

- 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 repackaged
  - Drugs in unit dose
  - Solutions like cough syrup in individual unit dose containers and not in big bottle
  - Drugs in crash cart are most readily available such as individual injectibles for EPI and Atropine
Pharmacy is Closed  MM.05.01.13

- **Standard**: The hospital obtains medications safety when the pharmacy is closed
- **Rational**: If pharmacy not open 24 hours a day patients may still need medications
- **Hospital needs to provide for urgent or emergent needs when the pharmacy is closed**
- **This standard does not affect hospitals that have a pharmacist on duty 24 hours a day**
- 7 EPs

Night Cabinet Standard

- **EP1**: Hospital has a process to meet the patient’s need when pharmacy is closed
  - For example, nurse supervisor gets needed meds out of the night cabinet
- **EP2**: When non-pharmacist is allowed to obtain meds after hours, medications are limited to those approved by the hospital
  - For example, hospitals have a list of the drugs in the night cabinet that can be accessed after hours and periodically review to see if you add or delete drugs

Pharmacy is Closed  Night Cabinet

- **EP3**: These medications must be stored outside the pharmacy
  - Like in the night cabinet
  - TJC does not want supervisor going into the pharmacy to get drugs when it is closed
  - Several hospitals report being cited by CMS for not having pharmacist do first dose review when pharmacy closed and not using telepharmacy
- **EP4**: Only trained, designated prescribers and nurses can access these approved medications
Pharmacy is Closed  Night Cabinet

- EP5 Need to have a quality control procedure such as an independent check by another nurse or secondary verification system like bar coding to prevent retrieval errors
- EP6 Pharmacist needs to be on call or available to answer questions or retrieval medications not in night cabinet
- EP7 Hospital needs to implement its process when the pharmacy is closed

Recalled/Discontinued Medication MM.05.01.17

- **Standard:** The hospital follows a process to retrieve recalled or discontinued medications (all 4 EPs SM)
- EP1 The hospital has a written P&P that outlines what to do in the event a medication is recalled or discontinued for safety reason by the FDA
  - See EC.02.01.01 EP 11 The hospital responds to product notices and recalls
  - Send notices to nursing units
  - Hospitals can sign up on the FDA website to get notices of drug recalls and discontinued medications

Recalled/Discontinued Medication

- EP2 The hospital implements its P&P when a drug is recalled or discontinued for safety reasons
- EP3 Hospital must notify the prescribers when there is a drug recalled or discontinued
  - For example, when Vioxx and Darvocet N recalled hospital had process to notify doctors and what would be substituted
- EP4 Hospital notifies patient that their medication has been recalled or discontinued by the FDA when required by law or your P&P
Standard: Hospital safely manages returned medications

Rationale: Medications may be returned to the pharmacy when allowed by law or regulation

Previously unused, expired, or returned medications need to be accounted for, controlled and disposed of to keep patient safe and to prevent diversion

4 EPS and all apply to sample medications (SM)

EP1 The hospital determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy

For example, the patient is discharge and unused medications are returned to pharmacy

For example, Dilaudid outdates tomorrow so nurse sends it back to pharmacy

EP2 The hospital has a process for returning medications to the pharmacy’s control which includes P&P to prevent diversion

EP3 Hospital determines if and when outside sources are used for destruction of medication

EP4 Hospital implements it process for managing unused, expired, or returned medications

What is the hospital P&P to return and destroy these drugs?

Are they flushed or incinerated (p-waste)

What is the process to document wasted drugs?
Administration of Meds MM.06.01.01

- **Standard:** The hospital safety administers medications
  - Pharmacist dispense the medication
  - It is the nurse’s role to safety administer that medication
  - There are 9 EPs

Administration of Meds MM.06.01.01

- **EP1** The hospital defines in writing, LIPS or clinical staff who are allowed to administered medication
  - This includes with or without supervision
  - It must be in accordance with law and regulation
  - Example would be medication technicians with a certificate to pass certain medications in LTC in Ohio
  - Nursing students in their program can administer medications

Administration of Medications by Nurse

- **EP2** LIPS and clinical staff who are authorized are the only ones who can administer medications except self administration when permitted
  - So a nurse could not delegate to the nursing assistant to give the patient this medication in a cup when they come back from the bathroom
  - Many states require LPN to have medication course before being able to administer medications
  - Example would be only RNs can administer blood and many nurse practice acts restrict LPN role such as may be able to irrigate central line
Administration of Medications

- EP3 to EP9 Prior to administration the individual must:
  - Verifies that the medication selected matches the medication order and product label
  - Visually inspects the medication for particulates, discoloration, or other loss of integrity
  - Verifies the medication has not expired and there are no contraindications

Administration of Medications

- EP3 to EP9- Prior to administration the individual must (Continued):
  - Verifies the medication is being administered at the proper time, in the prescribed dose, and by the correct route
  - Discusses any unresolved concerns about the medication with the patient’s prescriber
  - The patient or family is informed about any potential clinically significant adverse drug reactions or other concerns regarding administration of a new medication

Administration of Medications

- Remember PC.02.03.01 EP10 that requires education and training to provided to the patient on the safe and effective use of medication
  - Use teach base to make sure patient understands and understand issue of low health literacy
  - Make sure use an interpreter if patient has limited English proficiency

- This section also references MM.06.01.03 EP 3-6 about self administration of medication by patients
- CMS Tag 412 and 413 in Nursing section and Tag 502 in Pharmacy
Administration of Medications

- Verify medication is stable by visually looking for particulates or discoloration in vial
- Make sure drug is not expired
- Verify no contraindications like allergies or sensitivities or drug not indicated with certain medical conditions
- Verify administered at proper time, dose, and route such as yes it is Lanoxin 0.125 mg orally and is to be given at 9 am

Administration of Medications

- Advise patient and when appropriate, family, about significant adverse reactions when giving a new medication
  - Watch out for hives or red neck syndrome for Vancomycin or this medication is a diuretic and will make you urinate frequently
  - Address any concerns with physician before administering
  - Discuss any unresolved significant concerns about the medication with the prescriber and document clarification on order sheet and in nurses notes when indicated

Self Administered Medications MM.06.01.03

- **Standard:** Self administered drugs are administered safety and accurately
- Self administered may refer to medications given to the patient themselves or by a family member
- Doctor writes an order for Nitro at the patient’s bedside or an inhaler
- 7 EPs
- CMS CoP 412, 412 and 502
Self Administered Medications

- EP1- Hospital can decide if self administration is allowed
  - If allowed, then need a written process to address training, supervision, and documentation to guide this process
- EP2 The hospital need to implement its written process (P&P) for self administered drugs

Self Administered Medications

- EP3 Patients and families need to be educated on the medication name, type and reason for use,
- EP4 Must include how to administer medication, including process, time, frequency, route, and dose (is it an oral drug, rectal suppository, given subq)
- EP5 Must include anticipated actions and potential side effects of the medication

Self Administered Medications

- EP6 Must include information to patient and families involved on how to monitor the effects of the drug
  - Such as how to take their pulse before taking a dose of Digoxin
- EP7 Must ensure patient or family member is competent before being allowed to administer medications
  - Would not leave a bottle of Nitro at the bedside of a patient who had Alzheimer’s disease
Investigational Drugs MM.06.01.05

- **Standard:** Hospital safely manages investigational medications
- **Rationale:** Investigational drugs can be of great help to the patient
- The hospital contributes to the safety of patients participating in investigational or clinical medication studies by controlling and monitoring the use of these medications
- 4 EPs

Investigational Drugs 06.01.05

- EP1: Hospital needs written process (P&P) that addresses the use including review, approval, supervision, and monitoring
- EP2: There is a written process for use of investigational medications specifies that the pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications

Investigational Drugs 06.01.05

- EP3: P&P 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: Hospital implements its process (P&P) for the use of investigational drugs
Investigational Drugs

Investigational Meds need to be safety controlled and administered

- Have a clear P&P for the reviewing, supervising and monitoring their use
- Nurses who administer need information on drug and its side effects
- Problematic standard

See ISMP recommendations on reducing errors in investigational drugs at http://www.ismp.org/pressroom/PR20071107_2.pdf
Medication Errors 07.01.03

- Standard: The hospital responds to actual or potential adverse drug events (ADEs), significant adverse drug reactions, and medication errors
- There are 5 EPs
- EP 1, 2, 3, and 5 apply to sample medications
- Medication errors are the most common type of medical errors
- RCA and FMEA are patient safety tools used by hospitals
- CMS will ask for 3 RCAs in QAPI worksheet

Medication Errors 07.01.03

- EP1 Hospital needs a written process (P&P) to respond to actual or potential adverse drug events, significant ADRs, and medication errors (ME)
  - If a medication error occurs what do you want the nurse to do?
  - Serious ones may necessitate an immediate call to the physician and nurse supervisor
  - Some may need just to fill out the incident report
  - Some may be reported to ADE hotline

Medication Errors 07.01.03

- EP2 Hospital has written process (P&P) that addresses prescriber notification in event of ADE
  - Physician or prescriber needs to know if patient vomited after pain medicine given or developed hives to new medication

- EP3 Hospital complies with external and internal reporting requirements of ADE and ME
  - Such as reports to the FDA MedWatch and alerts from USP, the FDA Safety Series, ISMP, Pa Patient Safety Authority, IHI, ASHP, and others
Medication Errors 07.01.03

- EP5 The hospital implements its process for responding to ADE, significant adverse drug reactions, and medication errors
  - Make sure staff know the hospital’s policy and procedure?
  - Are incident reports filled out as required by the P&P?
  - Do you use IHI adverse event trigger tool to identify errors and look for opportunities?

Medication Errors

- EP6 Medication administration errors, ADRs, and drug incompatibilities are immediately reported to the attending physician
  - As defined by the hospital (use national definition)
  - And report to the hospital wide PI program
  - This is for hospitals that use the TJC for deemed status
  - CMS requires definition of each and P&P must state when immediate notification of physician as if harm to the patient under Tag 508

Evaluation of Medications MM.08.01.01

- Standard: The hospital evaluates the effectiveness of its medication management system
  - Evaluation includes reconciling medication information
  - EP1 Hospital needs to collect data on the performance of its MM system
  - EP2 This data needs to be analyzed
  - EP3 The hospital compares data over time to identify risk points, levels of performance, patterns, trends, and variation of its medication management system
Evaluation of Medications

- EP4 The hospital reviews the literature and other external sources for new technologies and best practices.
- EP5 The hospital identifies opportunities for improvement based on the data analysis, literature searches, evidenced-based practice, and review of new technologies and best practices.
  - Do you have smart pumps, automated dispensing units, bar coding, CPOE etc.

- EP6 The hospital takes action on improvement opportunities identified as priorities for its MM system.
- EP7 Need to evaluate when changes made to confirm that it resulted in an improvement.
- EP8 If the improvement desired was not reached or sustained then need to take action.
  - Back to the drawing board.
  - See Medication-Use Evaluation Guideline at www.ashp.org/


ASHP Guidelines on Medication-Use Evaluation

Steps of the MUE Process

While the specific approach varies with the practice setting and patient population being served, the following seven steps occur in the ongoing MUE process.

1. Establish organizational authority for the MUE process and identify responsible individuals and processes.
2. Develop screening mechanisms (indicators) for comprehensive assessment of the medication-use system.
3. Identify the key stakeholders and use of important aspects of medication use.
4. Inform health care professionals and others as necessary of the practice setting’s goals about the objectives and expected benefits of the MUE process.
5. Establish criteria, guidelines, treatment protocols, and standards of care for specific medications and medication-use processes. These should be based on sound
Trigger Tool for Measuring Adverse Drug Events

The use of "triggers," or clues, to identify adverse drug events (ADEs) is an effective method for measuring the overall level of harm from medications in a healthcare organization. The Trigger Tool for Measuring Adverse Drug Events provides instructions for conducting a retrospective review of patient records using triggers to identify possible ADEs. This tool includes a list of known ADE triggers and instructions for measuring the number and degree of harmful medication events. The tool provides instructions and forms for collecting the data you need to measure the number of ADEs per 1,000 doses and the percentage of admissions with an ADE.

This tool requires:
- Background

Resources

- Medication station-identifying risks in medication use process,
- Evaluating risk points in your MM system,
- Performing medication reconciliation in short stay areas,
- After hours medication needs,
- http://www.jointcommission.org/Pharmacists/journal_articles.htm

CMS Memo March 14, 2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CMS Memo: 03/14/2014

Center for Clinical Standards and Quality/Office of Certification

TO: State Survey Agency Directors
FROM: Survey and Certification Group

DATE: March 14, 2014

SUBJECT: Requirements for Hospital Medication Administration, Particularly Involving IV Medications and Post-Operative Care of Patients Receiving IV Opioid Analgesics

Memorandum

- Inpatient administration: We are updating our guidance for the hospital medication administration requirements to:
  - Make clear that the current administration requirements apply to the routine intravenous (IV) administration of parenteral opioids and that some elements of the standard practice guidelines are not applicable to all situations (e.g., the required use of a non-drug administration pole in all situations).
  - Require restraints and sedation in addition to pain and anxiety management as appropriate.
  - Require that IV medications be given through a central venous catheter, or another appropriate site, if the patient is at risk for aspiration or other medical conditions.
  - Require the use of a pain scale for evaluating the effectiveness of opioid therapy and the need for additional pain management.
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  - Require the use of a pain scale for evaluating the effectiveness of opioid therapy and the need for additional pain management.

- Immediate Post-operative Care: Clarifications are also being made to the guidance for the routine administration of pain medication to patients undergoing surgery and procedures for patients requiring post-operative care. These changes are intended to clarify the role of the anesthesia personnel in the administration of pain medication and the responsibilities of the surgical team in the post-operative care of patients.
The End! Questions???

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Board Member  
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TJC 9 do not use abbreviations  
are in IM chapter, tracer and NPSG  
medication information also attached

IM.02.02.01 Do Not Use Abbreviations

www.jointcommission.org/facts_about_the_official/

<table>
<thead>
<tr>
<th>Do Not Use</th>
<th>Abbreviation</th>
<th>Use Instead</th>
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<tbody>
<tr>
<td>V.G. (v/g)</td>
<td>Use &quot;v/g or &quot;v/g&quot;</td>
<td>v/g or &quot;v/g&quot;</td>
</tr>
<tr>
<td>T.D. (oral)</td>
<td>Miswritten</td>
<td>Use &quot;oral or &quot;oral&quot;</td>
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<tr>
<td>IM (internal or oral)</td>
<td>Miswritten</td>
<td>Use &quot;oral or &quot;oral&quot;</td>
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<tr>
<td>IM.02.02.01</td>
<td>Do Not Use Abbreviations</td>
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</tbody>
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* Applies to all abbreviations and all medication related documentation that is handwritten in the patient’s record.  

*Exceptions: A "digivet" may be acceptable when regular and documented, the week or precision of the dose, the concentration used in modern practice, especially in addition to the requirements of the abbreviation that may be used in medication orders or other written record documentation.

Patient Flow  CAH and HAP Programs

- Surveyors are to interview staff during each of the individual tracers on what patient flow processes are being measured
- What other PI measures are in use
- What has the hospital learned?
- How has this data been used to make improvements
- Surveyor will look for variability in workload during the day and between days of the week
- Ask about wait, boarding, and turnaround times
Medication Management System Tracer

- Medication management will look at activity of tracing a patient who is receiving a high risk medication
  - Will go to the unit where the patient is located
  - Will evaluate the process and 8 steps in the MM chapter such as patient specific information, select and procure the medication, ordering, transcribing, dispensing, administration etc.
  - Will evaluate how the pharmacy reviews specific medications

Medication Management System Tracer

- Pharmacy
  - Will look at how pharmacy gets high risk medications and how they store it, and dispense it
  - Will evaluate drug security by the pharmacy
  - Will look at LASA issues
  - How does the pharmacy work with other departments and disciplines
  - How does pharmacy keep current on drug recalls
  - Will ask for copies of drug recall notices
Medication Management System Tracer

- Lab
  - Explore the role of the lab in evaluation of medication
  - Identify a trigger for lab testing (dig level for patient on dig, theophylline, INR for patient on warfarin, etc.)
- Dietary
  - Review any dietary restrictions
  - Evaluate if any dietary interactions with medications
  - Is there a process in place to educate the patient
  - May talk with a physician about prescribing issues
  - Discuss communication during hand offs

Medication Management System Tracer

- Conference room discussion
  - May ask the hospital to describe their process of the medical management system
  - May ask to summarize their strengths, vulnerabilities and risk points
- Additional issues during tracer
  - How does the staff and others report medication errors and near misses
  - How does the hospital determine if there is a system breakdown
  - What data is collected?

Medication Management System Tracer

- What is process for reporting abuses and losses of controlled substances?
- What is process to override automated dispensing unit?
- What PI is collected related to medications?
- What is P&P for medications brought into the hospital by patients?
- How does the hospital educate the staff and patient about medication safety?
Medication Management System Tracer

- How are patients involved in safe medication management?
- What is the role of information management in the role of medication management?
- What is the process to report, respond, and analyzed medication errors, ADEs and drug incompatibilities?
- What is the process for implementing standing orders including how they are developed, approved and how are they regularly reviewed?

Medication Management Tracer

- When was the last time the unit was informed of a drug recall?
  - How were you notified
    - Surveyor will look for recent recall notices
    - Will check the FDA website for safety alerts and recall notices at www.fda.gov/medwatch
  - You can sign up at FDA to get notices and ASHP has information on their website

Medication Management Work Tool

Medication Management - Work Tool

<table>
<thead>
<tr>
<th>Patient Identifier:</th>
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<tbody>
<tr>
<td>Medication Ordered</td>
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| Medication Ordered | Date Ordered | Time Ordered | Amount Ordered | Frequency | Route | Physician Review | Amount Administration | Time Administration |

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Blood Transfusion

- Will interview lab staff in the blood bank and the person hanging the blood about the following:
  - Protocol for unused blood products
  - Evaluation and maintenance of administration equipment
  - Data collection, communication and use
  - Storage when blood is not being used

NPSG Chapter Outline

- Goal 3: Improve the Safety of Using Medications
  - There are only 2 of the 5 sections left in and medication reconciliation now added
    - This is NPSG.03.04.01 (3D) on labeling of medications and
    - Also NPSG.03.05.01 (3E) on reducing harm from anticoagulants
  - There are 8 elements of performance to NPSG.03.04.01
    - 2010 revision to include the preparation date and expiration date and time
  - There are also 8 elements of performance to NPSG.03.05.01
Label all Medication

- Label all medications and medication containers (syringes, medicine cups, basins), and other solutions on and off the sterile field or procedural setting
- EP1 In perioperative and other procedural setting you must label all medications and solutions that you are not going to immediately administer
  - Need to do this even if only one medication is being used and even if obvious
  - Immediately administered medicines is where you draw it up and take it directly to the patient without any break in the process

Label all Medication and Solutions

2. In the perioperative and procedural setting, labeling occurs any time a medication or solution (normal saline) is transferred from the original packaging to another container

3. Need name of medication on label, strength, amount, quantity, diluent and volume, preparation date, expiration date if not used within 24 hours and time if expires in less than 24 hours
  - Preparation date was removed March 2010
  - Expiration date and time are required

Label all Medication and Solutions

- 4. All medications or solutions are verified by 2 persons verbally and visually if person preparing it will not be administering it
- 5. Label each medication or solution as soon as it is prepared unless immediately administered
  - Want you to prepare medications one at a time
- 6. Discard any unlabeled medication or solution immediately
7. Discard all labeled containers on the sterile field after surgery or procedure is done
   ▪ This means you saved the original containers until you are done
   ▪ Case of Ben Kolb who was given a concentrated dose of adrenaline instead of Lidocaine
8. Review all medication or solutions on and off the sterile field by entering and exiting staff responsible for MM
   ▪ Such as at the change of shift

Label all Medications 03.04.01

- Use extended definition of medicine by TJC
- Applies to anesthesia meds, and other procedural settings and not just invasive procedures
- Pre-labeled empty syringes or containers are not acceptable
- Can purchase prefilled, pre-labeled syringes for procedure trays

Label all medications

- MM.05.01.09 EP 3 and 4 state what has to be on label
- Label to include name, strength, amount (if not apparent from the container), expiration date if not used within 24 hours or if it expires in less than 24 hours, IVs date prepared and diluent
- Label can be developed by the facility or commercially available, Sterile labels can be purchased
- All labels are verified both verbally and visually by two qualified persons
- No more than one medication or solution labeled at one time
- Shift change or break, all meds and solutions and their labels are reviewed by entering and exiting persons
- Focus on single dose vials and multi-dose vials now
Anesthesia

- Would not apply if anesthesiologist draws up medication and immediately gives it and disposed of entire content of syringe without leaving area
  - Remember USP 797 requirements that drugs should not be prepared more than an hour in advance unless prepared in pharmacy
- However, if medication is prepared and slowly administered over course of procedure must be labeled
- Must be labeled if prepared for bulk of day’s cases or if prepared by someone other than the administering provider
- Use preprinted adhesive labels that can be applied to syringes and checked against original container
- Meds prepared by pharmacist in the OR would not require second person to verify

Anticoagulant Therapy 03.05.01

Requirement: Reduce the likelihood of patient harm associated with the use of anticoagulation therapy.

Rationale:

- This only applies to hospitals that provide anticoagulation therapy and long term anticoagulant prophylaxis such as atrial fib
- Does not apply to routine situations in which short term anticoagulant prophylaxis is used to prevent DVT or PE related to procedures or hospitalization
- If the expectation is that lab values for coagulation will remain close or within normal limits

Anticoagulants

- There are 8 EPs
  1. Use only oral unit dose products, prefilled syringes, and pre-mixed bags, when these products are available
    - Helps prevent compounding errors
    - Make sure preloaded syringes with pediatric doses for pediatrics patients when available
    - Big issue with the Joint Commission
Anticoagulants

2. Use approved protocols for the start and maintenance of anticoagulation therapy
   - Also appropriate to the condition being treated, and to the potential for drug interactions
   - Example would be Heparin protocol and Coumadin protocols

3. When starting a patient on Coumadin (Warfarin) you need to have a baseline INR and need INR on patients receiving this drug to adjust the dosage and document in the medical record

4. Use authoritative resources to manage potential food and drug interactions for patients taking Coumadin

5. Make sure all IV continuous Heparin is on an IV programmable pump in order to provide consistent and accurate dosing

6. Have a written policy that addresses baseline and ongoing lab tests that are required for anticoagulants
   - August 2010 Perspective changed removed “Heparin and LMW (low molecular weight heparin) therapies” and replaced it with “anticoagulants”

7. Provide education regarding anticoagulation therapy to prescribers, staff, patients, and families
   - Patient/family education includes the importance of follow-up monitoring, compliance issues, drug food interactions (dietary restrictions), and potential for ADR and interactions
   - Added prescribers to the list of those who need educated as reported in the December 2009 Perspective
Anticoagulants

8. Evaluates anticoagulation safety practices and take action to improve practices and measure how effective those actions are in the time frame set by the hospital

- See MM.08.01.01
- Hospitals should evaluate the effectiveness of its medication management system
- This is an important thing to do
- Collecting data on the performance of the medication management system can tell you if the process is working well or not

Anticoagulant Therapy

- Need a policy and procedure and make sure staff educated on policy
- Policy should address what lab tests are required for heparin and LMW heparin and baseline
- Patients on Coumadin need current INR to monitor and adjust
- Use approved protocols for the initiation and management of anticoagulant therapy

- Consider high risk such as double checks, product selection, dose calculation, patient identification, settings on IV pump, and proper IV line
- Have a formalized education program for both staff and patients
- To reduce compounding and labeling errors use only oral and parental unit dose and premix infusions
- Make sure all concentrations available are really needed
Anticoagulant Therapy

- Make sure you have enough IV pumps
- Make sure no more than one or two types of IV pumps (CMS hospital CoP requirement)
- Follow anticoagulant safety practices
- Medications should be clearly labeled
- Separate LASA and the Heparin errors
- Computer order entry, bar coding with eMAR, and automated dispensing units may help

Medication Reconciliation .03.06.01

- Standard: Maintain and communicate accurate patient medication information
- EP1 Obtain a list of medications the patient is taking when admitted or treated as an outpatient
  - The medications the patient is taking can be documented in another format that is useful to the hospital
  - Current medications include PRN medications
  - It is often difficult to obtain complete information on medications from some patients but a good faith effort must be made to get the information from the patient or other source

- EP2 The type of information to be obtained needs to be defined in non-24 hour settings and different patient circumstances
  - Examples would include the emergency department, primary care, outpatient radiology, ambulatory surgery and diagnostic settings
  - Medication information to be collected might include name, dose, route, frequency, and frequency
  - Patients are to be educated on medications under MM.06.01.03, PC.02.03.01 and PC.04.01.05
Medication Reconciliation .03.06.01

EP3 The medication information brought in by the patient needs to be compared with the medications ordered

- A qualified person, who is determined by the hospital, has to do the comparison
- Discrepancies would include omissions, duplications, contraindications, unclear information, and changes
- References HR.01.06.01 Staff are competent to perform their responsibilities

EP4 Provide the patient with a list or written information on the medications they need to take when discharged from the hospital or at the end of the outpatient encounter

- An example would be to include the name of the medication, dose, route, frequency and purpose
- The information is given to the family when indicated
- Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications
- References PC.04.02.01 about communicating to providers when the patient is discharged

EP5 Explain the importance of managing medication information

- This is to be done when the patient is discharged from the hospital
- This is also to be done at the end of the outpatient care provided
- This could be instructing the patient to give a list to their primary care physician
- Also to update the information list when medications are discontinued or added
- This should also include OTC medications
Medication Education

- MM.06.01.03 Self administered medications are administered safety and accurately (has 7 EPs)
- PC.02.03.01 The hospital provides patient education and training based on each patient’s needs and abilities (27 EPs but only 6 apply to hospitals)
- PC.04.01.05 The patient is informed and educated about follow-up care before discharge or transfer (8 EPs but only 6 apply to hospitals)

References

- Institute for Safe Medication Practices (ISMP) at www.ismp.org
- The Food and Drug Administration (FDA) at www.fda.gov
- The Institute for Healthcare Improvement (IHI) at www.ihi.org
- The Society of Health System Pharmacists (ASHSP) at www.ashp.org

Resources

- National Patient Safety Agency (NHS) at http://www.npsa.nhs.uk/
- American Society of Anesthesiologist (ASA) at http://www.asahq.org/
- Agency for Healthcare Research and Quality (AHRQ) at www.ahrq.gov
- Pa Patient Safety Authority (PPSA) at www.patientsafetyauthority.org
- Safe Medication at www.safemedication.com
Sound alike/look alike drugs

- Drugs with similar names can lead to medication errors,
- This is a partial list
- A complete list is available from the USP Medication Errors Reporting (MER) Program.
- Confusion can be between similar brand names and similar generic drugs,
- Some may look alike when written or sound alike when communicated verbally.

Preventing Errors from LASA Drugs

- See article on this from ISMP at http://www.ismp.org/msaarticles/nameprint.htm,
- Look for possible name confusion when adding a new drug to the formulary
- When feasible, use magnifying lenses
- Have good lightening in nursing stations
- Have copyholders under good lighting to keep prescriptions and orders at eye level during transcription to improve the likelihood of proper interpretation of look-alike product names

TJC Clarifies Multi-dose Vials
This presentation is intended solely to provide general information and does not constitute legal advice. Attendance at the presentation or later review of these printed materials does not create an attorney-client relationship with the presenter(s). You should not take any action based upon any information in this presentation without first consulting legal counsel familiar with your particular circumstances.

Thank you for attending!!

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