

Joint Commission Medication Management Standards in Radiology – 3rd Edition



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Instructional Objectives

After studying the information presented, the reader will be able to:

- Describe the rationale for the inclusion of imaging services in the organizational medication management plan.
- Discuss the role of the Joint Commission Medication Management Standards in initiating the changes in the management of medication processes in the imaging departments/services.
- Identify what patient information is needed to prescribe and administer medications safely.
- Describe the changes in procedures related to the identification of contrast media and contrast agents as medications.
- Discuss the appropriate method of securing medications prepared for use during an imaging procedure.

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“A well-planned and implemented medication management system supports patient safety and improves the quality of care.”

(The Joint Commission)

I. Introduction

The Joint Commission Medication Management Standards (Joint Commission) are among the most rigorous and challenging for an organization to implement, according to the article, *Maintaining Compliance* (Kienle, Uselton, Lee, 2008). Medication management standards, revised in 2014, (The Joint Commission, 2013) address all stages of the medication processes and are no longer viewed as primarily a pharmacy responsibility. The management of medications is considered a system-wide responsibility that impacts every clinical area in the facility.

Imaging services are assuming a more visible role in healthcare facilities. This increased visibility is directly related to the rapid development of sophisticated diagnostic technology as well as the increasing therapeutic use of imaging technology. As would be anticipated with this increase in activity and level of intervention, more regulations are being imposed to support the provision of safe and effective services.

Historically, imaging departments were not required to function under the facility’s medication management policies since the major substances used in imaging procedures were not classified as medications. With the increase in the administration of these substances as part of diagnostic evaluations and an identified increase in medication errors in these departments, the need to incorporate imaging into the medication management structure became a necessity. In 2004, the Joint Commission created specific expectations for contrast agents (Kienle, Uselton, 2008) by stating, “Contrast media are considered a medication.”

The second reason for the enhanced regulatory oversight is the change in the political climate of the world. The Homeland Security legislation and resultant regulations require all facilities that are storing and administering medications to take precautions to ensure the safe storage and use of medications (Frist, 2002). Medication storage is associated with the highest percentage of requests for information. The medication management standard for medication storage has three main areas: security, safety, and integrity (Kienle, Uselton, 2008). The security of pharmacologic agents is mandated by federal standards. The security is to protect the public being served and the individuals who are working with these medications. For most imaging departments, new ways to address the storage, maintenance, and administration of these medications were needed.

II. Regulatory Agencies

The major change in regulations affecting imaging services occurred in 2004 when the Joint Commission developed new and revised standards for medication management. This amendment was the first time the Joint Commission directly identified contrast media as a medication and required the inclusion of imaging into the facility medical management plan.

With the development of medical management standards, the Joint Commission included the following statement:

“For the purpose of these standards, *medication* includes prescription medications, sample medications, herbal remedies, ...diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions, radioactive medications,... intravenous solutions (plain, with electrolytes and/or drugs) and any product designated by the Food and Drug Administration (FDA) as a drug.” (Joint Commission, 2007, p MM-1)

This statement from the Joint Commission made it clear that imaging services are now to be included in the medical management plan the same way as all other services where medications are used.

The FDA also includes contrast media in the medication category. The definition of a drug used by the FDA in making this determination is:

- A substance recognized by an official pharmacopoeia or formulary
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
- A substance (other than food) intended to affect the structure or any function of the body
- A substance intended for use as a component of a medicine but not a device or a component, part, or accessory of a device

The third major regulatory agency that directly impacts the medical management process in imaging departments is the Center for Medicare and Medicaid Services (CMS), the governmental organization that administers Medicare and Medicaid programs. CMS develops standards for the provision of safe and quality care and services. CMS has given the Joint Commission deemed status, which means that the Joint Commission acts on behalf of CMS when surveying organizations for compliance with standards and regulations.

III. Definitions

The Joint Commission defined the major terms used in the medical management standards chapter. These terms and other definitions are found in the glossary supplied by the Joint Commission in the standards documents. The following words, which are components of the medical management system, are important for the discussion of medical management by imaging services and staff.

Medication Management. The process an organization uses to provide medication therapy to patients. The medical management system includes eight processes. The definitions for each process follow:

Planning. A hospital plans its medication management processes.

Selection. A safe and appropriate selection of medications for use and procurement.

Storage. Safely storing the medications in all places in the organization including emergency medications and medications patients bring in from home.

Ordering. Synonymous terms for when a licensed independent practitioner transmits a legal order of prescription. This directs the review, preparation, dispensing, and administering of a specific medication to a specific patient.

Dispensing. Activity needed to get a medication ready for administration exactly as ordered including providing, labeling, furnishing or otherwise making available a supply of medications to the individual for whom this was ordered, or to his/her representative, by a licensed pharmacist. Dispensing does not involve providing a patient a dose of medication previously dispensed by the pharmacy.

Administering. Provision of a prescribed and prepared dose of an identified medication to the individual for whom it was ordered, including directly introducing the medication into or onto the individual's body.

Monitoring. Ongoing evaluation of a patient to whom a medication was administered, to ascertain the effectiveness and efficacy of the medication therapy and to prevent the occurrence of any serious adverse outcomes. This includes responding to actual or potential adverse drug events, reactions, and/or errors.

Evaluating. Measurement of the effectiveness of the medication management system including confirmation of areas of compliance and defining areas which would benefit from system improvements. (Joint E-dition, 2009)

IV. Medication Management Standards

The medication management standards apply to the entire organization; they are not limited to pharmacy issues (Kienle, 2015). The Joint Commission categorized the medication management standards into eight critical processes (Joint E-dition, 2009).

1. Planning

Planning processes for medication management are multidisciplinary, but traditionally, these processes have excluded imaging services personnel. Because of the recent focus on imaging areas, physician and clinical directors of radiology, interventional radiology, and nuclear medicine need to be included in an organization's planning process to ensure consistency of practice and address the unique needs of the areas (Kienle, 2015).

The first Joint Commission standard, **MM.01.01.01**, addresses the need to plan each part of the system with the goal of providing medications in a safe manner at a defined and measured level of quality. To accomplish this, the organization needs to develop, adopt, and communicate policies all are expected to follow.

Standard MM.01.01.01 focuses on policies that define the need to ensure all required patient information is accessible to all who participate in the medication processes.

- Patient's age
- Sex of patient
- Diagnoses
- Allergies
- Current medications
- Patient's height and weight (when necessary)
- Any laboratory results (when necessary)
- Any additional information required by the organization (Joint, E-dition, 2009).

It is easy to see that medications, except in an emergency situation, cannot and should not be given to a patient until there is sufficient knowledge about that patient to minimize the risk of an adverse event from an ordered and administered medication.

To meet this standard,

- The organization should have a written policy stating what information should be available to the staff in order to prescribe and administer medication safely.

- From the perspective of the imaging staff, adequate time must be available to receive this information, and staff must know when the medication should not be administered as ordered.
- Through a review of error-related information provided to the Joint Commission, it is clear that the lack of patient information is a major contributor to the commission of these errors. The Joint Commission has directed that the patient's age, sex, current medications, diagnoses, comorbidities, relevant laboratory values, and allergies are known before medication processes such as ordering, and administering are implemented (Joint E-dition, 2009).

Much of the information about the patient should be obtained as a part of the patient hand-off procedure developed for each facility and discussed in a later part of this booklet (The Joint Commission, 2007).

This same standard addresses the requirement to report drug abuse or losses of any controlled substances. Often, staff may be aware of drug abuse by patients or by other staff but do not feel it is their responsibility to report this information. Many individuals feel that the identification of these issues of abuse belongs to the doctor or the supervisor. Neither the law nor the Joint Commission standard indicates who is responsible for reporting these abuses. It is expected that reporting is the responsibility of anyone with knowledge of this abuse.

The Joint Commission includes a standard dealing with contracted services (Joint Commission, CAMH, 2007). Radiopharmaceuticals dispensed from a nuclear pharmacy that is not part of the hospital organization need to comply with the Joint Commission standards in Joint Commission-accredited organizations. Hospital executives must know of the outsourced service, approve of the outsourced service, and establish and monitor expectations for the performance of the contracted service.

Standard **MM.01.01.03** states, "The hospital safely manages high-alert and hazardous medications." (Joint E-dition, 2009)

High-alert medications have been identified by staff in each organization as well as by agencies that are closely involved with safe medication practices. These medications are generally those that are more likely to be abused than others or that are known to be involved in a greater number of errors than other medications. Examples of these medications are heparin and insulin (errors) and prescribed pain medications (abuse). High-alert medications also include look-alike, sound-alike medications that are more prevalent today as we are dealing with multiple drugs in similar categories with names that are difficult to differentiate.

Standard **MM.01.02.01** states, “The hospital addresses the safe use of look-alike/sound-alike medications.” A list of these medications is developed and distributed to those who need this information. This list is reviewed annually and updated as appropriate.

As with all standards, steps are taken to reduce the likelihood of medication errors when using look-alike/sound-alike medications.

Hazardous medications are those in which “studies indicate that exposures to them have a potential for causing cancer, developmental or reproductive toxicity, or harm to organs.” (Joint E-dition, 2009) Using an evidence-based process for care delivery will help identify these medications and their level of risk for a given individual.

To meet this standard, hospitals must have a written list of high-alert and hazardous medications. This list must be communicated and available to all who are involved in the medication management processes. Additionally, there must be a plan as to how the presence of high-risk or hazardous medication is managed in the organization. Staff involved in the ordering or administering of these medications need to be made aware of this management plan.

Hazardous drugs are identified by matching the National Institute for Occupational Safety and Health (CDC NIOSH 2016) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (CDC NIOSH 2016) against the drugs on a hospital formulary.

Radiopharmaceutical agents listed on the NIOSH list should be included on the hospital list of hazardous drugs if those agents are used in the facility. The safety steps taken for protection of patients, employees, and the environment should be included in the hospital’s policy and procedure. Hospitals must have Material Safety Data Sheets (MSDS) readily retrievable for all chemical agents and medications used within their facilities (Kienle, 2015).

Contents, storage, and use of emergency medications in the imaging areas must be addressed. Code carts, reaction kits, and other medications used for emergency treatment must comply with the hospital’s policy and process for emergency medication containers. This may include establishment of the contents through the Pharmacy and Therapeutics Committee (P&T) and a numbered seal applied to the completed container by the hospital pharmacy. The clinical department is usually responsible for logging the seal number daily to demonstrate the availability of the emergency container and the integrity of the seal. The Joint Commission now has a new complementary tool, *Safe Handling of Hazardous Drugs*, available (Joint Commission Resources, 2016).

2. Selection of medications for use and procurement

Standard **MM.02.01.01** pertains to selection and procurement of medications for which members of the medical staff, licensed independent practitioners, pharmacists, and staff may be involved in ordering, dispensing, administering, and/or monitoring the effects of medications and are responsible for developing written criteria for determining which medications are available for dispensing or administering to patients.

Note: This standard applies to sample medications anywhere in the facility and/or facilities (Joint Commission Revisions, Prepub, 2013).

Standard **MM.02.01.01** states that available medications are selected and procured based on identifiable criteria, including indication for use, effectiveness, drug interactions, potential for errors and abuse, adverse drug events, sentinel event advisories, other risks, and costs (Joint Commission E-dition, 2009). A multi-disciplinary committee (P&T Committee) (Kienle, 2015) is convened on a regular basis to develop criteria, which will be used to determine “which medications are available for dispensing or administering to patients.” (Joint E-dition, 2009)

Medications used in an organization must be listed in the formulary. This mandate includes contrast media and radiopharmaceuticals, which traditionally were not extensively reviewed by the P&T Committee process because they were used in specialty areas. Introduction of a controlled substance radiopharmaceutical (DatScan, 2011) into the marketplace has brought new challenges with it. Controlled substances must meet stringent federal and state ordering, access, and monitoring regulations and procedures, which are different from other agents.

Prior to the changes in the Joint Commission standards related to medication management, many imaging departments selected and procured medications (contrast agents) independent of the pharmacy, or in consultation with the pharmacist, but not as a part of the established system for the selection and procurement of medications. It was believed that contrast agents were not medications and that the leadership in the imaging department was the most knowledgeable in selecting and procuring these agents by working with the appropriate vendors.

To meet this standard:

- Appropriate members of the medical and staff leadership in imaging need to be appointed to serve on the committee or body, which addresses selection and procurement of medications.

- All the medication-related policies in the facility need to include imaging services and how each policy impacts each department and each member of the staff.
- Methods to monitor the patient response to medications new to the hospital formulary need to be in place before the medication is used.
- Additional standards addressing approval, selection, medications substitutions/outages are listed in the Joint Commission Standards Manual. Management of these processes should be documented in the pharmacy policy manual.

3. Storage

Joint Commission Standard **MM.03.01.01** (Joint Commission E-dition, 2009) ensures that all medications are stored safely throughout the hospital. This standard also applies to medication samples. The hospital stores medications according to the manufacturer's recommendations or, in the absence of such recommendations, according to a pharmacist's instructions (Joint Commission, 2013).

Storage of contrast media, radiopharmaceuticals, and adjuvant medications must comply with regulatory standards. Requirements for storage are grouped into three areas:

- Security of the medication. CMS Conditions of Participation (CoPs) require that medications be secure, and locked when required by regulation or hospital policy. Controlled substances must always be locked.
- Safety of its use. Safe medication storage is defined by hospital policy. Best practices, including separation of look-alike and sound-alike medications and injection safety, should be general practice.
- Integrity of the dosage form, such as expiration dating and temperature control. Assuring that a medication is within expiration date defined by the manufacturer and adherence to manufacturer's recommendations when items are moved, such as from refrigerator storage to room temperature storage.

Medication storage policies must address the related laws and regulations regarding storage and security such that medications are only accessible to authorized personnel.

- The only drugs that should be routinely stocked are those on the approved formulary.

- Medications need to be secured to maximize availability while reducing risks for medication diversion. This includes the storage of emergency medications.
- The storage needs to be planned in such a manner that reduces the risk for dispensing errors.
- Narcotics must be secured and controlled according to the standard procedures in the facility.
- All stored medications need to be labeled with the contents, expiration date, and any warning regarding the use of that medication.
- All medication storage areas need to have regular inspections to check for security and currency of drugs being stored.

Note: CMS defines secured as meaning “all medications...are in locked containers in a room or are under constant surveillance” (Federal Register, 2006, 42 CFR Part 482). This would mean that medications, including contrast media, cannot be left unattended at any time, even during the preparation for the procedure to be done. This also pertains to medications that have been drawn up in a syringe for administration at a later point in a procedure.

Standard **MM.03.01.03** states, “The hospital safely manages emergency medications.”

Patient emergencies occur frequently in healthcare settings. Therefore, the hospital must plan how it will address hospital emergencies and what medications and supplies it will need (Joint E-dition, 2009) (Uselton, Kielne, Murdaugh, 2008). Emergency medications must be consistently available in the most ready-to-use form and must be replaced as soon as possible after use. In the past, some imaging departments developed a separate storage box for emergency medications without need for approval from the pharmacy approval body in the organization. This is no longer an acceptable part of the medication management plan for the organization nor consistent with the Joint Commission standards. According to the Joint Commission, 43% of the hospitals surveyed in 2007 were not compliant with one or more of the Elements of Performance (EOP) for this storage-related standard. Examples of this non-compliance include the findings that medication carts and medication rooms are not locked, medications are left unattended on the top of medication carts or counters, controlled substances are not reconciled at the end of the shift, and unauthorized storage or a ‘stash of medications’ are found. These elements apply to medication samples, as well.

Standard **MM.03.01.05**, states, “The hospital defines when medications brought into the hospital by patients, their families, or licensed independent practitioners can be administered.” This statement applies to sample medications, as well.

The hospital controls the use of such medications to ensure safe and appropriate medications are being used by the patient (Joint E-dition, 2009), including all standards and or elements related to sample medications.

Before medications are administered to a patient in the hospital, these medications must be identified and visually evaluated to determine the medication’s integrity. The medication will be sent to the pharmacy for identification, no matter what the label may indicate. This gives the pharmacist the ability to identify the medication and to inspect the medication to make certain it is not damaged in any way that is visible. When a medication cannot be identified, it cannot be used in the hospital.

This type of situation may be less of a problem for those who are practicing in the radiology department since medications that are used for radiological procedures are generally not those that can be brought in from outside the facility. Hospital outpatients may wish to take a medication they have brought with them to an appointment. At this point in time, unless this would be prohibited because of the procedure to be performed, the medication can be taken but not administered by a member of the staff.

4. Ordering, prescribing, and transcribing

Standard **MM.04.01.01** is related to ordering of medications. The direct meaning of this standard is, “medication orders are clear and accurate” (TJC, 2013). The EOP (EOP, 2013, Standard MM.04.01.01) also apply to sample medications. Imaging areas rely on the use of protocols for provision of many medications. Traditionally, the medical director of radiology established the procedures to be used with the imaging areas. CMS state, and Joint Commission accreditation regulations and standards and best practices now require that the function of review and approval of all protocols be carried out by the P&T Committee. If protocols are used, they must comply with regulatory and Joint Commission accreditation standards:

- Use evidence-based practice (EBP) standards.
- Required elements of the order are (Kienle, 2015):
 - ✓ Name of patient
 - ✓ Age and weight of patient, or other dose calculation requirements where applicable
 - ✓ Date and time of orders

- ✓ Drug name
- ✓ Dose, frequency, and route
- ✓ Exact strength or concentration when applicable
- ✓ Quantity and/or duration when applicable
- ✓ Specific instructions for use when applicable
- ✓ Name of prescriber
- Unambiguous orders
 - No use of prohibited abbreviations or dose designation. All organizations prohibit the use of the following:

U	IU
QD	QOD
MS	MSO ₄
MgSO ₄	
 - ✓ Doses involving decimals must be correctly stated:
 - ✓ Doses less than one must have a leading zero, use 0.5 mg not .5 mg.
 - ✓ Doses of whole numbers should not have a trailing zero, use 5 mg, not 5.0 mg.
- A method to monitor and assess the effectiveness of the protocol must be in place by the organization to detect and improve any non-compliant issues.

Much of the content of this standard is derived from the analysis of medication errors and is intended to lead to a reduction in those errors.

All organization staff should review the hospital policy addressing the various types of medication orders approved for use in the facility in which they are working. The types of orders may include PRN (when necessary) orders, standing orders, automatic stop orders, and titrating orders (often used in interventional radiology), among others. It is important to know the required elements of a complete order so the order is not carried out until all the elements are addressed. Even if the staff believes they know what is intended, the written order must be complete before being implemented (Joint E-dition, 2009).

The **Ordering** category has imposed some of the most significant changes on the imaging staff, compared with other categories.

Prior to the identification of contrast agents as medications, rules such as obtaining a written order were not consistently implemented since it was felt that written orders did not need to be in place for diagnostic contrast agents. Now, all the rules and regulations pertaining to the ordering and transcribing of medication in the organization pertain to contrast agents in the imaging department as well.

Some of the EOP of standard **MM 04.01.01** are:

- Definition of specific medication orders
- Written policy defining the components of a medication order
- Written policy on indication for use
- Precautions for ordering look-alike/sound-alike drugs
- Written policy defining what to do when there are illegible, incomplete, or unclear orders
- Written policy minimizing verbal and/or phone orders
- Prohibits “resume previous medications”
- Requires a diagnosis, condition, or indication for each medication ordered

The Joint Commission also provides standards addressing comparability of care across the organization. This means that, for the same process, there cannot be a difference in standards between departments, services, and populations. When this is applied to the **ordering** category in medication management, it means:

- The classification of personnel who are authorized to accept medication orders, including verbal and telephone orders, needs to be defined and included in the medical staff rules and regulations.
- All of the individuals in these positions need to meet the same criteria, regardless of the departments in which they are working.
- The criteria for what constitute a complete order are the same in imaging as they are in the rest of the facility.
- The Joint Commission standard on the read-back of any verbal or telephone order is followed using the same process as is used in the rest of the facility (The Joint Commission, 2007, 2A).
- The Joint Commission standard defining the Do Not Use list of abbreviations is followed (The Joint Commission, 2007, 2B).
- The monitoring of each of these elements is included in the overall continuous quality improvement activities when addressing elements of medication ordering and transcribing.

According to the Joint Commission, 26% percent of the hospitals surveyed in 2006 were not compliant with one or more of the EOP for standard MM.04.01.01. That number decreased to 20% in 2007 (Kienle P, Uselton, 2008). In 2015, the Joint Commission reported that non-compliance with medication orders was 25% (Mansur, 2015). Because of this non-compliance with **MM 04.01.01**, the Joint Commission states, “policies must be developed that describe required elements for medication orders, and surveyors will review compliance with those policies.” According to the Joint Commission, if titration orders are used (often in

radiology), the organization must have a policy in place delineating what must be included in the order.

The major aspects of non-compliance are:

- Orders are not legible or complete.
- PRN orders do not have an indication for use.
- Staff does not have knowledge to address the use of verbal orders, automatic stop orders, or unacceptable orders such as “resume previous medications.”

In 2007, the Joint Commission modified the interpretation of **MM 05.01.01** (formerly MM 4.10) to allow for intravenous (IV) contrast and the role of the licensed independent practitioner (LIP) defined through protocol and policy, in the direct supervision and timely intervention of a patient during and after IV contrast media is administered. The protocol/policy must be approved by the medical staff and the role of the LIP must be defined so that there can be timely intervention by the LIP in the event of a patient emergency.

Standard **MM.05.01.09** states, “Medications are labeled.” (Joint Commission, 2013) There is a need for a pharmacist to review the appropriateness of all medication orders for the medications dispensed in the hospital (Joint Commission E-dition, 2009). The EOP for this standard requires:

- Medication containers are labeled whenever medications are prepared but not immediately administered.
- Information on medication labels is displayed in a standardized format, in accordance with law, regulation, and standards of practice.
- All medications prepared in the hospital are correctly labeled with the following: medication name, strength, and amount (if not apparent from the container).
- A pharmacist must review all medication orders BEFORE dispensing or removing medications from floor stock or an automated storage and distribution device.

Exceptions to this standard are when a LIP controls the ordering, preparation **and** administration of the medication or when a delay in administering medication would harm the patient (Joint Commission E-dition, 2009).

The standard defines the process to be followed when there is less than 24/7 on-site pharmacist coverage (Joint Commission E-dition, 2009).

This process is particularly important for the staff when medications are removed from their original container but are not immediately administered. The label must include the drug name, strength and amount, the expiration date when not used within 24 hours, the expiration time when expiration occurs in less than 24 hours,

and the date prepared or if a diluent was used and its name and volume, if not written on the container (Joint Commission, E-dition, 2009).

If medications are prepared for multiple patients, the label must also include the patient's name, the location where the medication is to be delivered, directions for use, and any additional applicable instructions (Joint E-dition Commission, 2009). This also pertains to sample medications. In imaging, where patients may be moved from place to place, preparing medications for more than one patient should be avoided, if at all possible, and medications should be prepared in the room in which they are to be administered, whenever possible.

If a medication is prepared by someone other than the person who will be administering the drug, the label needs to include the location where the medication is to be delivered. Again, it is recommended that the drug is prepared in the room where it will be administered and by the person who will be administering the medication or who will be handing the prepared medication to the physician for administration.

Contrast media

Since 2004, when contrast media was determined to be a medication, there has been significant discussion, debate, and revisions per the need for pharmacy review of orders for various types of contrast media before being administered. Initially, an interim standard was developed that included few changes to the original practice while encouraging the radiology community to develop processes that would address patient safety issues as well as the practical issues related to administration and the pharmacy review of these orders. Currently, the Joint Commission standards represent the significant efforts of the radiology community to meet the goals of safety and efficacy. It is important for radiology staff authorized to accept orders and to administer medications in the department to stay abreast of any changes in these standards as they are updated.

- The administration of oral and rectal contrast media without prior pharmacist review constitutes a safe standard of practice (ACR, 2016). These media can be administered without pharmacist review as long as the following is in place:
 - The organization has approved clinical practice guidelines (protocol) and screening tools in place for the safe administration of contrast media. If the facility is a hospital, the guidelines and tools need to be approved by the medical staff and pharmacy.

- Those who can retrieve the medications from the place where they are stored are designated and trained to perform this function.
 - ✓ Only authorized licensed staff can retrieve medications. Radiology Technologists can only access medications they are authorized to administer.
 - ✓ Only RNs or MDs have access to medications other than contrast media.
- There are quality control procedures in place to identify and prevent retrieval errors.
- The appropriateness of the contrast media is reviewed by a qualified healthcare professional.
- A pharmacist is available on-call.
- There are retrospective processes in place to evaluate the system. This is to include sampling of records where there was no prior review by the pharmacy (ACR, 2016).

There are two disclaimers to this clarified process. The first is that this does not pertain to orders for contrast agents dispensed to an inpatient floor for administration if the testing to be done is not urgent. Secondly, this does not apply to the use of contrast agents by routes other than those administered orally or rectally (Joint Commission Perspectives, 2006, p 9).

It is important that staff providing care in the imaging department is aware of approved guidelines and screening tools, to receive education based on these guidelines, and tools and to demonstrate competency in their use. Staff must gain an understanding of signs and symptoms of allergic reactions, the general treatments for allergic reactions, and an understanding of potential adverse drug events.

For IV contrast media, the hospital radiology staff will be “allowed to define, through policy or protocol, the role of the LIP in the direct supervision of a patient during and after IV contrast media is administered” (ACR Practice Parameters, 2014, p 2).

The role of an LIP is must be defined to ensure there is timely intervention by this LIP if a patient emergency occurs (ACR Practice Parameters, 2014, p 2). Both the medical staff and the pharmacy committee must approve all policies and protocols related to medication administration. If a medication needs to be given that is not included in a protocol, a qualified physician or pharmacist must review the appropriateness of the medication.

As a follow-up, the organization will retrospectively evaluate the implemented system by taking a sample of records where contrast media was administered

without prior pharmacy review to determine if the process is working as designed. This review will also help determine if there are any opportunities for improvement of the processes being evaluated (Joint Commission Perspectives, June 2005, August, 2006, January 2007).

5. Dispensing

An additional practice to be considered by radiology management is the practice of dispensing forms of contrast and preparation drugs directly to patients. Generally, these are given to outpatients, so the patient can prepare for the procedure.

Many facilities have stopped this practice and provide information and/or prescriptions for the needed medications instructing the outpatient to obtain these preparations as they would any other prescribed medication. For in-patients, a medical order can be written in the record and the medication can be appropriately dispensed from the pharmacy.

Standard **MM.05.01.11** states, “The hospital safely dispenses medications.” (Joint Commission, 2013) The EOP for this standard require:

- The hospital dispenses quantities of medications that are consistent with patient needs.
- The hospital dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice.

Note: Dispensing practices and recordkeeping include anti-diversion strategies. This EOP is also applicable to sample medications.

Dispensing of medications is limited by law to qualified pharmacists and physicians. In a hospital, dispensing is limited to pharmacists unless otherwise provided for by hospital policy.

Use of a contracted nuclear pharmacy introduces a situation different from provision of other medications in the hospital, since the orders for radiopharmaceuticals and adjunctive nonradioactive medications are typically transmitted from the hospital or clinic’s nuclear medicine department to the outsourced vendor’s nuclear pharmacy. Ordered doses are then typically dispensed and delivered from the vendor of the nuclear pharmacy to the customer hospital or clinic’s nuclear medicine department.

Consistency of sterile compounding practices was introduced by U.S. Pharmacopeial Convention (USP) <797>, Pharmaceutical Compounding—Sterile Preparations,

where a section specifically deals with preparation of radiopharmaceuticals. Non-radiopharmaceuticals must be prepared with the more stringent provisions of the

full Chapter. Most medication orders, both radiopharmaceutical and non-radioactive adjunctive medications within hospital nuclear medicine departments and medical clinics, must be prepared under the full provision of USP <797>. Use provision must comply with all of the requirements, including aseptic technique and specific issues related to the number of punctures (Kienle, 2015). The regulatory and Joint Commission requirement for oversight of the preparation of radiopharmaceuticals has come under focus during surveys. General expectations include oversight by either the pharmacy services or a physician who is qualified to assess the preparation of sterile medications.

Standard MM.05.01.17 states, “The hospital follows a process to retrieve recalled or discontinued medications.” (Joint Commission, 2013) The EOP for this standard state:

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

Standard MM.05.01.19 states, “The hospital safely manages returned medications.”

- The hospital implements its process for managing unused, expired, or returned medications.

Standard MM 05.01.03 states, “The hospital safely obtains medications when the pharmacy is closed.” The rationale for this standard is as follows, “...the hospital provides for the patient’s urgent or emergent medication needs when the pharmacy is closed.” (Joint E-dition, 2009) In general, the hospital must provide an approved way of getting pharmacist coverage or consultation 24 hours a day. There must also be a system in place allowing defined individuals who are trained and approved, to obtain medications from a secured storage area outside of the pharmacy.

6. Administration

Standard **MM.06.01.01** states, “The hospital safely administers medications” (Joint, E-dition, 2009). Staff in imaging departments must follow the same medication administration policies as others in the organization that administer medications.

- The facility policy addresses the classifications of employees who may administer medications and any limitations regarding what may be administered, by classification. For example, radiology technologists may be allowed by licensure, state regulation, and/or hospital policy to administer certain contrast agents but may not be authorized to administer other oral or intramuscular medications. Registered nurses may administer specifically approved IV medications but may not have authority to administer some of the agents used for conscious sedation.
- Radiology technologists should be specifically listed to administer oral, rectal, and IV contrast media, and nuclear medicine technologists should be listed in the hospital policy to administer radiopharmaceuticals. Nuclear medicine technologists may also administer other non-radioactive adjunctive agents (Kienle, 2015).
- A similar definition of who in imaging can administer what level of medications needs to be developed and approved by the medical staff. This is then documented in the medical staff rules and regulations.

It is further noted in this standard that before a medication is administered, the person administering that medication needs to inspect the medication for signs of “loss of integrity” (Joint E-dition, 2009) and to verify that the medication has not expired.

CMS regulations and the Joint Commission accreditation standards require a pharmacist’s review of an order prior to administration, with a possible exception (if permitted by hospital policy) for urgent situations. The Joint Commission also allows a possible exception to a pharmacist review (if permitted by hospital policy) if the LIP is immediately available to oversee the ordering, preparation, and administration of the medication.

Additionally, before a patient receives a new medication, they (or their family) need to be provided information about any “clinically significant adverse drug reactions.” (Joint E-dition, 2009) In radiology, this will be an important discussion to have since, for many, the substances used in some radiological procedures represent the first time a patient has received these medications/substances.

Staff members who administer medications should also follow the classic five rights of medication administration to ensure consistency in practice. The reduction in variation in processes contributes to the reduction of medical errors. Since medication administration errors are the number one medical error committed in facilities today, following a prescribed routine is essential.

The five rights of medication administration are (Iyer, 2001, p 494) (Grissinger, 2010):

- 1) Right patient
- 2) Right drug
- 3) Right time
- 4) Right dose
- 5) Right route of administration

These rights are generally part of medication administration policies. They are also a part of most literature discussing nursing practice or malpractice. Therefore, they do set a community or national standard that is used in most litigation on issues related to accurate medication administration (Iyer, 2001, p 494):

- All who administer medications should complete an educational course on the state and facility regulations regarding this procedure. This educational offering should include a review of the Joint Commission medication management standards for those who are accredited by Joint Commission. For those facilities that are accredited by another agency, there should be a review of the related medication management standards.
- All who administer medications should have this responsibility included in their job description.
- All who administer medications should meet the defined competencies for safe administration of these medications.

The Joint Commission's National Patient Safety Goal (CAMH NPSG. 01.01.01) requires use of two hospital-designated patient identifiers when administering medications. Even if the patient has been positively identified in the waiting room, the two identifiers must be confirmed just prior to administration of the medication. Such identifiers are determined by the department staff and must be used consistently by all staff in that department.

It is common practice to use these identifiers when first meeting the patient or when one is about to begin a procedure. These identifiers must be used every time medication is administered to a patient, even if the person administering the medication is certain they know this patient and feel they do not need to validate their identity.

- All staff should be aware of the identifiers that have been defined for their department.

Regulatory and accreditation standards require documentation of all medications administered to a patient. The documentation must specify the elements required by hospital policy, and generally include the medication name, strength, dose, route, access site, administration devices used, and rate of administration (Kienle, 2015).

7. Monitoring

Standard **MM.07.01.01** states, “The hospital monitors patients to determine the effects of their medication(s).” (Joint Commission, 2009) The EOP further states:

- The hospital monitors the patient’s perception of side effects and the effectiveness of his or her medication(s).
- The hospital monitors the patient response to medication(s) by taking into account clinical information from the medical record, relevant laboratory values, clinical response, and medication profile.

Each hospital has a Performance Improvement Committee, which is charged with evaluating the practices within the institution, overseeing quality assurance and performance improvement activities, and monitoring for achievement of goals and sustainability of practices. Medication management activities commonly are included in this process, which are medication error reviews that monitor adverse drug reactions and other processes established around the medication use system.

Medication errors, adverse drug reactions, and incompatibilities must be reported to the attending physician and the hospital’s performance improvement program. State and federal regulations will further delineate cases and circumstances in which reporting must be filed to regulatory agencies. If oral contrast is distributed and managed by radiology (and not by pharmacist review of the patient’s order), a process must be in place to ensure that the protocols are being followed (Kienle, 2015).

The requirement to have a system in place for determining the “effects of medications” that are administered (Joint E-dition, 2009), has always been an overall part of the evaluation of patient status; however, it is now a separate standard. The intent is to demonstrate the significance of continuously monitoring the patient’s response to medications used as a treatment or as a part of a procedure.

8. Evaluation of the system

Evaluating a medication use system in radiology comprises several different areas (Kienle, Uselton, 2008, p 17):

- Compliance with regulatory requirements, including the Nuclear Regulatory Commission, CMS, state hospital and board of pharmacy requirements, federal and state Drug Enforcement Administration regulations
- Compliance with accrediting organizational standards
- Clinical indicators, as determined by the department in concert with the hospital's quality assurance and performance improvement plans
- Use of evidence-based medical practices and best practices established by applicable radiology and pharmacy organizations (Kienle, Uselton, 2008, p 17).

Evaluation of a medication management system is completed most often by a team of physicians, nurses, and pharmacists who consider the total clinical information available regarding the status of the patient after receiving the prescribed medications. Other disciplines that interact with the patient can and should provide signs or symptoms they observe while providing care to any patient.

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

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

Standard **MM.08.01.01** states, "The hospital evaluates the effectiveness of its medication management system." EOP for this standard state:

- The hospital collects data on the performance of its medication management system.
- The hospital analyzes data on its medication management system.
- The hospital compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management system.
- The hospital takes action on improvement opportunities identified as priorities for its medication management system.

Each time a patient is given a medication by any route, he or she should be monitored to determine the response to the medication and for any adverse reaction to that medication. This is particularly relevant for the first dose of a new

medication since it is important to determine if the patient has any negative reactions to that new medication before additional doses are administered (Joint E-dition, 2009).

In the case of contrast media, the patient is generally receiving this media for the first time and should be monitored closely after this initial administration for signs of allergy or any other adverse reactions.

Compliance with Standard **MM.07.01.03** is demonstrated by:

- Having a written process addressing notification and response requirements when an adverse drug event or a medication error occurs
- Complying with all internal and external reporting requirements
- Ensuring that incident reports are completed on all near-miss events as a method of identifying risk points in a medication management process (Joint E-dition, 2009)

All staff involved in a medication management system can provide input in many ways by:

- Completing incident report forms for all medication errors and all near-miss medication errors
- Collecting and reviewing data on the medication administration processes that are being measured in the department or facility
- Participating in root-cause analyses when an adverse event occurs
- Serving on committees and task forces that focus on medication management and/or patient safety
- Actively implementing revised processes developed as a result of the review of the medication management system

The requirements for **MM.08.01.01** pertain to sample medications, also.

Note: The Joint Commission recently announced a new medication management standard for hospitals, critical access hospitals, and nursing care centers. Standard **MM.09.01.01** addresses antimicrobial stewardship and becomes effective January 1, 2017 (TJC, 2016). The standard states, “The (critical access) hospital has an antimicrobial stewardship program based on current scientific literature.” (Standard and EOP will be posted fall 2016 E-dition and will be published in the 2017 *Comprehensive Accreditation Manual for the Critical Access Hospital, Hospital, and Nursing Care Center Accreditation Programs*).

V. Medication Errors in Imaging Departments

The inclusion of imaging services in the medication management plan of the organization became a requirement of Joint Commission accredited organizations on January 1, 2004. The need for an inclusive medical management plan followed the publication of various studies that indicated the number of medical errors in hospitals and related facilities was increasing, and medication errors made up more than 50% of all the identified medical errors.

An estimated 300 million radiologic procedures are conducted per year in the United States, and 20% of these procedures involve medications (Santell, 2006). In cardiac catheterization laboratories, radiology, and other diagnostic departments, medications such as contrast media are administered, rates are adjusted for IV fluids, and IV access lines are flushed. In addition to specific medications that are used in radiology, high-alert medications such as IV sedatives, vasopressors, and blood coagulation modifiers are given in this setting. Nearly 1,000 event reports submitted to the Pennsylvania Patient Safety Authority specifically mentioned medication errors that occurred in care areas providing radiologic services (Pennsylvania Patient Safety Authority, 2009). Most commonly reported medication errors in radiology included:

- Administration of wrong and unauthorized drugs
- Administration of wrong dose errors

Contrast agents and radiopharmaceutical products were cited in 25% of all medication error reports; however, many of the drugs listed are used across many patient care settings.

In April 2006, information presented in a report from the USP stated a proportionately higher number of medication errors resulting in patient harm occurred in radiology than occurred in intensive care units (USP, 2006). The USP report identified three ways in which radiologic services exclusively may lead to harmful errors compared to other settings:

- 1) The amount of time a patient may spend undergoing a radiologic procedure is very brief compared with the time he or she will spend in the primary inpatient care setting.
- 2) While a patient is being transferred to and from the radiology area, an opportunity for miscommunication and lack of access to patient information provide a window for errors to occur. As a rule, patient care provided in radiology is very focused on a particular procedure. Drugs that were administered pre-radiology-examination, or those to be continued post-radiology-examination, may not be given adequate attention. These

medications are not related to imaging procedures but are often infusing when the patient comes to the imaging department (Thompson, 2006).

- 3) Often, radiology staff will directly dispense and administer medications; however, there is no standard on how much or what kind of medication-use training radiology staff receive.

If a medication error occurs while care is being delivered to the patient in the imaging department, it is considered a radiology error, whether the medication was ordered by the radiologist or whether it was or was not a part of the radiological procedure. Radiologists and radiology staff must have sufficient information about the patient and the medications that have been administered to do what is needed to prevent errors from occurring. Much of this information should be included in the report given when the care of the patient is transferred from the inpatient unit staff to the imaging staff.

Standard **MM.01.01.01** underscores the need for accessible patient-specific information. Such material includes sufficient information about the medications the patient is currently receiving and any allergies the patient has identified. Reviewing some of the information from the USP study helps validate the need to have this patient-specific information before administering medications to a patient. Among the errors described in the USP report were (Darves, 2006, p 2):

- Failure to note contrast agent allergies
- Failure to avoid drug-drug interactions
- Erroneous switching of infusion rates for IV medications following the completion of radiologic procedure
- Incorrect programming and operation of IV pumps
- Improper dosing of contrast agents or sedating medications

In a follow-up report to the USP information (Santell, 2006) Santell stated, “The transition of patients from their primary hospital bed to the radiology exam room opens up the risk of error.” Such a statement may be one that should be posted in imaging departments as a continuous reminder to those who accept patients to do what can be done to get the information needed for the delivery of safe, error-free care.

As all personnel within imaging departments begin to demonstrate competence and compliance with the medication management standards and with any related Joint Commission standards, and National Patient Safety Goals, risks for error will be limited. Qualified staff that order and/or administer medications will need to demonstrate competency in the implementation of policies related to medication ordering and administration. Furthermore, staff will need to demonstrate an understanding of the information they must receive on each

patient regarding medications being administered and whether any of these medications are known to interact negatively with contrast media.

The Joint Commission identified the hand-off of patients from one provider to another as one of the highest risk times for a medical error to occur. To meet the Joint Commission standard related to patient hand-off, the staff needs to understand that when the patient moves from the inpatient unit to the imaging department, the accountability for the care of that patient is transferred, as the hand-off information is being provided and accepted. Accountability for the care of that patient remains with the imaging staff until the patient is transferred to another provider who is qualified to accept the care of the patient and who has received the required information about the patient as a part of the hand-off process.

In 2003, the Joint Commission developed a set of National Patient Safety Goals that included the goal of improving “the effectiveness of communication among caregivers.” In the 2007 Joint Commission’s Annual Report on Quality and Safety, the Joint Commission identified inadequate communication between care providers or between care providers and patients/families as a consistent root cause of sentinel events (an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof (TJC Sentinel). The Joint Commission decided that attention needs to be given to the way healthcare is communicated.

Most facilities have developed standardized methods defining the information that should be included during the hand-off of patients from one provider to another. The key to hand-off is to remember to provide the receiving provider with the information needed to safely care for the patient for a brief period of time following the transfer until there is the opportunity for a more in-depth review of the medical record. Such communication needs to include what occurred in the imaging department, how the patient responded, and if there is follow-up needed on the basis of the outcome of the testing or treatment.

A common communication tool is **SBAR** (**S**ituation, **B**ackground, **A**ssessment, **R**ecommendation), which was developed by Michael Leonard, MD and colleagues. SBAR works well and assists in the provision of safe care. Following the SBAR tool should guide what information needs to be received before accepting the care of a patient and what information needs to be given upon transfer of that patient.

An important requirement in communication hand-off is that the information must be provided by an individual knowledgeable of the situation and who is able to respond to questions regarding the information provided. For many facilities, this

may require modifications in their current transfer processes in order to meet this standard.

An example of how the use of the SBAR or a similar process can help reduce the risk for medication errors is to consider its use for patients who arrive with medication infusing. The transferring report should provide critical information about the infusion (fluid, medication, rate, etc.), and the receiving staff member should review this information for clarity before accepting the transfer of accountability. It is also helpful to view the actual infusion with the other person to assure both are in agreement regarding the content and flow rate of the infusion. Tracking these points of care that may have contributed to an error that occurred in a different department is needed to develop system responses to the risk points created by this transfer of care.

Consideration should be given to the **2010 National Patient Safety Goal (NPSG) 08.04.01** that addressed medication reconciliation:

“In settings where medications are used minimally, or prescribed for a short duration, modified medication reconciliation processes are performed.” (The Joint Commission-National, 2007 p 17)

The rationale is that in-patient care settings where medications are used minimally or prescribed for a short duration (including outpatient radiology), obtaining a list of the current medications being taken at home is important; however, obtaining information on dose, route, and frequency of use is not required (The Joint Commission-National, 2007 p 17). The purpose is to safely prescribe any medications such as IV contrast media or local anesthesia and to assess for allergic or adverse drug reactions. While this NPSG is now a component of the Joint Commission standards of care, it is important to recognize the emphasis put on the topic of medication reconciliation as a major patient safety issue.

Medication reconciliation at this level of importance is not regularly occurring within the hand-off scenario. This patient safety goal is particularly important to patients coming to the imaging departments since this is a place where new medications are ordered and administered. Proceeding with new medications without knowledge of the current medications is inappropriate and has been found to be the cause of many of the medication errors that are occurring in radiology.

Reconciliation of medications

Since many patients who are served in imaging departments are outpatients, the reconciliation of medications becomes more difficult since not all patients come

to the facility with a list of current medications in-hand. Requiring this list to be available should be a part of the scheduling and intake process since this is the best way to avoid some of the adverse medication reactions that occur.

Unfortunately, many in our society are taking multiple medications, including over-the-counter medications and supplements, putting them at increased risk for a medication error each time they seek care or treatment from anyone who might be ordering or administering additional medications or drugs.

One of the highest risk procedures in the imaging department is in the area of sedation. For example, many people are given what is considered a small amount of sedation to ease the anxiety that develops when needing to have a magnetic resonance imaging (MRI) procedure in a closed tube. If there is no reconciliation of current medications, the effect of adding a small dose of lorazepam or similar medication will not be known. Because of other medications taken by the patient, the addition of the Ativan may move the patient from a state of mild sedation to one of conscious sedation. Besides considering this as an adverse event, conscious sedation protocols would not have been followed, leaving all involved in a vulnerable position in regard to the care delivered.

A description of the rationale for medication reconciliation, and what is expected to complete the medication reconciliation process, is provided in a memorandum from the Joint Commission this topic. This is important information for each practitioner involved in any aspect of medication management and can be found in Appendix A.

VI. Future Joint Commission Surveys

The Joint Commission conducts all surveys on an unscheduled basis. While it has always been an expectation that providers would always be compliant with the Joint Commission standards, the unscheduled surveys add a new sense of responsibility to such continued compliance. One way to assist staff in measuring levels of compliance while identifying areas that need to be addressed is to have random mock surveys of the imaging department. Another suggestion is to participate in organizational mock tracer activities.

A suggestion that would accomplish assessing compliance, staff involvement in performance improvement, and staff education regarding standards and how they are being met would be to divide the staff into separate mock survey teams. Each month, a different team would be assigned to survey the department against the standards, policies, etc. and to report findings both in writing and at a staff meeting. The deficiencies noted one month would be followed during the next month's survey.

When the Joint Commission or any regulating agency 'drops by' to review compliance and performance, staff will be prepared to respond and to take an active part in sharing what they know about what they do, why they do it, how they are prepared to do their job, and what is being done in their department in regard to patient safety and continuous improvement.

As suggested in an article in *Hospital Pharmacy*, the use of an audit form that lists the major areas to assess is helpful and allows those surveying to focus on specific issues each time (Fogel, Todd, Wilson & Como, 2006, pp. 1090-1094). A copy of a form developed by this group of authors is in Appendix B. Adding additional elements to this form will make it useful to address levels of compliance with the medication management standards in imaging departments.

It is recommended that any deficiencies that are found through mock surveys or audits be addressed through informational sessions and educational programs. Rather

than having these programs developed and provided by staff in the education department, it is suggested that the deficiencies be addressed by individuals or teams in the imaging department. This approach should lead to improved compliance since the users of the information are also the teachers of what needs to be done.

VII. Addressing Medication Errors in the Future

Because of the various studies on the number and causes of medication errors conducted by the Institute of Medicine (IOM), the United States Congress mandated a follow-up study be completed by the IOM. This study was to address the problem of medication errors. The report of this study “Preventing Medication Errors” was published in 2006 (Institute of Med, 2006). The report includes data and discussions on understanding the causes and costs of medication errors and provides information on how the medication system in place can and must be improved in order to eliminate those errors that can be avoided and to reduce the potential for unavoidable errors to occur. The content of the report includes discussions on the understanding of the causes of medication errors and the cost of these errors. Data for the report have been collected over several years following the publication of the second IOM report in 2000: *To Err is Human: Building a Safer Health System*.

The scope of the study includes topics such as:

- Use of evidence-based reviews of the literature on the nature and causes of medication errors, their impact on patients, and the differences in causation across populations and care settings (Institute of Med, 2006)
- Alternative approaches to reducing medication errors (Institute of Med, 2006).
- Providing guidance to patients, providers, and policy makers on the topic of eliminating medication errors
- Development of an applied research agenda on the issues related to the impact of medication errors

The publication begins with the premise that the level and consequences of medication errors are unacceptable (Institute of Med, 2006). What makes medication errors so unacceptable is that the way to eliminate at least 50% of these errors is known and proven to be effective. Gaining compliance with what needs to be done is very difficult in the complex system we call healthcare.

In hospitals, medication errors most commonly occur at the prescribing and administration stages of the medication process. This is not surprising since these are the stages with the greatest volume of transactions as well as the largest number of people involved in completing these stages.

A 2007 survey conducted by the Joint Commission showed that “hospitals were most likely to receive an RFI (Requirement for Improvement) because of non-compliance with medication management standards in three areas: storage, orders and pharmacist review of orders.” (Kienle, Uselton, 2008, p 1)

In a presentation, a Joint Commission Surveyor (Rich, 2012) identified the top medication standards that were deemed non-compliant in surveys conducted in 2011. The list follows:

- MM.03.01.01 Medication Storage 33%
- MM.04.01.01 Medication Orders 24%
- NPSG.03.04.01 Labeling Procedures 16%
- MM.05.01.01 Pharmacist Review 15%
- MM.01.01.03 High Alert Medications 5%
- MM.05.01.07 Medication preparation 6%
- NPSG .003.06.01 Medication Reconciliation. Added (NPSG, 1/1/2016)
- MM.05.01.09 Medication Labeling 5%

A survey recently completed by registered nurses on medication administration provides some important information about what is really occurring with aspects of the medication administration processes and why these respondents believed errors were continuing to occur. While this survey was completed by registered nurses, the actions and opinions most likely mirror that which we would find in radiology where medications are administered on a regular basis.

The survey (Orlovsky, 2007) found that nearly all respondents (97%) “worry” about medication errors; 68% said errors could be reduced with more consistent syringe labeling. Additional results showed that 48% of nurses said medication errors are most likely to occur during the **preparation or administering of medication**; 47% revealed that they’re most likely to occur during the transcription of the initial order.

“Among the contributing factors to medication errors, the fact that they’re **too busy or too rushed was the number-one response from nurses (78 percent)**,” RG Hughes (2008) added. “Some of the others were illegible handwriting (68 percent), similar drug names (56 percent) and **working with too many medications** (60 percent).” **It’s very interesting that we are still seeing the top safety concerns that we saw in 2001** (Orlovsky, 2007).

With all this various survey data, leaders in the healthcare facilities should be able to define and implement strategies to address this major, long-standing problem in our healthcare system. Correcting the processes that lead to errors will result in significant saving of lives as well as money that is now spent on litigation related to medication errors.

VIII. Prevention Strategies for Hospital Care

The *Preventing Medication Errors* (Institute, 2006) publication provides significant information on prevention strategies titled, Risk Reduction Strategies.

The Institute for Safe Medication Practices (Preventing Medication Errors, Institute, 2006) recommends the following risk reduction strategies for preventing the types of medication errors observed in radiology:

- Examine the medication-use processes in radiology areas, as well as medications for patients on continuous IV infusions to uncover risks that might lead to harmful errors.
- Patient care units that are transferring patients to radiology can address a plan to manage the patient's infusion therapy, recognize the potential need to interrupt the infusion during the procedure, and how the therapy will be affected by the length of the radiologic procedure.
- Some organizations employ nurses who are dedicated to radiologic services or send a nurse to radiology to accompany the patient if the patient has a high-alert drug infusing. A verbal hand-off between the accompanying nurse and the radiology staff, including verification of infusing IV therapy, must occur.
- Adequate supervision by a physician or nurse must be provided where technicians are administering contrast media and other medications. Ultimately, the responsibility for patient safety falls to the licensed medical professional supervising the technician.
- Include radiology staff when evaluating and validating the level of training and competency to perform medication administration or related tasks. Keep all technicians in the information loop.
- Organizations must consider current and recent patient information before ordering, dispensing, and administering any medication in the radiology setting that may affect the procedure. Pharmacists can help in the assessment of patients about to undergo radiologic procedures by providing a continually updated list of drugs that should be withheld before a procedure and the corresponding time intervals.

From the Institute for Safe Medication Practices, *ISMP Medical Safety Alert 2006*.

Some of these strategies can be implemented by individual practitioners, but many need to be implemented organizationally to be effective. The remainder of this self-study booklet will address some of these strategies in the hope that

those who read this information will decide to incorporate the individual strategies into their everyday practice and support the organization implementation of those strategies that require organizational collaboration and cooperation of all involved in the medication management program.

Technological Interventions

Implement computerized order entry (CPOE).

Even though there are some issues that are created when using CPOE, the major benefits of the system are so significant that this technology should be implemented. One of the major causes of medication errors is the inability to read many of the orders that are written. Also, writing the orders does not allow for the automatic inclusion and integration of the order into the clinical-decision data set that is used for making ongoing treatment decisions.

Using computerized order entry along with a standardized prescription format will reduce variation, reduce the need for ‘interpreting’ what the order means, and reduce the need to transcribe orders on multiple forms.

A study done in 2013 by Radley, et al and published in the *American Medical Informatics Association* found that CPOEs “can substantially reduce the frequency of medication errors in inpatient acute care settings”. CPOE usage is widespread in hospitals across the United States; unfortunately, specialty areas such as radiology and the emergency department often lag behind medical/surgical units in the adoption of CPOE, given the departments’ nonstandard use of medications and unique workflows (Naseman, 2016).

Interventions Using Clinical Pharmacists

Include a pharmacist during patient care rounds.

The use of appropriate medications in a safe and effective manner requires a significant body of specialized knowledge. The growth in the number of clinical pharmacists and their use in acute care facilities attest to the fact that understanding the actions, interactions, effects, side effects, etc. of the multiple medications that are now available to practitioners is often too complicated to be addressed by individual practitioners. Having the presence and availability of people with the specialized knowledge in this area of medicine improves the chance that appropriate medications will be ordered for specific patients at correct dosages.

In many facilities that have the advantage to employ clinical pharmacists, the process for medication oversight is a part of what these individuals do on a daily basis. This brings the pharmacist out of the pharmacy to directly collaborate with

other members of the care team to ensure the medication regimen is appropriate for the conditions being treated.

The clinical pharmacist is an invaluable resource when faced with issues of drug: drug interaction or with any adverse event related to the administration of a medication. These individuals should also be a major participant in medication reconciliation by reviewing the listing of a patient's medications to determine if there are medications that should not be taken together, etc.

The use of drugs and medications has become one of the major aspects of the care delivered while a person is hospitalized in addition to the ongoing use of medications that will occur upon discharge from the facility. With the continuous addition of new drugs, as well as the development of more and more generic drugs, the knowledge of a clinical pharmacist almost becomes a necessity since this is the discipline dedicated to the understanding and evaluation of drug therapies.

One can certainly envision a time when pharmacists are the major providers of all aspects of drug therapy, including the ordering and administration processes. In many facilities, certain medication orders must be approved by the clinical pharmacist before they can be dispensed to the units for administration. It may not be long before pharmacists also administer select medications in select departments such as in an intensive care unit, where reactions to medications may be less predictable and more intense, requiring a level of monitoring that may not be possible with the current staffing.

No matter what decision is made on the use of clinical pharmacists, there must be the understanding that a way to significantly reduce medication errors is to involve those who are experts. This may mean changing the regulations and or the traditional roles of other disciplines within the system. This is often the greatest barrier to making such changes.

Have a pharmacist available on-call after hours of pharmacy operation.

In the times when there was less complexity involved in medication management, when the pharmacy closed for the day, the nurse supervisor could access medications needed when new orders were written. Because the major medications that would be ordered were placed in a separate lock box, it was determined that the nurse was not dispensing the medications since the pharmacist already dispensed them to this lock box. The nurse was only retrieving the medication to fill the new medication orders. In most cases, he/she would not know if the new order would lead to a drug interaction or other adverse events.

There are many facilities today that do not have on-site pharmacy services 24/7 and are still using some semblance of this lock box in order to be able to provide basic care to the patients at the facility. An on-call pharmacist can provide consultation and guidance for the retrieval of the correct and appropriate medication, thus reducing the potential occurrence of avoidable errors.

The on-call pharmacist can also be contacted to discuss signs and symptoms of a patient suspected of having an adverse reaction to an ordered medication. They can also provide telephone or computer consultation to physicians who need assistance in determining the most effective medication to order or guidance on the dosage and frequency of the medication.

With the national shortage of pharmacists, especially those who are hospital-based, the use of an on-call system can be the best way to have this coverage.

Interventions Related to Medication-Use Processes

Employ special procedures and written protocols for the use of high-risk IV and oral medications.

There has been much research done on the use of standardized protocols for high-risk medication therapy. Standardized protocols provide a single approach, thereby reducing the variation in the process. The template for this is the use of a heparin protocol. This is required as a part of the medication management standards.

As heparin IV solutions were becoming a major therapy for specific cardiac diagnoses, individual physicians and groups of physicians each developed their 'own' protocol. In many facilities, three or more heparin protocols existed. The pharmacy and nursing staff were required to know each of these and to keep them separate as they cared for patients with different attending physicians.

A review of medication errors indicated that many of these errors occurred in places where there were multiple protocols for the same medication as busy nurses 'pulled' the wrong protocol or as busy physicians failed to order their specific protocol, assuming the nurse and pharmacist would know which one to use.

In imaging departments, there may be interventionists who perform the same procedures but use different protocols for the staff to follow. Encouraging them to work together to accept one standardized protocol will reduce the potential for errors to occur.

Institute policies and procedures regarding the labeling of all medications.

As described in the earlier portions of this self-study booklet, adopting a standard way of labeling medications is included in the standards. This is another example of doing what can be done to reduce variation in processes and thereby reducing risk points where errors can occur.

Miscellaneous Non-Technological Interventions

Adopt a systems-oriented approach to medication error reduction.

When all facets of medication management are considered, it becomes clear that “medication safety becomes everyone’s responsibility” (IOM, 2001). Making the commitment to reduce medication errors must be done on an organizational level to ensure all components of the system are addressed.

When addressing this in the Quality Chasm report, the IOM indicated that correction of the multiple, interrelated deficiencies calls for “profound changes and a paradigm shift away from a paternalistic, provider-centric system” (IOM, 2001). This profound change needs to be built with some of the primary factors focused upon the patient as a source of control, evidence-based decision-making, anticipation of needs, and cooperation among clinicians. All of this means that reduction of medication errors will not be accomplished by fiat and not without the active participation of all involved, including the staff and the patients.

Take steps to reduce workplace fatigue, such as planned naps, careful scheduling, or bright light therapy.

The work done by the IOM and published in 2004 entitled Keeping Patients Safe included information on creating a safe environment for practice. The focus was on the environment for nursing practice but pertains to all clinical areas where there is 24/7 staffing needed to meet the needs of patients in those facilities (Institute of Med, Keeping Pts Safe, 2004).

The discussion on the effects of fatigue from shift work and extended hours stated that “the effects of fatigue include slowed reaction time, diminished attention to detail, errors of omission, compromises problem solving, reduced motivation, and decreased vigor for completion of required tasks” (Institute of Med, Keeping Pts Safe, 2004, p227-228). It was determined that much of the fatigue experienced by this clinical staff was due to shift work and extended work hours.

One of the interventions noted to reduce the effect of shift work (generally considered night shift or rotating shifts) is to schedule on-the-job naps and also to use bright lighting in the work areas where this would not disturb the patients. It is

felt that taking time to nap will result in a more productive person following that nap, with the commission of fewer errors than when fatigued.

Those cultures, which regularly use the siestas at some point in the workday, have learned the benefit of providing the opportunity to leave the work environment for a period of time and returning refreshed and ready to be safe and productive.

The avoidance of this concept in this country is similar to the non-acceptance of time to think while on the job. In Japan, sitting at the desk and appearing to be 'doing' nothing but thinking is considered appropriate since the outcome of this thinking will likely result in improved productivity. (Alston, 1989) In this country, if one is seen doing this same thing, they are generally considered to be doing nothing and are highly encouraged to begin 'working'.

Evidence does demonstrate that fewer errors are made when rested, and less rework needs to be done when adequate planning (thinking) has taken place. It is time to use this evidence and research outcomes to dramatically change the way we work if we hope to dramatically change some of the adverse outcomes of our work.

It is also known that "...shifts of 12 or more hours with limited hours of rest..." result in employees who report greater fatigue at the end of the shift (Institute of Med, Keeping Pts Safe). While the introduction of 12 hours shifts into the healthcare arena was met with great acceptance since it offered flexibility for many, over time, it has been demonstrated that working these shifts has a direct impact on the number of errors, either by commission or omission. Add to these extended shifts the fact that overtime is a regular phenomenon, and it is easy to see how the effects become exacerbated to the point of creating an unsafe worker who is providing care to a group of very sick people.

It may be time to consider a return to an eight-hour shift schedule for many reasons, including the safety issues. This movement is taking hold slowly but is predicted to become the norm as more and more facilities look at the systemic issues related to the development of a safe environment, both for patients and staff.

Use Failure Mode and Effects Analysis (FMEA) or other strategies for risk management.

FMEA is a process developed by engineers to test and retest designs and products before taking the product to market. This analysis identifies the risk points in the design and production, enabling the staff to make adaptations to the design that will successfully reduce those risks.

FMEA has only been introduced into healthcare processes within the last decade. Prior to this time, many programs, designs, redesigns and changes have been implemented with minimal testing and trials. This has resulted in much rework as the presence of areas of weakness in the plans and designs became evident after implementation.

Taking the time to do as much testing and trialing as possible will generally provide evidence of areas that can be strengthened or redesigned. Doing this before implementation makes the redesign and ultimate implementation easier to accomplish.

All staff in a hospital should make themselves available to serve on an FMEA team at some point. There are many opportunities for this teamwork since all the Joint Commission-accredited organizations are required to complete an FMEA on a critical process annually. Because of the critical nature of medication management, the Joint Commission is highly recommending that the focus is on an aspect of medication management, when possible.

Organizations that realize the value of the FMEA process are also starting to complete several each year. Suggestions for areas that may benefit from this kind of study often come from the staff most closely involved with the processes that appear to have areas of weakness or risk for error.

With the increasing deployment complexity and sophistication of the equipment and related processes within the clinical imaging environment, system failures are more likely to occur. As many hospitals implement continuous improvement processes, with a focus on quality and safety being paramount, tools such as FMEA have an increasing likelihood for being deployed in equipment and process-rich departments such as radiology. Improvement processes such as FMEA are no longer voluntary for hospitals that admit patients (Thornton, 2011).

There is much information in publications from the IOM that focus on patient safety and how to reach the continued presence of a safe work environment. It is generally agreed that there needs to be a transformation of the healthcare system in order to accomplish this level of safety. Hopefully, each of you will sustain your interest in this topic and take the lead to improve what you can within your department or organization.

**“Knowing is not enough; we must apply.
Willing is not enough; we must do.
-Goethe**

Appendix A

Using Medication Reconciliation to Prevent Errors

Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every transition of care in which new medications are ordered or existing orders are rewritten. Transitions in care include changes in setting, service, practitioner or level of care. This process comprises five steps: 1) develop a list of current medications; 2) develop a list of medications to be prescribed; 3) compare the medications on the two lists; 4) make clinical decisions based on the comparison; and 5) communicate the new list to appropriate caregivers and to the patient.

Accurate and complete medication reconciliation can prevent numerous prescribing and administration errors. Failure to reconcile medications may be compounded by the practice of writing "blanket" orders, such as "resume pre-op medications," which are highly error prone and are known to result in adverse drug events. (1) Such orders are explicitly prohibited by the Joint Commission's Medication Management standards (MM.3.20).

Medication errors related to medication reconciliation typically occur at the "interfaces of care"—when a patient is admitted to, transferred within, or discharged from a health care facility. (2), (3) Furthermore, the home care department of one hospital discovered that 77 percent of all patients were discharged with inadequate medication instructions. (4) Medication reconciliation systems and processes have successfully reduced medication errors in many health care organizations. Pharmacy technicians at one hospital reduced potential adverse drug events by 80 percent within three months by obtaining medication histories of patients scheduled for surgery. (1)

The Joint Commission's sentinel event database includes more than 350 medication errors resulting in death or major injury. Of those, 63 percent related, at least in part, to breakdowns in communication, and approximately half of those would have been avoided through effective medication reconciliation. The Institute for Safe Medication Practices (ISMP) has received numerous reports of medication reconciliation errors; its Medication Safety Alert newsletter of April 21, 2005 includes a sampling of such errors that resulted from failed communication. (5)

Causes of Medication Errors Identified

In September 2004, the USP added three "Causes of Error" to its MEDMARX® reporting program to capture errors involving medication reconciliation failures. From September 2004 to July 2005, USP received 2,022 reports of medication reconciliation

errors. Of those reports, 66 percent occurred during the patient's transition or transfer to another level of care, 22 percent occurred during the patient's admission to the facility, and 12 percent occurred at the time of discharge.

Of the types of medication reconciliation errors reported to MEDMARX, the majority involved improper dose/quantity, followed by omission error and prescribing error. Other less frequently reported types of error included: wrong drug, wrong time, extra dose, wrong patient, mislabeling, wrong administration technique and wrong dosage form.

The causes of medication reconciliation errors reported to MEDMARX included performance deficit (performance that falls short of expectations) (nearly 88 percent), transcription inaccurate/omitted (84 percent), documentation (83 percent), communication (82 percent), and workflow disruption (80 percent). USP also published several case examples of reconciliation failures during patient admission, transfer, and discharge. (6)

Risk Reduction Strategies

Medication reconciliation is a key initiative in the Institute for Healthcare Improvement's (IHI) 100,000 Lives Campaign. The IHI website (www.ihl.org) includes a section on Medication Reconciliation Review, including samples of a reconciliation tracking tool and a medication reconciliation flow sheet. (7) The Massachusetts Coalition for the Prevention of Medical Errors (8) has identified practices to reconcile medications throughout an organization. The core recommendation of the Coalition is to "adopt a systematic approach to reconciling medications, starting with reconciling at admission." This successful initiative is based on the work of 50 Massachusetts hospitals (76 percent of the hospitals in the state) that pilot-tested the initiative to hone the practices and tools used to implement them. The Massachusetts Coalition's practices for reconciling medications at admission include:

- Collect a complete list of current medications* (including dose and frequency along with other key information) for each patient on admission.
- Validate the home medication list with the patient (whenever possible).
- Assign primary responsibility for collecting the home list to someone with sufficient expertise, within a context of shared accountability.
- Use the home medication list when writing orders.
Place the reconciling form in a consistent, highly visible location within the patient chart (easily accessible by clinicians writing orders).
- Assign responsibility for comparing admission orders to the home medication list, identifying discrepancies, and reconciling variances to someone with sufficient expertise.

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- Reconcile medications within specified time frames (within 24 hours of admission; shorter time frames for high-risk drugs, potentially serious dosage variances, and/or upcoming administration times).
- Adopt a standardized form to use for collecting the home medication list and for reconciling the variances (includes both electronic and paper-based forms).
- Develop clear policies and procedures for each step in the reconciliation process.
- Provide access to drug information and pharmacist advice at each step in the reconciliation process.
- Improve access to complete medication lists at admission. Provide orientation and ongoing education on procedures for reconciling medications to all health care providers.
- Provide feedback, on-going monitoring. (8)

Joint Commission Requirements and Recommendations

In July 2004, the Joint Commission announced 2005 National Patient Safety Goal #8 to "accurately and completely reconcile medications across the continuum of care." During 2005, accredited organizations were required to develop and test processes for medication reconciliation to be implemented by January 2006. The requirements of the Goal for 2006 are:

8a) Implement a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient. This process includes a comparison of the medications the organization provides to those on the list. [**Note:** While this safety goal does not require a separate form for the medication list, many organizations have found it useful to develop and implement one or more forms to support the medication reconciliation process.]

8b) A complete list of the patient's medications is communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization. **

Implementation Expectations for Requirement 8b state: At a minimum, reconciliation must occur any time the organization requires that orders be rewritten and any time the patient changes service, setting, provider or level of care and new medication orders are written. For transitions not involving new medications or rewriting of orders, the organization should determine whether reconciliation must occur.

It is important to note the full scope of this safety goal: "... across the continuum of care." This means medication reconciliation applies to all care settings—including ambulatory, emergency and urgent care, long-term care, and home care—as well as inpatient services.

In addition, the Joint Commission recommends that health care organizations consider:

1. Placing the medication list in a highly visible location in the patient's chart and including dosage, drug schedules, immunizations, and allergies or drug intolerances on the list.
2. Creating a process for reconciling medications at all interfaces of care (admission, transfer, discharge) and determining reasonable time frames for reconciling medications. Patients, and responsible physicians, nurses and pharmacists should be involved in the medication reconciliation process.
3. On discharge from the facility, in addition to communicating an updated list to the next provider of care, provide the patient with the complete list of medications* that he or she will be taking after discharge from the facility, as well as instructions on how and how long to continue taking any newly prescribed medications. Encourage the patient to carry the list with him or her and to share the list with any providers of care, including primary care and specialist physicians, nurses, pharmacists and other caregivers.

* Medications in these references include prescription medications, over-the-counter medications, vitamins, herbals, nutraceuticals, and supplements.

** With regard to Requirement 8b, the medications that need to be communicated to the next provider, organization, level, or setting of care are all the medications that the patient is to be on following discharge or transfer, not just the prescription medications that are "ordered" at discharge. The list of "discharge medications" provided to the next provider or organization should already have been reconciled in the hospital against the list of medications the patient was receiving while in the hospital as well as against the original list of medications the patient was taking prior to entry to the organization.

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Appendix B

Medication Management Evaluation Form

Patient Care Area _____ Month/Year _____

In response to each question, mark 'Yes' to indicate full-compliance with the question. Mark 'No' for failure to comply in any manner and indicate a reason for deficiency and any corrective action taken. Write n/a by any question that does not apply to your area.

Radiology Medication Evaluation

- | | | |
|---|-----|----|
| 1. Are all items labeled completely and adequately? | Yes | No |
| 2. Are there expired or deteriorated items? | Yes | No |
| 3. Are all items arranged systematically with externals separated from internal preparations? | Yes | No |
| 4. Are all non-drug items separated from drug items? | Yes | No |

General Medication Evaluation

- | | | |
|---|-----|----|
| 5. Are all medications secure within the automated medication management system or according to the standard for those not stored in this system? | Yes | No |
| 6. Do all open multi-dose vials have an auxiliary expiration date label (30 days per standard)? | Yes | No |

Refrigerator/Warmer Evaluation

- | | | |
|---|-----|----|
| 7. If a medication refrigerator is used, is the temperature between 36 to 46°F?
If temperature monitor is present, are limits set? | Yes | No |
| 8. Are only medications stored in the medication refrigerator? | Yes | No |
| 9. Is the refrigerator defrosted? | Yes | No |
| 10. If a warmer is used, is a thermometer present and recorded temperature range is between 59 to 86°F or 15 to 30°C? | Yes | No |

Emergency Drug/Reaction Kit Evaluation

- | | | |
|--|-----|----|
| 11. Is the Reaction kit, or emergency crash cart, properly sealed? | Yes | No |
| 12. Are the expiration dates adequate? | Yes | No |

Add additional questions related to ordering, administration, evaluation, communication, etc to make a comprehensive quick evaluation form to use for interim monitoring of compliance and to identify areas needing improvement.

This format can also be used to survey all other aspect of standards compliance within the department.

Write expiration date(s) here _____.

Radiology Representative _____

Date _____

(Audit form for medication management evaluation for radiology areas—Hospital Pharmacy [November, 2006] Volume 4)

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