

Chapter 2

Medication Distribution and Inventory Control Systems

Learning Outcomes

After completing this chapter, the technician should be able to:

- Describe distribution processes used in the inpatient and outpatient setting.
- Explain the role of the formulary in purchasing and inventory systems.
- Apply the proper principles and processes when receiving and storing pharmaceuticals.
- Identify key techniques for reviewing packaging, labeling, and storage conditions when handling pharmaceuticals.
- Describe the methods of inventory control that may be used to maintain adequate stocks of pharmaceuticals and medical devices.
- Demonstrate both an understanding of pharmaceutical products that require special handling within the purchasing and inventory system.
- Explain the ordering, receiving, and stocking process for pharmaceuticals and medical devices.
- Describe inventory procedures for recalled products, controlled substances, chemotherapy products, investigational drugs, and other products requiring special handling.
- Demonstrate an understanding of the appropriate processes in the handling of pharmaceutical recalls and the disposal of pharmaceutical products.
- Describe the characteristics of durable and nondurable medical equipment.

This chapter applies to Section II of the PTCB exam, Maintaining Medication and Inventory Control Systems.

The Formulary System

Most hospitals and health care systems develop a list of medications that may be prescribed for their patients. This list, usually called a *formulary*, serves as the cornerstone of the purchasing and inventory control system. The formulary is developed and maintained by a committee of medical and allied health staff called the Pharmacy and Therapeutics (P&T) Committee. This group generally consists of physicians, pharmacists, nurses, and administrators, although other disciplines may be present, including dieticians, risk managers, and case managers. The group collaborates to ensure that the safest, most efficacious, and least costly medications are included on the formulary. The products on the hospital formulary dictate what the hospital pharmacy should keep in inventory. Third-party prescription drug benefit providers (PBMs) will also establish plan-specific formularies for their ambulatory patients. Ambulatory (retail) pharmacy staff frequently encounter insurance plan-specific drug formularies in serving their customers and adjust their inventory accordingly. Most retail pharmacies do not restrict items in their inventory rigidly. This is because in this setting, inventories are largely dependent on the dynamic needs of their patient population and, to some degree, the patients' insurance plans. Therefore, the concept of formulary management differs greatly depending on the perspective (ie, that of the hospital compared with that of the retail pharmacy).

Nonformulary Protocol

Typically, when a prescriber orders a nonformulary product, the pharmacist requests verbal or written justification for its use and challenges the request, as appropriate, if a comparable or therapeutically equivalent product is available on the hospital formulary. In certain cases, the utilization of a nonformulary product is warranted when it is believed its benefit is superior to the other alternative formulary items that may exist (usually for a patient-specific or disease-specific reason). The P&T committee regularly reviews nonformulary drug utilization to identify trends and review concerns, and this process may prompt the addition of new products to the formulary over time.

Ordering Pharmaceuticals

Some pharmacies employ a dedicated purchasing agent to manage the procurement and inventory of pharmaceuticals. Others employ a more general approach whereby a variety of staff are involved in ordering pharmaceuticals. The state-of-the-art practice involves the use of computer and Internet technology to manage the process of purchasing and receiving pharmaceuticals from a drug wholesaler. This process includes online procurement and purchase order generation and electronic receiving processes that involve bar code technology and hand-held computer devices (Figure 2-1). Use of computer technology for these purposes has many benefits, including up-to-the-minute product availability information, comprehensive reporting capabilities, accuracy, and efficiency. Use of computer technology also facilitates compliance with various pharmaceutical purchasing contracts.

Receiving and Storing Pharmaceuticals

One of the most useful experiences for a new pharmacy technician is to witness the receipt of pharmaceuticals by the pharmacy department. This experience is useful for a number of reasons:

- It helps the pharmacy technician become familiar with various processes involved with the ordering and receipt of pharmaceuticals.
- It may help the technician become familiar with formulary items.
- It may demonstrate the system used to ensure that only formulary items are put into inventory.
- It helps familiarize the technician with the locations in which drugs are stored.



Figure 2-1. Handheld Bar Code Scanning Device.

Receiving is one of the most important parts of the pharmacy operation. A poorly organized and executed receiving system can put patients at risk and elevate health care costs. For example, if the wrong concentration of a product were received in error, it could lead to a dosing error or a delay in therapy. Misplaced products or out-of-stock products jeopardize patient care as well as the efficiency of the pharmacy—both undesirable and costly outcomes. To avoid these unfavorable outcomes, pharmacy technicians should become familiar with the process for receiving and storing pharmaceuticals.

The Receiving Process

Some pharmacies create processes whereby, as much as is possible, the person receiving pharmaceuticals is different from the individual ordering them. This is especially important for controlled substances because it

effectively establishes a check in the system to minimize opportunities for drug diversion.

In a reliable and efficient receiving system, the receiving personnel verify that the shipment is complete and intact (ie, check for missing or damaged items) before putting items into circulation or inventory. The receiving process begins with the verification of the boxes containing pharmaceuticals delivered by the shipper. The person receiving the shipment verifies that the name and address on the boxes is correct and that the number of boxes matches the shipping manifest. Many drug wholesalers use rigid plastic crates because they protect the contents of each shipment better than foam or cardboard boxes. Plastic crates are also environmentally friendly because they are returned to the wholesaler for cleaning and reuse. In any case, each box should be inspected for gross damage.

Products with a cold storage requirement (ie, refrigeration or freezing) should be processed first (see Table 2-1 for storage temperatures). The shipper is responsible for ensuring the cold storage environment is maintained during shipping and will generally package these items in a transportable foam cooler. The shipper will include frozen cold packs to keep products at the correct storage temperature during shipment.

Receiving personnel play a critical role in protecting the pharmacy from financial responsibility for products damaged in shipment, products not ordered, and products

not received. If there is any obvious damage or other discrepancies with the shipment, such as a breach in the cold storage environment or an incorrect product, they should be noted on the shipping manifest, and if warranted, the appropriate part of the shipment should be refused. Ideally, gross shipment damage or incorrect box counts should be identified in the presence of the delivery person and should be documented when signing for the order. Other problems identified after delivery personnel have left, such as mispicks, product dating, or internally damaged goods must be resolved according to the vendor's policies. Most vendors have specific procedures to follow in reporting and resolving such problems.

The next step of the receiving process entails checking the newly delivered products against the receiving copy of the purchase order. This generally occurs after the delivery person has left. For the supplier a purchase order, created when the order is placed, is a complete list of the items that were ordered. Some pharmacies may still use a traditional paper purchase order. However, the state-of-the-art practice employs electronic, Web-based technology to place orders with respective wholesale distributors (Figure 2-2). In this case, the order is transmitted and received in an instant, and the wholesaler's inventory of particular products is available in near real-time. This technology allows for more efficient operations and effective communication between the pharmacy and wholesaler, and simplifies order reconciliation and billing processes.

The person responsible for checking products into inventory uses the receiving copy to ensure that the products ordered have been received. The name, brand, dosage form, size of the package, concentration strength, and quantity of

Table 2-1. Defined Storage Temperatures and Humidity^t

Freezer	-25° to -10° C	-13° to 14° F
Cold (Refrigerated)	2° to 8° C	36° to 46° F
Cool	8° to 15° C	46° to 59° F
Room Temperature	The temperature prevailing in a working area.	
Controlled Room Temperature	20° to 25° C	68° to 77° F
Warm	30° to 40° C	86° to 104° F
Excessive Heat	Any temperature above 40°C (104° F)	
Dry Place	A place that does not exceed 40 percent average relative humidity at controlled room temperature or the equivalent water vapor pressure at other temperatures. Storage in a container validated to protect the article from moisture vapor, including storage in bulk, is considered a dry place.	

^t United States Pharmacopeia 26/The National Formulary 21, pp. 9–10; 2003. United States Pharmacopeial Convention, Inc., Rockville, MD.

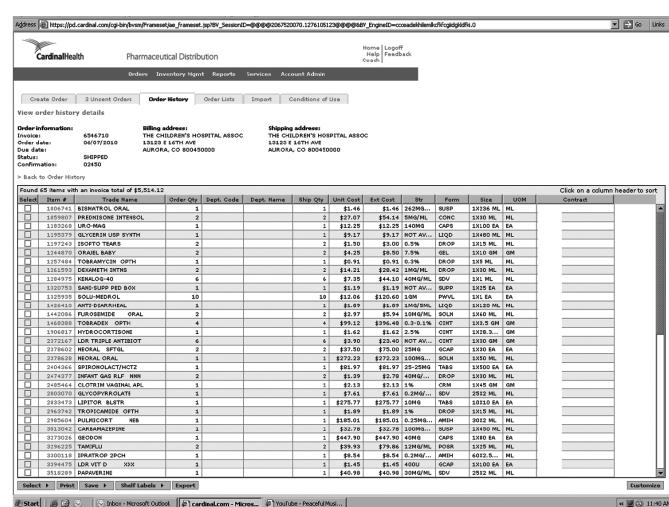


Figure 2-2. Electronic Purchase Order.

product must match the purchase order. Generally, once the accuracy of the shipment is confirmed, the purchase order copy is signed and dated by the person receiving the shipment. At this point, the product's expiration date should be checked to ensure that it meets the pharmacy's minimum expiration date requirement. Frequently, pharmacies will require that products received have a minimum 6 months' shelf life remaining before they expire. If a pharmacy uses a Barcode Medication Administration (BCMA) system, it is critical that each bar code is scanned at the time each product is received. This ensures the product bar code is in the BCMA system so it will scan correctly when it gets

to the bedside. This applies even if the product has been received before from the same manufacturer. Some bar codes contain lot and expiration dating information, which could change with each manufacturer batch production. In the event a bar code does not scan, it is customary for the receiving technician to manually add the item to the BCMA system or overlay an internal bar code on the product prior to shelving it. It is noteworthy to mention that on occasion, the manufacturer/wholesaler may inadvertently ship an excess quantity of an ordered product to the pharmacy. The ethical response is to notify the manufacturer or wholesaler of this situation immediately and arrange for

DEA FORM-222
U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions		No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04).		OMB APPROVAL No. 1117-0010		
TO: (Name of Supplier)		STREET ADDRESS				
CITY and STATE		DATE		TO BE FILLED IN BY SUPPLIER SUPPLIERS DEA REGISTRATION No.		
L I N E No.		TO BE FILLED IN BY PURCHASER				
1	No. of Packages	Size of Package	Name of Item		National Drug Code	Packages Shipped
2						
3						
4						
5						
6						
7						
8						
9						
10						
◀ LAST LINE COMPLETED (MUST BE 10 OR LESS)			SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT			
Date Issued		DEA Registration No.		Name and Address of Registrant		
Schedules						
Registered as a		No. of this Order Form				

DEA Form-222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S COPY 1

Figure 2-3. DEA Form 222.

Received to stock 4 x 50's Oral Polio Vaccine, 0.5 ml 50 x 4's Haemophilus B vaccine vials 13 each Piperacillin 40 gm vials 30 DTP vials, 7.5 ml One vial Piperacillin broken in shipment. 4/15/97 Joe Johnson Pharmacy Technician	
---	--

Receipt on blank piece of paper must include precise detail of the amount, product description, person receiving product, and the date of receipt.

Figure 2-4. Receipt of Pharmaceutical on Blank Paper.

the return of any excess quantity. Controlled substances require additional processing upon receipt. Regulations specific to Schedule II controlled substances require the completion of DEA form 222 (Figure 2-3) upon receipt of these products. The form must be filed separately with a copy of the invoice and packing slip accompanying each shipment. If a pharmacist or pharmacy technician other than the receiving technician removes a product from a shipment before it has been properly received and cannot locate the receiving copy of the purchase order, then a written record of receipt should be created. This is done by listing the product, dosage form, concentration or strength, package size, and quantity on a blank piece of paper (Figure 2-4) or on the supplier's packing slip or invoice and checking off the line item received (Figure 2-5). In both cases, the name of the person receiving the product should be included and the document should be given to the receiving technician to avoid confusion and an unnecessary call to the wholesaler or manufacturer.

Invoice					
Shipper		Buyer			
Pharmaceutical Labs 185 Commerce Avenue Ft. Washington, PA		Community Hospital 1 Valley Road Suburbia, MD 20777			
Invoice # 12346 Invoice Date 4/01/97					
Quantity	Product #	Product Description	Unit Price	Amount	
5 ✓ rec.	6190	Orimune 50 x 1	\$450.00	\$2,250.00	
4 ✓	7183	Haemophilus B Vaccine	\$ 52.92	\$2,646.00	
13 ✓ rec.	4391	Piperacillin 40 g Vial	\$110.00	\$1,320.00	
30 ✓	2727	DPT Vaccine 7.5ml Vial	\$ 56.50	\$1,695.00	
Quantity received as indicated one vial Piperacillin broken in shipment. Received 4 x 50's Orimune 50 Haemophilus B Vaccine 13 Piperacillin 40 gm vial 30 DPT Vaccine 7.5 ml 4/15/97 Joe Johnson Pharmacy Technician					

Receipt on an invoice or packing slip can be done the same way as receipt on a blank piece of paper or the quantities can be checked or modified as received.

Figure 2-5. Receipt of Pharmaceutical on Packing Slip/Invoice.

The Storing Process

Once the product has been properly received, it must be properly stored. Depending on the size and type of the pharmacy operation, the product may be placed in a bulk central storage area or in the active dispensing areas of the pharmacy. In any case, the expiration date of the product should be compared with the products currently in stock. Products in stock that have expired should be removed. Products that will expire in the near future should be highlighted and placed in the front of the shelf or bin. This is a common practice known as *stock rotation*. The newly acquired products will generally have longer shelf lives and should be placed behind products that will expire before them. Stock rotation is an important inventory management principle that promotes the use of products before they expire and helps prevent the use of expired products and waste.

Product Handling Considerations

Pharmacy technicians usually spend more time handling and preparing medications than do pharmacists. This situation presents pharmacy technicians with the critical responsibility of assessing and evaluating each product from both a content and labeling standpoint. It also gives technicians an opportunity to confirm that the receiving process was performed properly.

Just as checking the product label carefully at the time a prescription or medication order is filled is important, so is taking the same care when receiving and storing pharmaceuticals. It is best to read product packaging carefully rather than rely on the general appearance of the product (eg, packaging type, size or shape, color, logo), because a product's appearance may change frequently and may be similar to other products. Technicians play a vital role in minimizing dispensing errors caused by human fallibility. Technicians are generally the first in a series of double checks involved in an accurate dispensing process.

When performing purchasing or inventory management roles, the technician must pay close attention to the product's expiration date. For liquids or injectable products, color and clarity should also be checked for consistency with the product standard. Products with visible particles, an unusual appearance, or a broken seal should be reported to the pharmacist.

Because pharmacy technicians handle so many products each day, they are in a perfect position to identify

packaging and storage issues that could lead to errors. Technicians must pay close attention to three main issues:

- *Similar drug names*—Various drugs with similar names can cause problems when stored in an immediately adjacent shelf position. All staff members should be alerted to look-alike or sound-alike products.
- *Similar package sizes*—Stocking products of similar name, color, shape, and size can result in error if someone fails to read the label correctly. Sometimes the company name or log is emphasized on the label instead of the drug name, concentration, or strength.
- *Similar label format*—Storing products that are similar in appearance adjacent to one another can result in error if someone fails to read the label.

Alerting other staff members to products that fall into one of these categories is essential. Some pharmacies routinely discuss product-handling considerations at staff meetings or in departmental newsletters. Dispensing errors may be averted by simply relocating a look-alike/sound-alike product to a different shelf location or placing warning notes (ie, auxiliary labeling or highlights) on the shelf or on the product itself. Pharmacy technicians should also discuss their concerns with co-workers and may advocate changes to products with poor labeling with the manufacturer.

Maintaining and Managing Inventory

An inventory management system is an organized approach designed to maintain just the right amount of pharmaceutical products in the pharmacy at all times. A variety of inventory management systems are used, ranging from simple to complex. They include employing an order book where pharmacy staff simply write down what they believe is necessary to order (aka the “eyeball” method), the minimum/maximum (par) level, the Pareto (ABC) Analysis, and the fully automated, computerized system.

Economic Models

The Pareto ABC system, also known as the *80/20 rule*, relies on the premise that managing 20% of the inventory will cover 80% of the costs (Figure 2-6). It essentially groups inventory products by aggregate value and volume of use into three groupings (A, B, and C). This analysis is useful to determine where inventory control efforts are best directed. For example, Group A may include 20% of all items that make up 65% of the inventory

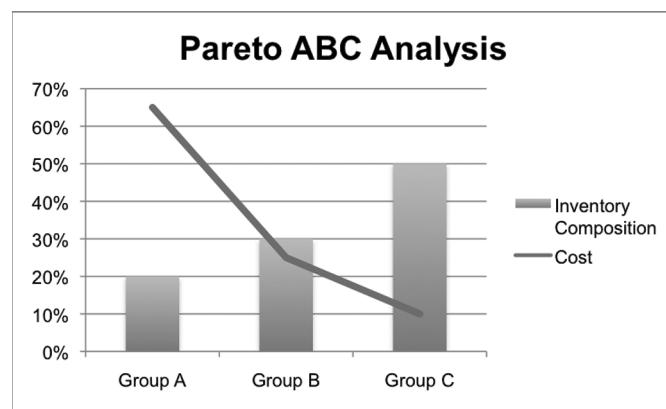


Figure 2-6. Pareto ABC Analysis.

cost. Tight control over these items would be sensible. Group B may include 30% of items that make up 25% of the inventory cost. An automatic order cycle here based on well-established par levels might be useful. Group C may include 50% of items that make up 10% of the inventory cost. Less aggressive monitoring of these items may be justifiable.

Manual Systems

Manual inventory models require the active oversight of pharmacy technicians and are usually based on a minimum/maximum, or par-level, system. The **par-level system** uses predetermined stock minimum and maximum quantities to be maintained. Once item par-levels are established, they are usually identified on or near the shelf label of individual pharmaceutical items kept in inventory (Figure 2-7). Staff members can create a pharmaceutical order using a hand-held bar code scanning device or enter product stock numbers directly into a personal computer. They strive to maintain physical pharmaceutical inventories within the minimum to maximum range to avoid running short on a product or overstocking. Running short on a product can affect patient care, and overstocking adds unnecessary operational expense.

Manual systems require pharmacy staff to routinely scan inventory levels and place orders accordingly. With both electronic and manual systems, pharmacy staff should be aware that the diversity of their patients' specific needs or dynamic seasonal volume may require modification in a particular product's par-level.

Automation

In contrast to a manual system, with an automated perpetual inventory system, each dispensing transaction is subtracted from the perpetual inventory that is maintained

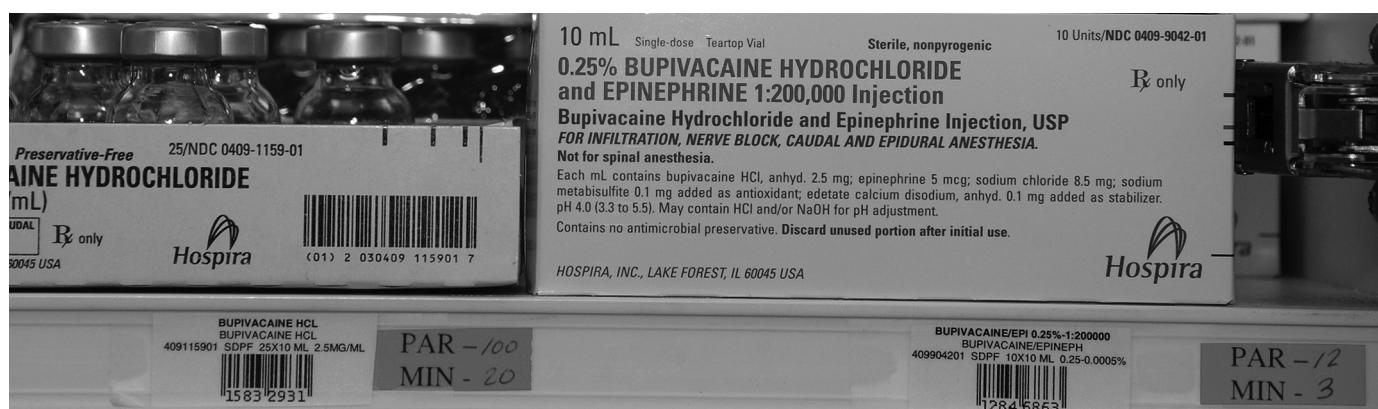


Figure 2-7. Shelf labels correspond to each product and are placed on the storage bin or shelf. The minimum and maximum inventory level is written on this label, and the information is used as a relative guide for pharmacy staff involved in purchasing pharmaceuticals.

electronically in a computerized database; conversely, quantities of products received are automatically added to the inventory on hand in the computerized system. When the quantity of a pharmaceutical product in stock reaches a predetermined point (often called par) a purchase order is automatically generated to order more of the product. The system does not depend on any one employee to monitor the inventory or reorder pharmaceuticals.

The technology is available to have a computerized inventory in most pharmacies, but interfacing a computerized inventory system with existing pharmacy computer systems designed for dispensing and patient management systems is often difficult. In addition, other variables, such as product availability, contract changes, and changing use patterns (either up or down), make relying on the fully computerized model challenging. Consequently, even the most sophisticated electronic and automated systems still require human oversight.

Automated dispensing devices are capable of tracking perpetual inventory at the product level. They also limit access to only authorized personnel and record the identities of individuals who access inventory, as well as how much of a specific drug was removed for a given patient. A useful feature in many of these systems allows pharmacy personnel to automatically generate a fill-list of what needs to be replenished on the basis of a par-level system. The par-level inventory system relies on a predetermined order quantity and an order point. These systems typically include shelf labels that correspond to each product and are placed on the storage bin or shelf to alert staff to the minimum stock quantity (see Figure 2-7). The minimum and maximum inventory level is written on this

label, and the information is used as a relative guide for pharmacy staff involved in purchasing.

The use of automated dispensing devices in inpatient hospital nursing units, clinics, operating rooms, and emergency rooms has facilitated the use of computers for inventory management. Similar devices are evolving for the retail pharmacy and hold promise for making the dispensing process safer and more efficient, and also assisting in inventory management. These devices are essentially repositories, or *pharmaceutical vending machines*, for medications that will be dispensed directly from a patient care area. A variety of manufacturers of automated dispensing devices are in the market today—the Pyxis Medstation®, Meditrol®, Omnicell®, MED Carousel (Figure 2-8), and SureMed® are some examples.

These machines are generally networked via a dedicated computer file server within the facility. They allow both unit-dose and bulk pharmaceuticals to be stocked



Figure 2-8. Medication dispensing carousel.

securely on a given patient care unit location. Each unit's inventory is configurable and allows for variation and flexibility from device to device depending on its location. The machines are capable of tracking perpetual inventory at the product level. They also limit access to authorized personnel, record the identities of those who access inventory, and record how much was removed for each patient. A useful feature in many of these systems allows pharmacy personnel to generate automatically a fill-list of what needs to be replenished based on a par-level system. In essence, the nursing and medical personnel who use these automated dispensing devices have a computerized inventory and billing system that the pharmacy staff manages. Medications used to restock these devices may be taken from the pharmacy's main inventory, or a separate purchase order may be executed periodically for each device.

Just-in-time inventory management is a philosophy that simply means products are ordered and delivered at just the right time—when they are needed for patient care—with a goal of minimizing wasted steps, labor, and cost. Pharmaceuticals are neither overstocked nor understocked. In pharmacy, this business philosophy couples responsible financial management of pharmaceutical purchasing with the clinical aspects of patient care.

Many pharmacies use an order book system, also called a *want list* or *want book*. When pharmacists or pharmacy technicians determine that a product should be reordered, they write the item in the order book. Although this approach is simple, it also provides the least amount of organized control over inventory. Its success is highly dependent on the participation of staff. Therefore, it is usually not the sole method of inventory management and is often used in conjunction with one of the other systems mentioned.

Regardless of the inventory system used, pharmacy technicians are vital contributors. The pharmacy technician may frequently identify changes in use or prescription patterns of pharmaceuticals. Examples might include high use of asthmatic medications (ie, epinephrine, albuterol, or inhaled steroids) by the emergency department or various clinics, high doses of a particular antibiotic (eg, chloramphenicol or liposomal amphotericin b) for a seriously ill patient who is likely to be hospitalized for an extended period, or high-dose opioid use by one or more oncology patients. Alerting purchasing staff to orders for unusual amounts of medications helps avoid out-of-stock situations and facilitates optimal inventory management.

Drug Recalls

A drug recall effectively removes a manufactured product from the market.

Manufacturers, on their own accord or at the direction of the Food and Drug Administration (FDA), occasionally *recall* pharmaceuticals for such reasons as mislabeling, contamination, lack of potency, lack of adherence to the acceptable good manufacturing practices, or other situations that may present a significant risk to public health. A pharmacy must have a system for rapid removal of any recalled products.

Role of the FDA

The FDA plays an active role in initiating the drug-recall process. Unlike biologics and devices, the FDA has no statutory (legal) authority to recall drugs. Manufacturers voluntarily issue recalls in their duty to protect public health and the FDA helps manufacturers coordinate drug recall information and develop specific voluntary recall plans. It performs health hazard evaluations to assess public risk associated with products being recalled (Table 2-2).

Role of Pharmacy, Manufacturers, and Distributors

Because of their responsibility to protect the public consumer, manufacturers and distributors typically implement voluntary recalls when a marketed drug product needs to be removed from the market. Recall notices are sent in writing to pharmacies by the manufacturer of the product or by drug wholesalers. These notices indicate the class of recall, the reason for recall, the name of the recalled product, the manufacturer, all affected lot numbers of the product, response required, instructions on the extent of action required in contacting affected patients, and how to return the product to the manufacturer.

On receipt of the recall notice, a pharmacy staff member, usually a pharmacy technician, checks all pharmaceutical inventory stores to determine if any recalled products

Table 2-2. FDA Drug Recall Classes

FDA Drug Recall Classes	
Class I	The most serious of recalls; ongoing product use may result in serious health threat or death.
Class II	Moderate severity concern; ongoing product use may pose serious adverse events or irreversible consequences.
Class III	Lowest severity concern; ongoing product use unlikely to cause adverse health threat; however, a marginal chance of injury may exist, so the product is being recalled.

are in stock. If a recalled product is in stock, all products should be gathered, packaged, and returned to the manufacturer if requested. In some cases, the drug will simply be destroyed. The instructions and product package should be reviewed by the pharmacist-in-charge before returning it to the manufacturer or distributor. If patients have received a recalled product, the pharmacist-in-charge has a duty to follow the action required by the recall notice. Upon completion of all activity regarding the product recall, a summary of actions taken should be documented on the recall letter and filed in the pharmaceutical recall log. The FDA has been known to request documentation of all recall activities to ensure compliance, and ultimately patient safety. The technician should keep in mind that it may be necessary to order replacement stock to compensate for recalled items that were removed from stock.

Drug Shortages

Often, manufacturers will be unable to supply a pharmaceutical because of various supply and demand situations. These situations may involve the inability to obtain raw materials, manufacturing difficulties related to equipment failure, or simply an inability to produce sufficient quantities to stay ahead of market demand. Although unfortunate, it is a reality that must be dealt with to avoid compromising patient care. As with drug recalls, the pharmacist in charge should be notified so he or she may communicate drug shortages and recommend alternative therapies to prescribers.

Counterfeit Pharmaceuticals

Unfortunately, there is a global concern related to the fraudulent mislabeling and distribution of counterfeit drugs. These products are dangerous because they may not meet standards of quality or potency and are therefore harmful or ineffective in treating the disease for which they are intended. These products can range from those containing incorrect ingredients, sub-potency, and even toxic ingredients, even though the package or dosage form appears to be legitimate. Obviously, these products are illegal and pose serious threats to the patient and caregiver. Any pharmaceutical product is at risk for being counterfeited, and developing countries appear to be the most threatened by this malicious activity. Unfortunately, the level of sophistication of individuals engaged in the act of counterfeiting is growing, even in countries with more highly controlled markets, including the United States. In 2006, the World Health Organization formed an initiative aimed at combating counterfeit medication distribution.

It is a global partnership called *International Medicinal Products Anti-Counterfeiting Taskforce* (IMPACT). The organization has brought together international enforcement and regulatory agencies, customs and police authorities, pharmaceutical manufacturing representatives, wholesale companies, health-care providers, and patient delegates to coordinate efforts and raise awareness of this problem. As a result, laws, standards, monitoring and reporting programs, and penal sanctions are being developed and coordinated to minimize the threat of fraudulent medication distribution. In many states, pedigree laws have either been passed or are in the pipeline. Simply stated, these laws require the drug wholesaler to provide a statement of origin or otherwise prove the genealogy of drugs distributed. Every step in the distribution chain will have to be documented and verified, from the point of manufacturer origin all the way to the wholesale distribution point. An electronic pedigree (e-Pedigree) ensures through documentation that a drug was safely and securely manufactured and distributed.

Pharmacy technicians need to be aware of the existence of counterfeit pharmaceuticals and the methods that are being employed to address the issue. When managing drug shortages and working outside of the routine wholesale distribution channels, it is essential to ensure that pharmaceuticals are being obtained from a reliable source. It is acceptable to obtain and verify the licensing information from alternative drug suppliers, or those purporting to have product when other, reputable suppliers do not. The technician should also remain aware of those pharmaceutical products known or suspected to be at risk and communicate any concerns when procuring, receiving, and handling these products.



Pop Quiz!

A prescription indicates 1 tab q
3–4 h prn pain, dispense #30.
What is the EDS?

Ordering and Borrowing Pharmaceuticals

Pharmaceutical Purchasing (Buying) Groups

Most health-system pharmacies are members of a group purchasing organization (GPO). Health systems and hospitals join together in a purchasing group to leverage

their buying power and take advantage of lower prices manufacturers offer to large groups that can guarantee a significant volume of orders over long periods of time (typically 1 to 2 years). Retail chain pharmacies are also able to negotiate better pricing on the basis of volume. Contracts may involve sole-source or multisource products. Sole-source products are products available from only one manufacturer, whereas multisource products (frequently termed *generic* products) are available from numerous manufacturers. Sole-source products may be produced by only one manufacturer; however, they may be included in what is known as a *competitive market basket* (eg, proton-pump-inhibitors, such as omeprazole and lansoprazole) when there are competing brand-name products on the market.

GPOs negotiate purchasing contracts that are mutually favorable to members of the group and to manufacturers. In addition to lower prices, pharmacies benefit from reduced time staff spent establishing and managing purchasing contracts with product vendors. A GPO guarantees the price for pharmaceuticals over the established contract period, which may be 1 or more years. With the purchase price predetermined, the pharmacy can order the product directly from the manufacturer or from a wholesale supplier. Occasionally, manufacturers are unable to supply a given product that the pharmacy is buying on contract. The pharmacy may then have to buy or substitute a competing product not on contract at a higher cost. Most purchasing contracts will include language to protect the pharmacy from incurring additional expenses in this event. Generally, the manufacturer will be liable to rebate the difference in cost back to the pharmacy. Therefore, it is important for the pharmacy technician to document any off-contract purchases and share them with the pharmacist-in-charge for reconciliation with the contracted vendor.

Direct Purchasing

Direct purchasing from a manufacturer involves the execution of a purchase order (P.O.) between the pharmacy and the manufacturer. The advantages of direct purchasing include not having to pay handling fees to a third-party wholesaler, the ability to order on an infrequent basis (eg, once a month), and a less demanding system for monitoring inventory. Some disadvantages include the need for a large storage capacity; a large amount of cash invested in inventory; the complication of the pharmacy's return/credit process; and staff resources required in the pharmacy and accounts

payable department to prepare, process, and pay purchase orders to more companies. Other disadvantages have to do with the likelihood that the manufacturer's warehouse is not located near the pharmacy. The manufacturers depend on shipping firms to ship products reliably; however, delivery is often unpredictable or not available on weekends, and there may be delays in delivery.

For most pharmacies, the disadvantages of direct ordering outweigh the advantages. As a result, most pharmacies primarily purchase through a drug wholesaler. There are, however, some drugs that can only be purchased directly from the manufacturers. These products generally require unique control or storage conditions. Consequently, most pharmacies will have a combination of direct purchases from manufacturers and purchases from drug wholesalers.

Drug Wholesaler Purchasing/Prime Vendor Purchasing

Purchasing from a drug wholesaler permits the acquisition of drug products from different manufacturers through a single vendor. When a health-system pharmacy agrees to purchase the majority (90 to 95%) of its pharmaceuticals from a single wholesale company, a prime vendor arrangement is established, and, customarily, a contract between the pharmacy and the drug wholesaler is developed. Usually, the wholesaler agrees to deliver at least 95 to 98% of the items on schedule and offers 24-hour/7-day-per-week emergency service. The wholesaler also provides the pharmacy with electronic order entry or receiving devices, a computer system for ordering, bar-coded shelf stickers, and a printer for order confirmation printouts. It may also offer a highly competitive discount (minus 1 to 2%) below product cost and contract pricing and competitive alternate contract pricing. Some wholesalers will offer even larger discounts to pharmacies that may prefer a prepayment arrangement. In these situations, the wholesaler monitors the aggregate purchases of the pharmacy (eg, a rolling 3-month average) and bills the pharmacy this amount in advance (prepayment). This arrangement creates larger cash flow and investment capital for the wholesaler while saving the pharmacy money on its pharmaceutical purchases.

These wholesaler services make the establishment of a prime vendor contract appealing and result in the following advantages: more timely ordering and delivery, less time spent creating purchase orders, fewer inventory carrying costs, less documentation, computer-generated

lists of pharmaceuticals purchased, and overall simplification of the credit and return process. Purchasing through a prime vendor customarily allows for drugs to be received shortly before use, supporting the just-in-time ordering philosophy mentioned earlier in this chapter. Purchasing from a wholesaler is thus a highly efficient and cost-effective approach toward pharmaceutical purchasing and inventory management.

Borrowing Pharmaceuticals

No matter how effective a purchasing system is, the pharmacy occasionally must borrow drugs from other pharmacies. Most pharmacies have policies and procedures addressing this situation. Borrowing or loaning drugs between pharmacies is usually restricted to emergency situations and limited to authorized staff. Borrowing is also limited to products that are commercially available, thus eliminating such items as compounded products or investigational medications. Most pharmacies have developed forms to document and track merchandise that is borrowed or loaned. These forms also help staff document the details necessary for error-free transactions.

The pharmacy's borrow and loan policies and procedures should provide detailed directions on how to borrow and loan products, which products may be borrowed or loaned, sources for them, and reconciliation of borrow-loan transactions (the payback process). Securing the borrowed item may require the use of a transport or courier service or may include the use of security staff or other designated personnel. This information is vital for pharmacy technicians to understand so they can fulfill their responsibility when borrowing and loaning products.



Pop Quiz!

What form is required to order OxyContin tablets?

Controlled Substances

Controlled substances have specific ordering, receiving, storage, dispensing, inventory, record-keeping, return, waste, and disposal requirements established under the law. The *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act of 1970* and the *ASHP Technical Assistance Bulletin on Institutional Use of Controlled Substances* provide detailed information on the specific handling requirements for controlled substances.

The pharmacy technician should know two principles regarding controlled substances:

1. Ordering and receiving Schedule II controlled substances requires special order forms and additional time (1 to 3 days).
2. These substances are inventoried and tracked continuously. This type of inventory method is referred to as a perpetual inventory process, whereby each dose or packaged unit, such as a tablet, vial, or ml of fluid volume is accounted for at all times.

In some pharmacies, pharmacy technicians work with pharmacists to manage inventory and order, dispense, store, and control narcotics and other controlled substances. Controlled substances require additional processing when ordering, receiving, dispensing, storing, and inventorying occurs. These procedures are required by Drug Enforcement Administration (DEA) regulations, and in many cases, the state board of pharmacy. These regulations create the chain of accountability in the interest of minimizing drug diversion, illicit drug use, and public safety. State and federal regulations vary regarding length of storage requirements for purchase orders, invoices, and dispensing records. It is best to check both sets of regulations and comply with the stricter requirements.

Regulations specific to Schedule II controlled substances require DEA form 222 to be completed to initiate procurement of these products. Form 222 is a triplicate, hand-written form and each copy has a specific intent, as specified by the DEA. On receipt of DEA Schedule II products, the pharmacy must separately file the appropriate copy of the form 222, along with the supplier's copy of the invoice and packing slip accompanying each shipment. Alternatively, the pharmacy can be registered with the DEA to place Schedule II orders online through the wholesaler's electronic process. Schedule III, IV, and V controlled substances are generally obtained in a manner identical to other noncontrolled

Products Requiring Special Handling

Most pharmaceuticals, with the exception of controlled substances, investigational drugs, compounded products, repackaged drugs, and drug samples will be handled and processed in the inventorying and purchasing systems described above.

substances. However, the receipt and storage requirements of these products may depend on state regulation or the specific employer's policy. For example, state regulation may require a pharmacy to file separately the receipts of all controlled substances ordered during a particular year and maintain them in a readily retrievable manner for inspection. Some pharmacies may require all controlled substance inventories to be shelved separately from other legend drugs, whereas others may store them together.

Chemotherapy

Because of the hazards inherent with human exposure to antineoplastic or chemotherapy products, care and precaution must be exercised in the receipt, handling, and storage of these products. The distributor will generally ship antineoplastic drugs separate and apart from other products (eg, in their own container). Special care should be exercised when opening and unpacking totes containing these products. Although the distributor will take appropriate measures to properly pack and pad the items inside totes, it is still possible for damage to occur. Pharmacy technicians should be familiar with the organization's chemotherapy and hazardous materials spill management protocol. Most hospitals will have a "chemotherapy spill kit" on hand to be used in the management and cleanup of an accidental spill.

Investigational Drugs

Investigational drugs also require special ordering, inventory, and handling procedures. Generally, the use of investigational drugs is categorized into two distinct areas:

1. Investigational drugs used in a formal protocol that was approved by the institution
2. Investigational drugs used for a single patient on a one-time basis that have been authorized by the manufacturer and the FDA

In both cases, the physician may be responsible for the ordering and the pharmacy staff handles the inventory management of the investigational drug. Some pharmacies associated with academic affiliations or institutions conducting clinical research may have formally organized Investigational Drug Services managed by a pharmacist principally dedicated to pharmaceutical research activities. In these cases, the investigational drug service pharmacist may be responsible for the ordering, dispensing, and inventory management of investigational drugs

according to the research protocol. Pharmacy technicians often prepare or handle investigational drugs and participate in the required perpetual inventory record-keeping system. Again, it is important for pharmacy technicians to learn the department procedures for investigational drugs and to be competent in the handling, storage, dispensing, and inventory systems involved.

Restricted Drug Distribution System (RDDS)

The intent of the restricted drug distribution system is to ensure that specific drugs identified as high risk are safely procured, prescribed, dispensed, and administered. The FDA, the manufacturer, and the distributor collaborate to establish tighter controls over designated products.

If improperly administered, certain drugs can cause serious adverse effects, such as blood disorders, birth defects, or changes in cardiovascular status. Satisfying the requirements necessary to obtain these drugs may be limited to the presence of a specific disease state being treated by a physician who is registered under the RDDS. As a matter of satisfying restricted distribution requirements, the physician may have to attest to patient-specific criteria. This might include a failed treatment response to other medications, contraindications to other therapy, or provided laboratory data. In other cases, the physician may need to commit to administering the medication under controlled conditions, such as in their office.

In most cases, the RDDS will require:

- registration of the prescribing physician
- dispensing pharmacy
- patient name and other demographic information
- a patient agreement form for liability purposes
- the specific indication for the medication
- its dose and quantity to be dispensed

In some programs, lab results, adherence to a robust patient counseling or outreach protocol, and reimbursement information guaranteeing payment is required (Table 2-3). The primary goal of RDDS is safe, effective product use and reduced risk to the patient.

Compounded Products

Compounded pharmaceuticals are another type of product handled by pharmacy personnel. Unlike drugs ordered from an outside source, compounded products are extemporaneously prepared in the pharmacy as indicated by scientific compounding formulas. These products may include oral liquids, topical preparations, solid dosage forms, and sterile products.

Table 2-3. Examples of Restricted Distribution Products

Drug	Physician Enrollment and Training	Patient Enrollment	Specific Requirements			Administration in Medical Setting	Requires Lab Test Prior to Distribution
			Requires Registration of Retail Pharmacy to Dispense	Specialty Distributor or Centralized Pharmacy			
Abarelix (Plenaxis)	X		X*			X+	
Alosetron (Lotronex)	X						
Ambrisentan (Letairis)	X	X	X				X^^
Bosentan (Tracleer)	X	X			X		
Clozapine (Clozaril)	X	X	X				X^
Deferasirox (Exjade)	X				X		
Dofetilide (Tikosyn)	X	X	X			X++	
Getitinib (Iressa)	X	X			X		
Isotretinoin (Accutane)	X	X	X				X^^
Lenalidomide (Revlimid)	X	X			X		X^^
Mifepristone (Mifeprex)	X					X+	
Nataluzimab (Tysabri)	X				X**		
Sodium Oxybate (Xyrem)	X	X			X		
Thalidomide (Thalomid)	X	X	X				X^^

* dispensed by registered hospital pharmacy

** dispensed only to authorized infusion sites

+ administered in doctor's office

++ 3-day in-patient hospital stay required upon initiation

^ white blood cell count

^^ negative pregnancy test

The use of these products requires that prescribing patterns and expiration dates be monitored closely. Compounded products typically have short expiration dates, ranging from days to months. Because pharmacy technicians are likely to identify usage patterns and determine stock and product needs, procedures for monitoring patient use, product expiration dates, and additional stock needs must be well known and adhered to by technicians to prevent stock shortages. Specific pharmacy technicians may initiate compounding activities, but this may vary according to departmental procedures.

All chemicals are shipped according to Department of Transportation (DOT) and company safe practice standards, and include a materials safety data sheet (MSDS) for each chemical. Strong acids and alkaline chemicals and other toxic raw materials are frequently used in the process of compounding pharmaceuticals. The receiving

pharmacy technician should be familiar with the utility and safe product handling and storage requirements of these chemicals.

Rewrapped Pharmaceuticals

Although manufacturers supply many drugs in a prepackaged unit-dose form, the pharmacy staff is responsible for packaging some products. These items are generally unit-dose tablets and capsules, unit-dose oral liquids, and some bulk packages of oral solids and liquids. Each pharmacy establishes stocking mechanisms for these products and relies on pharmacy technicians to identify and respond to production and stock needs. Generally, designated technicians coordinate prepackaging activities, but some pharmacies may integrate repackaging with other pharmacy technician responsibilities. Knowledge of the pharmacy's procedures for repackaging is required to prevent disruptions in dispensing activities.

Nonformulary Items

Nonformulary items also require special handling. Nonformulary medications generally are not mixed into the shelving system of formulary products in the pharmacy; they fall outside normal inventorying mechanisms. Often, manual tracking mechanisms and computer system queries of active nonformulary orders are the two most common techniques used to monitor and order these products.

Medication Samples

The last products requiring special handling are medication samples. Traditional inventory management and handling practices do not work well with medication samples for two reasons:

1. Medication samples are not ordered by the pharmacy; the drug manufacturer usually provides them to physicians, upon request, free of charge. This often occurs without the pharmacy's knowledge.
2. Samples are not usually dispensed by the pharmacy.

These factors make it difficult to know whom to contact if a medication sample is recalled and to ensure that medication samples are not sold. Because of difficulties in controlling samples, organizations may allow samples to be stored and dispensed in ambulatory clinics only after the samples are registered with the pharmacy for tracking purposes. These difficult logistical and control factors have led many organizations to adopt policies that simply disallow medication samples altogether.

If your organization does allow medication samples, they will probably be stored outside the pharmacy, and pharmacy personnel will be required to register and inspect the stock. Pharmacy technicians are sometimes involved in inspecting medication sample storage units. These technicians are often responsible for determining if a sample is registered with the pharmacy, stored in acceptable quantities, labeled with an expiration date that has not been exceeded, and stored under acceptable conditions. Review your pharmacy's policies and procedures regarding medication samples to learn the role of the pharmacy technician. Many hospitals strive to maintain compliance with the standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Its standards on *Medication Management* are intended to promote consistently safe practices related to the procurement, storage, dispensing, and administration of pharmaceuticals, and the use of sample drug products falls into this standard.

Radiopharmaceuticals

Radiopharmaceutical agents are typically used in diagnostic imaging as contrast media and can include oral and injectable products. Other radiopharmaceutical products are used therapeutically to treat diseases of the thyroid gland and forms of cancer. Technically speaking, these drugs are radioactive and potentially hazardous to humans and the environment, because they emit low to moderate levels of radiation. Therefore, special procedures aimed at minimizing exposure are warranted. Pharmacy technicians should become intimately familiar with and closely follow policies and procedures associated with the procurement, handling, and storage of radiopharmaceutical products. See *Manual for Pharmacy Technicians*, 4th ed., Chapter 6 ("Specialty Pharmacy Practice for additional information").



Pop Quiz!

A patient brings in a prescription for Lantus U-100 insulin pens; dispense 1 box of 5 pens. The patient is to use 20 units Q AM. What is the EDS?

Proper Disposal and Return of Pharmaceuticals

Expired Pharmaceuticals

The most common reason drugs are returned to the manufacturer is because they have expired. The process for returning drugs in the original manufacturer packaging is relatively simple and not particularly time-consuming when done routinely. Returning expired products to the manufacturer or wholesaler prevents the inadvertent use of these products and enables the pharmacy to receive either full or partial credit for them. Some wholesalers limit credit given on returns of short-dated products. Generally, wholesalers will not give full credit on returns of products that will expire within 6 months. To return products, pharmacy personnel must complete the documentation required by the product's manufacturer or wholesaler and package the product for shipment. Many wholesalers have implemented electronic documentation systems to further simplify the return process. Technicians often perform these duties under the supervision of a pharmacist. Some pharmacies contract with an outside vendor

that completes the documentation and coordinates the return of these products for a fee. In this case, the pharmacy technician need only assist the returned goods vendor with locating and packaging the expired pharmaceuticals. Many states are now enforcing regulations issued in the 1970s by the Environmental Protection Agency under the Resource Conservation and Recovery Act (RCRA) that govern the proper disposal mechanisms of hazardous chemicals, including drugs. Thus, each pharmacy should have detailed procedures governing the proper, legal disposal of pharmaceutical waste. The pharmacy technician should be familiar with these procedures. Disposal of expired compounded or repackaged pharmaceuticals by the pharmacy technician should be completed under the supervision of the pharmacist.

Pharmaceuticals compounded or repackaged by the pharmacy cannot be returned and must be disposed of after they have expired. It is important to dispose of these products for safety reasons. Proper disposal prevents the use of subpotent products or products whose sterility can no longer be guaranteed. The precise procedure for disposal depends on the type and content of the product. Some products, such as expired repackaged solids, can be disposed of via the general trash removal system, while others, such as expired compounded cytotoxic products, must be disposed of according to hazardous waste removal procedures. Each pharmacy has detailed procedures for hazardous waste removal, and the pharmacy technician should be familiar with these procedures. Disposal of expired compounded or repackaged pharmaceuticals by the pharmacy technician should be completed under the supervision of the pharmacist.

Other products requiring disposal rather than return are chemicals used in the pharmacy laboratory. Most pharmacies stock a supply of chemical-grade products used in extemporaneous pharmaceutical compounding. Examples of chemical products include sodium benzoate or sodium citrate (preservatives), lactose or talc (excipients), buffers, and active ingredients such as hydrocortisone, triamcinolone, neomycin, or lidocaine powders. When such products expire, they should be disposed of in accordance with the pharmacy's hazardous waste procedures.

Expired controlled substances are disposed of in a unique way. These products may not be returned to the manufacturer or wholesaler for credit. They must be destroyed, and the destruction must be documented to the satisfaction of the Drug Enforcement Administration (DEA). The DEA provides a form, titled "Registrant's Inventory of Drugs Surrendered" (Form 41, Figure 2-9)

for recording the disposal of expired controlled substances. Ideally, the actual disposal of expired controlled substances should be completed by a company sanctioned by the DEA or by a representative of the state board of pharmacy. In other cases, the DEA may allow the destruction of controlled substances by a pharmacy, provided an appropriate witness process is followed and documented. The DEA form for disposal of controlled substances should be completed properly and submitted to the DEA immediately after the disposal has occurred. A DEA representative signs a copy of the record of disposal form and returns it to the pharmacy, where it is kept on file. Previously, the DEA allowed for shipment of expired controlled substances and the completed disposal form to the regional DEA office, but this practice is no longer permitted.

The use and disposition of investigational drugs must also be documented carefully. Expired investigational drugs should be returned to the manufacturer or sponsor of an investigational drug study according to the instructions they provide. The pharmacy technician may be responsible, under the supervision of the pharmacist, for documenting, packaging, and shipping the expired investigational agents. Investigational drug products that expire because of product instability or sterility issues should never be discarded. These doses should be retained with the investigational drug stock and be clearly marked as expired drug products, because the investigational study sponsor will need to review and account for all expired investigational drug products.

Pharmaceuticals that need to be returned because of an ordering error require authorization from the original supplier and the appropriate forms. The Prescription Drug Marketing Act mandates that pharmacies retain the authorization and retention records of returned pharmaceuticals in order to prevent diversion of pharmaceuticals. The pharmacy technician must be familiar with pharmacy procedures for returning medications to a supplier. Typically, a pharmacy will have a process for returning misordered medications to the prime drug wholesaler on a routine basis. This prevents the need to store overstocked or misordered products in the pharmacy. The pharmacy technician may be responsible for relevant documentation, filing of paperwork, and the packaging of returned products under the supervision of the pharmacist.

Pharmaceutical Waste Management

The environmental impact of pharmaceutical waste is becoming a prominent public health issue worldwide.

Pharmacy Technician Certification Review and Practice Exam

44

OMB Approval
No. 1117 - 0007

U. S. Department of Justice / Drug Enforcement Administration

PACKAGE NO.

REGISTRANTS INVENTORY OF DRUGS SURRENDERED

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: (Include Name, Street, City, State and ZIP Code in space provided below.)

Signature of applicant or authorized agent

Registrant's DEA Number

Registrant's Telephone Number

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

NAME OF DRUG OR PREPARATION	Number of Containers	CONTENTS (Number of grams, tablets, ounces or other units per container)	Controlled Substance Content, (Each Unit)	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
Registrants will fill in Columns 1,2,3, and 4 ONLY.	1	2	3	4	5	6
1						
2						
3						
4						
5						
6						

Figure 2-9. DEA Form 41.

A report following a multiple month study indicates that trace amounts of pharmaceuticals are present in the drinking water of 24 major U.S. metropolitan cities nationwide.⁷ This problem is concerning because many pharmaceuticals maintain potency or pose toxic health threats to humans and other animals, despite water purification through rural and metropolitan treatment facilities. Although some of the contamination comes naturally through human excretion, a larger concern is the routine waste disposal of medication by consumers and pharmacies through the sewer system and landfills. In fact, pharmaceuticals are widely considered as chemical pollutants (like pesticides and industrial sewage). Drugs that

affect the endocrine system (hormones), antimicrobials, and active byproducts are but a few of the pharmaceuticals found in increasing amounts in waterways and drinking water. The Environmental Protection Agency (EPA) and state health departments are expected to more rigorously enforce proper pharmaceutical disposal practices.



Pop Quiz!

What form is required to dispose of 10 outdated morphine tubexes?

Durable and Nondurable Medical Equipment, Devices, and Supplies

Durable medical equipment, devices, and supplies are reusable products, used for the treatment of an illness or injury, that are typically ordered by a physician or other health care provider for use in a patient's place of residence. Nondurable medical equipment, devices, and supplies are manufactured for one-time use only and are disposable (Table 2-4).

Pharmacies that supply durable medical equipment, prosthetics, orthotics, and supplies can provide an important service for patients. The use of durable and nondurable medical equipment can improve a patient's quality of life. Persons with impaired mobility often use durable medical equipment. Patients who have diabetes or hypertension can self-monitor their blood glucose and blood pressure at home with medical equipment. The pharmacist can provide education for the use of medical equipment. The Centers for Medicare and Medicaid Services require that all suppliers of durable medical equipment, prosthetics, orthotics and supplies be accredited to bill Medicare Part B. As of January 1, 2010, pharmacies that supply this type of equipment must be Medicare accredited.⁷ Medicare Part B covers 80% of this type of equipment and supplies. The patient must pay the 20% of the remaining cost. Persons with Medicaid can have their 20% coinsurance covered.

Many of the inventory management processes discussed in relation to pharmaceuticals also hold true for medical devices and associated supplies. One unique

feature of the medical device business, however, is that some of the equipment is provided to patients on a rental or lease agreement rather than an outright purchase. In these instances, it is important that returned equipment be properly processed before being rented or leased to the next patient. Processing always includes a thorough cleaning with an approved disinfecting agent and may include sterilization of parts that come into direct contact with the patient. Between patient uses or periodically according to the manufacturer's recommendations, equipment will also undergo a biomedical review to make sure it is in proper working order, has had indicated preventive maintenance performed, and is safe for patient use. Biomedical reviews are also performed in response to reported malfunctions.

It is important to ensure that patients have the proper supplies to use with any medical equipment. Patients often need assistance in completing forms to ensure proper reimbursement related to medical devices and supplies.

It is also often necessary for a pharmacy offering medical supplies and equipment to employ staff with special training and even certifications in the fitting and use of the devices. These staff members, who may be technicians, generally assist patients in choosing the appropriate device upon a physician recommendation, help the patients ensure proper fit and match supplies to the particular device, and help educate the patients on the use of their equipment. They may also be responsible for some of the cleaning and preventive maintenance on reusable equipment.

Table 2-4. Common Durable and Nondurable Medical Equipment

Durable Medical Equipment	Nondurable Medical Equipment
Wheelchairs	Home oxygen equipment
Walkers	Hospital beds
Canes	Infusion pumps
Crutches	Braces
Scooters	Blood glucose meters
Suction pumps	Blood pressure monitors
Commode and shower chairs	Nebulizers
	Exam gloves
	Diapers
	Absorbent bed pads
	Insulin syringes and pen needles
	Blood glucose test strips and lancets
	Dressing materials (bandages, gauze dressings, tape)
	Ostomy supplies



Pop Quiz!

True or False? Most expired and outdated pharmaceuticals require no special disposal methods.

Suggested Reading

- From *Manual for Pharmacy Technicians*, 4th ed.
 Drug Distribution Processes: See Chapter 3—Ambulatory Care Pharmacy Practice; Chapter 4—Institutional Pharmacy Practice; and Chapter 5—Home Care Pharmacy Practice.
 Inventory Procedures: See Chapter 19—Purchasing and Inventory Control and Chapter 2—Pharmacy Law.
 Compounding and Repackaging Requirements: See Chapter 15—Nonsterile Compounding and Repackaging.

Self-Assessment Questions

1. The decision to add a drug to a hospital's formulary should always be based on which drug is cheapest to purchase.
 - a. True
 - b. False
2. Formulary management of inventory in hospitals and ambulatory care facilities are the same.
 - a. True
 - b. False
3. Which of the following is *not* a part of the normal receiving process for pharmaceuticals received from the drug wholesaler?
 - a. Complete the required documentation on any investigational drugs included in the shipment.
 - b. Complete the required documentation on any controlled substances included in the shipment.
 - c. Verify that the box count is correct and that there are no damaged packages.
 - d. Verify that all items are received and that the inventory is not expired or close to expiration.
 - e. Sign and date the purchase order.
4. Provide the appropriate USP definition for each temperature.
 - a. > 40° C
 - b. 20° to 25° C
 - c. -25° to -10° C
 - d. 2° to 8° C
 - e. Prevailing temperature in the work area
5. DEA form _____ must be completed upon the receipt of schedule II controlled substances.
 - a. 41
 - b. 227
 - c. 222
 - d. 106
6. Which statement is *true* regarding the placement of medications on the shelves to prevent medication errors?
 - a. Generic label drugs should not be placed near the brand-name product.
 - b. Look-alike drugs may be mistaken for each other and should be stored in different locations when possible.
7. The Pareto ABC system relies on the premise that managing 20% of your inventory will cover 80% of your costs (the 80/20 rule).
 - a. True
 - b. False
8. The "par-level" system of inventory management
 - a. utilizes a want book to minimize ordering unnecessary pharmaceuticals
 - b. uses predetermined stock minimum and maximum quantities
 - c. utilizes state of the art automated perpetual inventory methods
9. Why may the FDA direct a manufacturer to recall a pharmaceutical?
 - a. because of contamination
 - b. because of lack of potency
 - c. because of lack of adherence to good manufacturing practices
 - d. because of any situation that may present a significant risk to public health
 - e. all of the above
10. A Class _____ recall is the most serious of recalls; continued use of the product may result in a serious health threat or death.
 - a. I
 - b. II
 - c. III
 - d. IV
11. The IMPACT organization was formed to deal with
 - a. drug recalls on a global scale
 - b. pharmaceutical waste
 - c. counterfeit drugs
 - d. durable medical equipment

Self-Assessment Questions

12. Which of the following is *not* an example of a drug that requires special handling during receiving in the pharmacy?
 - a. samples
 - b. controlled substances
 - c. injectables
 - d. investigational drugs
 - e. compounded or repackaged items
13. The DEA Form 41 is required when controlled substances are expired and need to be disposed of.
 - a. True
 - b. False
14. Purchasing pharmaceuticals directly from the manufacturer has more advantages to most pharmacies; as a result this is the preferred purchasing method over using a wholesaler.
 - a. True
 - b. False
15. Advantages of using a prime vendor contract with a wholesaler includes all of the following EXCEPT
 - a. more timely ordering and delivery
 - b. fewer inventory carrying costs
 - c. the pharmacy needs a large storage capacity
 - d. less documentation
 - e. supports the “just-in-time” philosophy
16. The intent of the RDDS is to insure
 - a. the specific drugs identified as high risk are safely procured, prescribed, dispensed, and administered
 - b. chemotherapy drugs are safely procured, prescribed, dispensed, and administered
 - c. chemotherapy drugs are safely wasted and disposed of
17. RDDS drugs can cause serious adverse health reactions such as
 - a. ototoxicity
 - b. blood disorders and birth defects
 - c. nausea and vomiting
 - d. hepatotoxicity
18. In most cases RDDS requires documentation of
 - 1.
 - 2.
 - 3.
 - 4.
 - 5.
 - 6.
19. Reusable medical devices must be
 - a. cleaned between patient uses
 - b. checked between uses to ensure that they are functioning properly
 - c. maintained with all manufacturer-recommended preventive maintenance
 - d. tested for proper function in response to any report of malfunction
 - e. all of the above
20. _____ is disposable.
 - a. Durable medical equipment
 - b. Nondurable medical equipment