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**:::VOLUME 16, LESSON 3:::**

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***Patient Safety and Compliance Issues with the  
Medication Use System in Radiology***

Continuing Education for Nuclear Pharmacists  
And  
Nuclear Medicine Professionals

By

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# **PATIENT SAFETY AND COMPLIANCE ISSUES WITH THE MEDICATION USE SYSTEM IN RADIOLOGY**

## **STATEMENT OF LEARNING OBJECTIVES:**

Upon successful completion of this lesson, the reader should be able to:

1. Distinguish between hospital certification and accreditation
2. State the CMS condition of participation related to radiopharmaceutical preparation in hospitals
3. List the six major areas of the medication use system
4. State the hospital requirements for access to contrast media and radiopharmaceuticals
5. Discuss the sections of USP <797> that apply to radiopharmaceutical preparation
6. State the expectations of hospital accrediting organizations related to sterile preparations in the nuclear medicine department

## **COURSE OUTLINE**

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# **Patient Safety and Compliance Issues with the Medication Use System in Radiology**

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Traditionally, medications such as contrast media or radiopharmaceuticals were handled by the Radiology Department with little or no input or oversight from the Pharmacy Department. In 2004, The Joint Commission (TJC) clearly stated that diagnostic agents (such as contrast media) and radiopharmaceuticals must comply with its Medication Management standards.<sup>1</sup> A few years later, the Centers for Medicare and Medicaid Services (CMS) Hospital Condition of Participation concerning preparation of radiopharmaceuticals in hospitals<sup>2</sup> was placed into the Medication Management standards. These two regulatory and accreditation issues, along with a more comprehensive approach to managing all medications, brought together Radiology Services and Pharmacy Services areas to assess best practices.

## **REGULATION OF HOSPITALS**

Hospitals in the US must meet federal Conditions of Participation (CoP) of the Centers for Medicare and Medicaid Services (CMS) to be certified to participate in the federal Medicare program. Hospital receiving any funding must either be certified through a survey from CMS, or be accredited by one of the three Accrediting Organization (AOs) deemed by CMS (The Joint Commission (TJC), the American Osteopathic Association's Healthcare Facilities Accreditation Program (HFAP), and DNV's National Integrated Accreditation for Healthcare Organizations (NIAHO) ) to be equivalent to their requirements.

Each state equivalent agency incorporates CMS CoPs into their own surveys. State agencies processes vary; some states survey hospitals every year or two, while others use the AO surveys to meet requirements. CMS or the State also survey hospitals based on patient complaints, specific compliance targets they may have, or to validate the results of an accreditation survey. Most medication-related CoPs are in the Code of Federal Regulations, cited under Pharmaceutical Services standards (42 CFR 482.25.) Some medication administration related

requirements are also found in the Nursing Services standard (§482.23(c)). Important to nuclear pharmacy and nuclear medicine areas is the following standard from the Nuclear Medicine Services section:

§482.53(b)(1) In-house preparation of radio pharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathy.

CMS provides Interpretive Guidelines to guide the hospital and the surveyor. They state:

In-house preparation of radio pharmaceuticals must be performed by, or directly supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, in the preparation of radio pharmaceuticals, consistent with Federal and State law.

The definition of “direct” supervision remains a point of discussion. CMS defines 3 levels of supervision as follows:

- (i) *General supervision* means the procedure is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
  - (ii) *Direct supervision* in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.
  - (iii) *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.
- ([http://edocket.access.gpo.gov/cfr\\_2010/octqtr/pdf/42cfr410.32.pdf](http://edocket.access.gpo.gov/cfr_2010/octqtr/pdf/42cfr410.32.pdf) )

The definition of “direct supervision” has been slightly revised, as follows:

- (1) For services furnished directly or under arrangement in the hospital or in an on-campus outpatient department of the hospital, as defined in § 413.65 of this subchapter, “direct supervision” means that the physician must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. For this purpose, the definition of “in the hospital” is as specified in § 410.27(g).
- (page 366, <http://edocket.access.gpo.gov/2009/pdf/E9-26499.pdf> )

Readers are cautioned to confirm the most recent definition when discussing the meaning of “direct supervision”.

Other regulations also apply, such as compliance with state departments of health, state boards of pharmacy, U.S. Food and Drug Administration (FDA), and United States Pharmacopoeia (USP) requirements.

## **ACCREDITATION OF HOSPITALS**

There are three AOs deemed by CMS to be at least equivalent to the federal hospital Conditions of Participation:

- The Joint Commission (TJC)
- The American Osteopathic Association’s Healthcare Facilities Accreditation Program (HFAP)
- Det Norske Veritas (DNV’s) National Integrated Accreditation for Healthcare Organizations (NIAHO)

All three AOs base their standards on the CMS Hospital Conditions of Participation.

Additionally, they include many more requirements, primarily based on patient safety and quality improvement. In each case, the medication management standards are far more extensive and more clinically focused, than the CoPs.

Accreditation is valid for up to three years and the triennial survey is unannounced. If the hospital is compliant with all requirements, the survey cycle is about every 3 years. If follow-up is needed, the AO may return for additional survey visits. DNV uses a different approach: though the accreditation cycle is every three years, they make an annual visit to the organization to assist with continuous compliance with the standards.

Procedural areas – and in particular, imaging areas – are a focus of the compliance surveys. Though this presentation is focused on the medication management related issues of regulation and accreditation, many other standards for imaging services are in effect, i.e. Human Resources requirements, Care of the Patient requirements, Environment of Care requirements, etc. The CMS CoP related to in-house preparation of radiopharmaceuticals appears in each of the three AO standards: TJC lists it under the Medication Management standards while HFAP and NIAHO list it under the Nuclear Medicine Services accreditation requirements

Generally, the Director of Pharmacy is responsible for oversight of all medication related areas. This includes areas such as administration (which may be in the Nursing standards), sedation (which may be in the Medical Staff or Patient Care standards) and radiopharmaceuticals (which may be in the Nuclear Medicine standards.) Standards outside of the Medication Management area still must comply with federal and state laws and regulations, hospital policy, and best practices.

## MEDICATION USE SYSTEM

The Medication Management standards apply to the entire organization; they are not limited to pharmacy issues. Most organizations approach medication management as a system, comprised of eight processes (Figure 1):

- Planning
- Selection of medications for use and procurement
- Storage
- Ordering, prescribing, and transcribing
- Dispensing
- Administration
- Monitoring
- Evaluation of the system

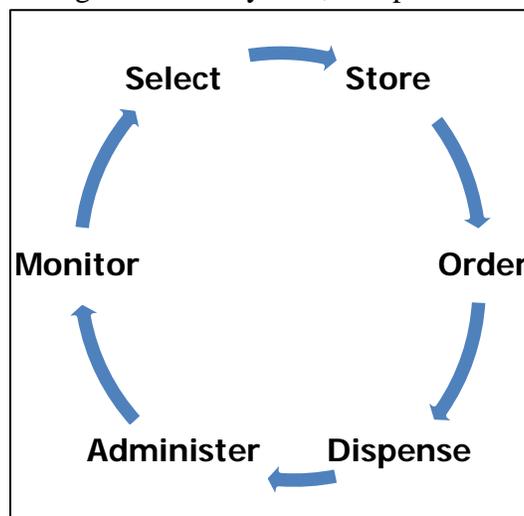


Figure 1.

### Planning

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

The Joint Commission includes a standard dealing with contracted services.<sup>3</sup>

Radiopharmaceuticals dispensed from a nuclear pharmacy that is not part of the hospital organization need to comply with these standards in Joint Commission accredited organizations. Hospital leadership must be aware of the outsourced service, approve of it, and establish and

monitor expectations for the performance of the contracted service. Additionally, Human Resource standards deal with competence of individuals.

Accreditation planning includes assessment of high-alert and hazardous drugs. High-alert agents in a hospital include insulin, anticoagulants, concentrated electrolytes, and other agents identified by the facility, such as neuromuscular blockers, oncology agents, and drugs used in special populations, such as neonates. Hazardous drugs are usually identified by matching the National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2010<sup>4</sup> against the drugs on the 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. Additionally, 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.

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. Often, this includes establishment of the contents through a medical staff committee (such as the Pharmacy and Therapeutics Committee) 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. When used or when the contents are about to expire, the container is replaced by the hospital pharmacy. Unauthorized stock of medications (such as in unlocked drawers within the treatment area) is prohibited.

### **Selection**

Accreditation standards require medications used in the organization to be listed in the formulary. This includes contrast media and radiopharmaceuticals. The Pharmacy and Therapeutics Committee (P&T) is responsible for this activity.

Traditionally, contrast media and radiopharmaceuticals were not extensively reviewed by the P&T process, since they are used solely in specialty areas. However, introduction of a controlled substance radiopharmaceutical<sup>5</sup> into the marketplace has brought new challenges. Controlled substances must meet stringent federal and state ordering, access, and monitoring regulations and procedures, which are different from other agents. The P&T Committee evaluation process will include the ability for the organization to comply with all applicable regulations.

## **Storage**

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

- Security of the medication
- Safety of its use
- Integrity of the dosage form, such as expiration dating and temperature control.

CMS CoPs require that medications must be secure, and locked when required by regulation or hospital policy. Controlled substances must always be locked. Most organizations lock all medications.

Safe medication storage should be defined by hospital policy. Separation of look-alike and sound-alike medications, injection safety, and other best practices should be incorporated into general practice.

Issues of integrity of medications generally deal with assuring that the medication is within the expiration date defined by the manufacturer. This encompasses checks for manufacturer's expiration dates, pharmacy or facility applied beyond-use dates for compounded preparations, and assurance of use of manufacturers' recommendations when items are moved, for example, from refrigerator storage to room temperature storage.

Access to authorized storage must be defined by hospital policy. Physicians, nurses, and technologists within the imaging department must be listed in the hospital policy, within their scopes of practice. There also may need to be a provision for the driver from the nuclear pharmacy to access the hot lab or a designated drop off room that has restricted access for

vendors' deliveries. Since medications are stored there, and often the driver delivers the radiopharmaceuticals prior to clinical staff availability in the department, CMS CoPs and accreditation standards require appropriate authorization by hospital leadership for the driver to access the area.

## **Ordering**

Imaging areas rely on 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 accreditation regulations and standards and best practices now require all protocols to be reviewed and approved by a medical staff committee. Generally, the P&T Committee oversees this function.

If protocols are used, they must comply with various regulatory and accreditation standards:

- Use of evidence-based practice standards
- Required elements of the order
  - Name of the patient
  - Age and weight of the patient, or other dose calculation requirement, where applicable
  - Date and time of the 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 the prescriber
- Unambiguous orders
  - No use of prohibited abbreviations or dose designations. All organizations prohibit the use of the following (in either upper or lower case, with or without spaces or periods):
    - U
    - IU
    - QD
    - QOD
    - MS
    - MSO<sub>4</sub>
    - MgSO<sub>4</sub>

Doses involving decimals must be correctly stated:

- Doses less than one must have a leading zero, for example: use 0.5 mg, not .5 mg.

- Doses of whole numbers should not have a trailing zero, for example: use 5 mg, not 5.0 mg.

Some organizations prohibit additional abbreviations or dose designation (such as abbreviations of drug names).

- If more than one item from a therapeutic category is ordered, the protocol must define objective parameters for use. For example, if there are two selections for pain medications, there must be some method to determine which agent should be given first, and why. Most organizations use a numeric pain scale for this purpose.
  - Periodic (as defined by hospital policy) review and re-approval of the protocol
  - A method to monitor and assess the effectiveness of the protocol and detect and improve any non-compliant issues

## **Dispensing**

Dispensing is limited by law to qualified pharmacists and physicians. Some states may allow other licensed independent practitioners (LIP) individuals to dispense under certain conditions. 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 non-radioactive medications are typically transmitted from the hospital or clinic's nuclear medicine department to the outsourced vendor's nuclear pharmacy, and ordered doses are then typically dispensed and delivered from the vendor nuclear pharmacy to the customer hospital or clinic's nuclear medicine department. In hospitals that do not have a licensed nuclear pharmacy or an in-house nuclear pharmacy service, the hospital pharmacy does not typically review the orders for radiopharmaceuticals nor provide the radiopharmaceutical doses.

USP <797><sup>6</sup> introduced consistency of sterile compounding practices. A section of USP <797> specifically deals with preparation of radiopharmaceuticals. Non-radiopharmaceuticals (e.g., reconstitution of sincalide for injection) 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 provisions of USP <797>. The Immediate Use Provision within USP <797> allows emergency doses to be made with lesser requirements if they are administered to the patient within sixty minutes from time of preparation or alteration. Sites who use the Immediate Use provision must comply with all of the requirements, including aseptic technique and specific issues related to the number of punctures. A discussion of USP <797> application for radiopharmaceuticals within nuclear medicine departments is available through the Society of Nuclear Medicine website under a link of expert discussion and advice provided by Drs. Joseph Hung and James Ponto. [<http://interactive.snm.org/index.cfm?PageID=7882>]

The CMS CoP regarding in-house preparation of radiopharmaceuticals applies to preparation of kits, such as kits for the preparation of technetium Tc 99m-labeled red blood cells.

Technologists who prepare kits within hospitals must comply with the following:

- Use of manufacturer's instructions for preparation
- Provisions of USP <797> section on Radiopharmaceuticals
- Documentation of competence to prepare the kit. This can be accomplished by working with the Director of Pharmacy to establish a competence similar to the one used for pharmacy technicians. The Compounded Sterile Preparations chapter in ASHP's *Competence Assessment Tools*<sup>7</sup> can be adapted for use.

The regulatory and accreditation requirement for oversight of the preparation of radiopharmaceuticals has come under focus during surveys. General expectations include oversight by either the pharmacy services (since mixing of sterile preparations is a key component of hospital pharmacy service) or a physician who is qualified to assess the preparation of sterile medications. If the hospital approaches this standard using the physician to oversee this process, surveyors will review the physician-in-charge credentials file to determine if he or she was trained in the preparation of sterile mixtures.

### **Administering**

Hospital policy must authorize individuals – usually by discipline – to administer medications in the organization. Though physicians and registered nurses can administer most medications, other imaging personnel who perform this function must be listed in the hospital policy.

Radiologic technologists should be specifically listed to administer oral, rectal, and intravenous contrast media, and nuclear medicine technologists should be specifically listed to administer

radiopharmaceuticals. In some cases, nuclear medicine technologists may also administer other non-radioactive adjunctive agents (such as pyrophosphate, adenosine, dobutamine, dipyridamole, furosemide, regadenoson, or sincalide). This must be done within the scope of practice defined by the state (if licensed) and/or national certifying board. Individuals who administer parenteral medications should have a competence documentation and periodic assessment of technique similar to that of nursing services employees at the same facility.

CMS regulations and accreditation standards require a pharmacist review of an order prior to administration, with a possible exception (if permitted by hospital policy) for urgent situations. (Scheduled procedures will not meet the test of urgency; this is reserved for use in a true emergency, such as a cardiac arrest.) 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.

Ideally, radiopharmaceuticals should undergo the same pharmacist review process as is done with all other medications. This becomes a challenge when radiopharmaceuticals are provided by an external service that has no access to patient records. Lack of patient information severely restricts the extent of any drug review process and limits the thoroughness of any review by a radiopharmacist. As electronic medical records develop more robust interfaces, a best practice would allow the nuclear pharmacist access to the patient demographics and current medications to fully review the medication elements.

Non-radiopharmaceuticals administered in nuclear medicine must either be reviewed by a pharmacist prior to administration, or a physician (or other LIP if permitted by state regulations and hospital policy) must be at the patient's side during preparation and administration of the non-radiopharmaceutical. Since these are scheduled procedures, provision of the orders to pharmacy in advance allows for review of the order and clear compliance with the standard.

TJC's National Patient Safety Goals<sup>8</sup> 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.

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.

## **Monitoring**

Nuclear pharmacies and nuclear medicine departments are familiar with the monitoring performed for the Nuclear Regulatory Commission (NRC), but may not be as familiar with the general hospital monitoring and evaluation processes.

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

Medication errors, ADRs, and incompatibilities must be reported to the attending physician and to the hospital's PI 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.

## **Evaluating**

Evaluating the medication use system in radiology encompasses several areas:

- Compliance with regulatory requirements, including NRC, CMS, state hospital and board of pharmacy requirements, federal and state DEA regulations
- Compliance with accrediting organizational standards
- Clinical indicators, as determined by the department in concert with the hospital's QA and PI plan
- Use of evidence-based medical practices and best practices established by applicable radiology and pharmacy organizations

## **SUMMARY**

Although contrast media and radiopharmaceuticals have always been prescription medications, it is only within the last few years where radiology and pharmacy partnerships to develop and improve medication use in the imaging areas have become common in hospitals.

Key areas to consider when assessing the patient safety and compliance issues related to medication use in radiology include:

- Knowledge of medication use requirements and standards of the regulatory agencies and accreditation organizations that oversee the hospital
- Recognition of the CMS CoP concerning in-house preparation of radiopharmaceuticals, and what disciplines are affected by the requirements
- Identification of areas of selection, storage, ordering, dispensing, administration and monitoring of contrast media, radiopharmaceuticals, and other medications used in the radiology department
- Compliance with USP <797> standards in the nuclear pharmacy and the nuclear medicine department

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## ASSESSMENT QUESTIONS

1. The genesis of the hospital regulations and accreditation stem from:
  - a. CMS Hospital Conditions of Participation
  - b. Joint Commission standards
  - c. FDA regulations
  - d. ASHP Best Practices
  
2. The driver for a nuclear pharmacy must be authorized by the hospital to access medications because the driver:
  - a. is an employee of an outsourced service.
  - b. has access to the hot lab/designated delivery site
  - c. carries medications from the nuclear pharmacy.
  - d. is transporting hazardous materials
  
3. The hospital accreditation cycle is for a period of:
  - a. One year
  - b. Three years
  - c. Two years
  - d. Four years
  
4. The hospital manager who generally has oversight for medication use in the organization is:
  - a. Chief Medical Officer
  - b. Director of Pharmacy
  - c. Chief Executive Officer
  - d. Physician Chief of Radiology
  
5. A common source to identify hazardous drugs used in an organization is:
  - a. NIOSH List of Hazardous Drugs
  - b. American Hospital Formulary Service
  - c. DEA list of Controlled Substances
  - d. Joint Commission Medication Management standards
  
6. Listing contrast media and radiopharmaceuticals in the hospital formulary is:
  - a. Necessary since they are hazardous drugs
  - b. Not necessary since they are used within a defined department
  - c. Necessary since they are medications used in the hospital
  - d. Not necessary since they do not interact with other medications

7. A controlled substance radiopharmaceutical must be ordered and stored:
  - a. To meet both controlled substance and radiopharmaceutical requirements
  - b. As other radiopharmaceuticals for consistency of practice
  - c. Within the hospital pharmacy to meet controlled substance storage requirements
  - d. By the Physician Chief of Radiology
  
8. Final approval for imaging protocols used in the hospital must be done by:
  - a. Director of Radiology
  - b. Director of Pharmacy
  - c. Chief Executive Officer
  - d. Medical staff committee
  
9. Preparation of non-radiopharmaceuticals in a nuclear pharmacy must comply with
  - a. The radiopharmaceutical section of USP <797>
  - b. USP <797>
  - c. ASHP Sterile Products guidelines
  - d. FDA Compliance Guidelines
  
10. The best practice for administration of a non-radiopharmaceutical in a nuclear medicine department includes review of the order prior to administration by:
  - a. The Director of Radiology
  - b. The patient's attending physician
  - c. A hospital pharmacist from that organization
  - d. The pharmacist at the nuclear pharmacy
  
11. Technologists who administer contrast media and/or radiopharmaceuticals must be authorized to administer those agents in the hospital based on:
  - a. Scope of practice and hospital policy
  - b. Scope of practice and the Director of Radiology
  - c. Either state regulation or hospital policy
  - d. Either state regulation or approval of the Director of Radiology
  
12. Joint Commission's National Patient Safety Goal requires patients to be identified prior to medication administration using:
  - a. Two patient identifiers selected by the technologist
  - b. Two patient identifiers determined by the hospital
  - c. The prescription number from the nuclear pharmacy
  - d. The patient's medical record number and reason for visit

13. CMS Conditions of Participation require that a medication error be reported to:
- a. The Director of Radiology and the department manager
  - b. The Director of Radiology and the hospital committee
  - c. The patient's attending physician and the hospital committee
  - d. The CEO and the hospital committee
14. A hospital uses a commercial radiopharmacy to supply all radiopharmaceuticals. The hospital contends that the review of unit dose orders by the radiopharmacist meets the requirements of CMS and other accrediting organizations. This could be true under which of the following conditions?
- a. The radiopharmacist has access to the patient record.
  - b. The unit dose requested is for diagnostic purposes only.
  - c. The radiopharmacy has a list of drug and dose used by the specific hospital.
  - d. The patient is not on Medicare.