

Tips

for Managing Radiopharmaceuticals

Pharmacy is responsible for providing appropriate oversight of radiopharmaceutical management.

Because radiopharmaceuticals have traditionally been procured outside of the pharmacy department, proper management of these medications has oftentimes been overlooked by pharmacy. Nevertheless, all three accrediting organizations recognized by the Centers for Medicare and Medicaid Services—The Joint Commission (TJC), Healthcare Facilities Accreditation Program, and National Integrated Accreditation for Healthcare Organizations from DNV Healthcare—require the pharmacy department to maintain oversight of all aspects of drug use in every area of the hospital, including the imaging and nuclear medicine departments. Pharmacy should provide oversight into drug selection, procurement, ordering, storage, preparation, dispensing, administration, documentation, and monitoring; because radiopharmaceuticals are legend drugs that require a prescription, they fall under the purview of the director of pharmacy.

The director of pharmacy also should play a complementary role in reviewing policies and procedures (P&Ps) in the nuclear medicine department. While the director of radiology is responsible for creating nuclear medicine imaging and therapy protocols, the pharmacy director should contribute to this process by reviewing the drug aspects of these P&Ps. For example, the pharmacy director should evaluate drug uses; ensure the product is on the formulary; confirm the product is FDA approved; and ensure the medication ordering processes, delivery and receipt, and storage and disposal practices comply with facility policies.

Radiopharmaceutical management is considered low-hanging fruit by surveyors, as management of these agents has traditionally been off the pharmacy director's radar.

Due to their radioactivity, pharmacy cannot touch, handle, order, or stock these medications; yet, pharmacy is still responsible for exercising due diligence in supervision and oversight of these products. For example, pharmacy should ensure the hot lab has adequate storage areas and security, approve adult and pediatric doses, and review drug protocols. In addition, for off-label usage, pharmacy must research the literature and provide backup documentation to support their use for formulary approval.

Per FDA's Compounding Policy Guide 460.200, the compounding of medications that are copies of commercially available products is not permitted.¹ If the medication is FDA-approved, it should be purchased from a cGMP-compliant drug manufacturing firm. The practice of using compounded copies of commercially available products opens the hospital to possible Board of Pharmacy and FDA action. The Society of Nuclear Medicine's position statement, *Use of Compounded Radiopharmaceuticals and Adjunct Drug Preparations*, reinforces the need to use FDA-approved drugs, the need for pharmacy oversight, formulary inclusion, and cautions about potential Medicare fraud with compounded medications.²

The ordering and delivery considerations for radiopharmaceuticals are unique.

Compared with most medications, which are purchased by the pharmacy department, radiopharmaceuticals are most often purchased by the nuclear medicine technologist directly from the nuclear pharmacy. After radiopharmaceuticals have been prepared they may only be used for a limited time; thus, frequently the nuclear medicine department will order radiopharmaceuticals the night before they are needed and they will be prepared the next morning to prevent wastage.

A hospital's P&P for radiopharmaceutical delivery must be specified and followed to ensure compliance. Due to their short half-life, radiopharmaceuticals often are delivered early in the morning when no staff is present. Your hospital's P&P should delineate an appropriate delivery process. Will the courier delivering the drug be permitted to enter the hot lab, store the drug, and then lock up the lab afterward? Will the courier be permitted to deliver the medication alone, or must hospital security accompany them to and from the hot lab? Consider that a courier commonly delivers time-sensitive radiopharmaceuticals to multiple facilities,

and waiting for an escort can inhibit efficient delivery and be an unnecessary burden for security personnel.

Environment of care standard EC.02.02.01, element of performance 6, requires TJC-accredited hospitals to minimize risk associated with selecting, handling, storing, transporting, using, and disposing of radiopharmaceuticals. TJC suggests that certain actions be taken to comply with this requirement, including creating a P&P that takes into consideration Nuclear Regulatory Commission standards; ensuring safe and secure transport and storage of radioactive materials; fully documenting the receipt, transfer, and disposal of radiopharmaceuticals; and conducting a regular inventory to verify safe storage at least every six months. In addition, in their July 11, 2012 newsletter, TJC clarified that "To escort or not to escort a delivery person through the building is solely the decision of the receiving organization," provided the receiving organization controls and maintains constant supervision of radioactive agents through the hospital to a secure area.³ The person delivering radioactive materials must be properly trained in accordance with your hospital's P&P and should be a radiation worker with specific training.

The formulary review process for radiopharmaceuticals is similar to the process for every other class of medication. All medications used in nuclear medicine, including imaging agents and adjunct medications, must be included in the hospital formulary. If radiopharmaceutical drug preparation is outsourced, the vendor should be able to assist in evaluating these medications for formulary status. Currently there are only 44 radiopharmaceuticals approved by the FDA for use in the US (view a list of FDA-approved radiopharmaceuticals here: <http://www.cardinalhealth.com/us/en/Nuclearmedicinecompliance/FDAApproved>). Typically, these medications are addressed by the director of pharmacy, working together with radiology, to specifically identify which drugs are used and must be on formulary. When evaluating radiopharmaceuticals for formulary, follow the same process used for other medications: evaluate the drug and its dosage, ensure it is FDA approved, review its approved indications, and review the supplier.

Compounding Practices that May Incur FDA

Action¹ When the scope and nature of a pharmacy's activities raise concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
2. Compounding drugs that were withdrawn or removed from the market for safety reasons.
3. Compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs without an FDA-sanctioned investigational new drug application in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.
4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
6. Using commercial scale manufacturing or testing equipment for compounding drug products.
7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state-licensed persons or commercial entities for resale.
8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available, FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.
9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

The foregoing list of factors is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

Create a specific standard operating procedure for the delivery of controlled substance radiopharmaceuticals. Currently there is only one radiopharmaceutical that is a Schedule II controlled substance, ioflupane I 123 injection, which is a diagnostic agent indicated for the diagnosis of Parkinsonian syndromes. Because it is both radioactive and a narcotic, if this agent is used in your hospital you must develop a P&P specific to its use. Developing this P&P will require a collaborative effort between pharmacy and nuclear medicine.

Properly addressing the institutional barriers to using a medication that is classified as both a controlled substance and a radiopharmaceutical is necessary to manage this potentially complex medication. Typically, a Schedule II controlled substance is managed purely by pharmacy—from ordering, through obtaining sign-offs, transmission to the supplier, and receiving and storing. However, the proper management of a controlled substance radiopharmaceutical dictates that the director of pharmacy order the drug, but it must be received by radiology, as it is a radioactive substance. The imaging department, particularly nuclear medicine, and pharmacy must collaborate closely to manage use of this medication. Nuclear medicine requests that pharmacy order the drug from the supplier, the medicine is received by the nuclear medicine department, pharmacy completes the paperwork to properly track the shipment, the medication is administered to the patient, and finally, any residual medication in the manufacturer's vial must be allowed to decay before it is discarded via the narcotic waste stream. Developing a robust P&P and ensuring it is followed closely will best ensure compliance with this complicated medication use process.

References

1. FDA Web site. CPG Sec. 460.200 Pharmacy Compounding (Reissued 05/20/2002). <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm>. Accessed February 12, 2013.
2. The Society of Nuclear Medicine and Molecular Imaging Web site. Position Statement *Use of Compounded Radiopharmaceuticals and Adjunct Drug Preparations*. <http://interactive.snm.org/index.cfm?PageID=7692>. Accessed February 12, 2013.
3. The Joint Commission Web site. July 11, 2012 newsletter: Actions to help ensure the safety and security of radioactive materials. <http://www.jointcommission.org/issues/article.aspx?Article=WRddMMzrLc%2fHKU1k9BTgkU1dfiPQtQrJPAZluZciWUk%3d>. Accessed February 12, 2013.



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