Chapter 1
Assisting the Pharmacist

Learning Outcomes

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

- Define the terms medication order and prescription, and list the common means by which they are received by the pharmacy.
- Define commonly used pharmacy terms and abbreviations used in medication orders and prescriptions.
- List the required elements on a prescription or medication order.
- Define National Drug Code (NDC) numbers and put into proper order for transmittal.
- Verify correct Drug Enforcement Agency (DEA) numbers.
- Describe the steps required for proper prescription and medication order processing.
- Describe when a patient signature is required at the point of sale.
- Describe how prescriptions are transferred between pharmacies.
- Explain good compounding practices and aseptic technique.
- Give examples of drugs with Risk Evaluation and Mitigation Strategy (REMS).
- List and describe the equipment used in both sterile and nonsterile compounding.
- Describe the process utilized to prepare cytotoxic and hazardous drugs.
- Define laminar airflow workbenches (LAFW) and biological safety cabinets (BSC).

This chapter applies to Section I of the PTCB exam, Assisting the Pharmacist in Serving Patients.

- Describe the types of questions that may be answered by a pharmacy technician.
- List common references found in many pharmacies and what information might be found in each.

Medication Orders and Prescriptions Defined

Typically, the term medication order refers to a written request on a physician’s order form or a transcribed verbal or telephone order in an inpatient setting. This order becomes part of the patient’s medical record. The term prescription refers to a medication order on a prescription blank to be filled in an outpatient or ambulatory care setting. The two serve essentially the same purpose. They both represent a means of communication for the prescriber to give instruction to the dispenser of the medication or to those who will be administering the medication.

Pharmacy Terms and Abbreviations

Pharmacy personnel use a number of terms in their work. An understanding of these terms helps a technician to be efficient and capable.

Some of these terms define classifications of drugs. For example, technicians must be able to differentiate between generic and brand name drugs. A generic name
describes a unique chemical entity and can be applied to that entity regardless of its manufacturer. A brand name is trademarked by a manufacturer to identify its particular “brand” of that chemical entity. For example, Ancef® is a brand name product of the generic entity cefazolin.

Another pair of terms used to categorize drugs is legend and over-the-counter. A legend drug, also called a prescription drug, is one that may not be dispensed to the public except on the order of a physician or other licensed prescriber. The term comes from the federal legend that appears on the packaging: “Federal law prohibits dispensing this medication without a prescription.” Over-the-counter medications may be sold to the public without a prescription as long as they are properly labeled for home use.

One last term, formulary, is used in slightly different ways in institutional and retail settings. A formulary is a listing of approved drugs available for use. In a hospital, it refers to the drugs that are stocked by the pharmacy and approved for use in the facility. In the retail setting, the term is generally applied to an approved drug list associated with a particular benefit plan.

Pharmacy abbreviations are commonly used as a kind of shorthand in prescriptions and medication orders to convey information about directions for use. The abbreviations are then “translated” on the prescription label. Appendix A lists many commonly used pharmacy abbreviations.

The abbreviations for time and frequency of medication administration come from Latin phrases. Other commonly used abbreviations include those for routes of administration and those that designate units of measure. Lowercase Roman numerals are often used to denote a quantity, such as a number of tablets (i = one; ii = two). (See Chapter 14 of Manual for Pharmacy Technicians for a review of Roman numerals.)

Another subset of abbreviations is called x-substitutions and includes the well-known and widely recognized Rx symbol, meaning prescription. Other common x-substitutions are dx for diagnosis and sx for symptoms.

Abbreviations in medical records and in prescriptions are thought to be contributing factors in some medical errors. One important example is the use of the letter U to abbreviate units. Because a U might be misread as a zero if sloppily written—and could therefore result in a tenfold dosing error—the Institute for Safe Medication Practices recommends that it never be used as an abbreviation in prescriptions or medication orders; the word units should always be written out in its entirety. Other abbreviations that some consider unsafe are q., qid, and qod, which may be indistinguishable from each other if legibility is poor. These three abbreviations have been included in the chapter because they are still widely used.

**Receiving and Processing Medication Orders in a Hospital**

Medication orders come to the hospital pharmacy in various ways. They can be delivered to the pharmacy or one of its satellites in person or via some mechanical method, such as fax transmission or a pneumatic tube system. Orders may also be telephoned to the pharmacy by either the prescriber or an intermediary, such as a nurse. There are some legal restrictions on who may telephone in an order or a prescription, and who may receive that information in the pharmacy—particularly when controlled substances are involved.

Ideally, every medication order should contain the following elements:

- Patient name, hospital identification number, and room/bed location
- Generic drug name (using generic drug names is recommended, and many institutions have policies to this effect)
- Brand drug name (if a specific product is required)
- Route of administration (with some orders, the site of administration should also be included)
- Dosage form
- Dose/strength
- Frequency and duration of administration (if duration is pertinent—may be open-ended)
- Rate and time of administration, if applicable
- Indication for use of the medication
- Other instructions for the person administering the medication, such as whether it should be given with food or on an empty stomach
- Prescriber’s name/signature and credentials (some hospitals require a printed name, physician number, or pager number in addition to the signature to assist with identification)
- Signature and credentials of person writing the order if other than prescriber
- Date and time of the order

When a new order is received, the first step is to ensure that the order is clear and complete. If information is missing—for example, the room number for the patient—the technician may be able to clarify the order without pharmacist intervention. Some clarifications, however, should
involve the pharmacist. (See the discussion of which questions can be handled by a technician later in this chapter.)

Once orders are deemed clear and complete, they must be prioritized so that the most urgent orders are filled first. Prioritizing orders means comparing the urgency of new orders with the urgency of all the orders requiring attention. This ensures that those orders needed the most will be processed first. Technicians can prioritize orders by evaluating the route, time of administration, type of drug, intended use of the drug, and patient-specific circumstances.

A number of steps are involved in processing an order in the computer. First, the patient must be positively identified to avoid dispensing medication for the wrong patient; many institutions are now using bar code technology and electronic charting to facilitate accuracy. Second, the order is typically compared with the patient’s existing medication profile, or a new profile is created for the patient. Then, the technician takes a number of order entry steps to update the patient’s medication profile.

The following step-by-step process outlines a fairly typical medication order entry process. Systems vary somewhat, however, and this is simply an example of what the process flow might look like.

1. Enter the patient’s name or medical record number and verify them to ensure that the correct patient record has been chosen.
2. Compare the order with the patient profile in detail to look for duplications, other possible problems, or to create the patient profile. Check for general appropriateness of the order; it should make sense in regard to patient profile information, such as the patient’s age, allergies, and drugs currently being taken. The following information is appropriately found in the hospital pharmacy’s patient profile, although system capabilities may limit access to some components:
   - Patient name and identification number
   - Date of birth, or age
   - Sex
   - Height and weight
   - Certain lab values, such as creatinine clearance
   - Admitting and secondary diagnoses (including pregnancy and lactation status)
   - Name of parent or guardian, if applicable
   - Room and bed number
   - Names of admitting and consulting physicians
   - Medication allergies; latex allergy; pertinent food allergies

3. Enter the drug. Selecting the correct drug product requires a working knowledge of both brand names and generic names (although most computer systems can search for either name) and a sensible approach to interpreting orders when abbreviations are used. When in doubt about a drug name or an abbreviation, however, it is always better to clarify the order with the prescriber or the person who wrote the order. Patient safety must be protected, and it is dangerous to make assumptions when interpreting orders. Most pharmacies take special precautions to ensure accurate interpretation of prescriptions and medication orders involving look-alike and sound-alike drugs. With most pharmacy computer systems, drug products can be reviewed by scrolling through an alphabetical listing of the brand or generic names or by entering a code or mnemonic that is associated with the product name in the computer. Many computer systems alert the operator if he or she attempts to enter medications that interact with current orders, conflict with the patient’s drug allergies, represent therapeutic duplications, or are nonformulary drugs. Many systems also check the dosage range and alert the pharmacist or technician if he or she enters a dose that exceeds the recommended dose for that patient. Although these alert systems help prevent errors, they are not always significant given the patient’s unique situation. Therefore, the technician must consult the pharmacist when the alert is posted.

Besides just choosing the “correct drug,” as has been outlined in this section, some other related choices are included in this step. For example, if an intravenous (IV) medication is being entered, it might be necessary to choose the correct diluent into which the drug is to be mixed. Another decision involved in choosing the correct drug is the choice of the package type and size—bulk or unit dose, 15 gram tube or 30 gram tube, 100 ml bottle or 150 ml bottle.

4. Verify the dose to ensure that the correct amount has been entered.
5. Enter the administration schedule. In institutions, standard medication administration times are
generally set. These schedules are usually based on therapeutic issues or nursing efficiency or are designed to coordinate services, such as laboratory blood draws or therapy schedules. Standard administration schedules and protocols are usually agreed upon by pharmacy, nursing, and the hospital’s medical staff. Many pharmacies have a written document, such as a policy, that staff can refer to when the appropriate administration time is unclear.

6. Enter any comments in the clinical comments field. The prescriber’s directions for proper use of the medications must be conveyed clearly and accurately. Additional instructions for the caregiver are often entered into the pharmacy information system for presentation on one of the many documents printed from the profile (or for the nurses’ use in an electronic system) or simply as additional information for the pharmacists’ use at a later time. These special instructions might include storage information, such as the need to refrigerate, or special instructions, such as for chemotherapy drugs. Another example would be physician-specified parameters for use, such as, “hold if systolic BP less than 100 mm Hg,” or “repeat in one hour if ineffective.” These types of instructions would typically be displayed on the medication administration record (MAR) and also on the medication label.

7. Verify the prescriber name.

8. Fill and label the medication. Once the computer entry has been completed and labeling materials generated, the medication order must be filled with the correct quantity of the correct drug. During this step, the technician should carefully review the label against the order and the product to be used to make sure the correct product has been chosen. This is the final opportunity for the pharmacy to catch an error before dispensing to a patient care area. The medication order is then filled and left for the pharmacist to check. With few exceptions, this pharmacist check is legally required before dispensing any drug to a patient care area.

Receiving and Processing Prescriptions in an Outpatient Pharmacy

When welcoming a patient to the pharmacy, it is important to first identify him or her. If the patient has been to your pharmacy before, another piece of identifying information, such as date of birth, address, or phone number should be obtained to confirm the patient’s identity. If the patient is bringing a prescription to you for the first time, he or she needs to be registered by obtaining the following information:

- Correct spelling of name
- Address and phone number(s)
- Insurance information from patient’s insurance card
- Date of birth
- Any drug allergies
- Other prescriptions or over-the-counter (OTC) medications the patient takes regularly
- Significant health conditions

Prescriptions may be received directly from the patient or from the prescriber by telephone, fax, or electronic transmission.

Many pharmacies also accept refill requests over the Internet through a pharmacy Web page.

Obtaining payer information is an important step in receiving a prescription in the outpatient setting. This information is used for a number of purposes, including establishing the primary payer for the prescription, the patient’s portion of the reimbursement (copay), and in some instances the drug formulary.

Reviewing a prescription for clarity and completeness is similar in the outpatient and the inpatient setting. The following prescription elements are typically present:

- Patient name
- Patient home address
- Date the prescription was written
- Drug name—either generic or brand
- Drug strength and dose to be administered
- Directions for use, including route of administration, frequency, and, as applicable, duration of use (some durations are open-ended)
- Quantity to be dispensed
- Number of refills to be allowed
- Substitution authority or refusal
- Signature and credentials of the prescriber, and DEA number, if required
- Reason for use, or indication (not generally required)

In an ambulatory practice, some special clarity and completeness issues must be considered. Receiving a prescription includes determining whether the prescription will be filled with generic or brand-name drugs. In many states when a prescriber uses “Dispense as Written” or DAW on a prescription blank, the brand name must be
Assisting the Pharmacist

Prioritization of prescription processing in the outpatient pharmacy is generally an issue of customer service rather than patient care.

Prescription processing includes many of the same steps as medication order processing in the inpatient setting:

- Identifying the patient: It is important to make sure that prescriptions are filled for and dispensed to the correct patient. Proper attention needs to be paid to similar or identical names to make sure the medication is profiled on the right patient profile. Another important concern for the outpatient staff at this stage is to ensure that there is no forgery and that the individuals obtaining controlled substances are lawfully entitled to do so.
- Creating, maintaining, and reviewing patient profiles: A number of pieces of information are typically collected in the patient profile—some according to law (which varies from state to state) and some for efficiency and convenience purposes for both the pharmacy and the patient. These pieces of information include the following:
  - Patient’s name and identification number
  - Age or date of birth
  - Home address and telephone number
  - Allergies
  - Principal diagnoses of patient
  - Primary health care providers for patient
  - Third-party payer(s) and other billing information
  - Over-the-counter medications and herbal supplements used by the patient
  - Prescription and refill history of the patient
  - Patient preferences (e.g., child-resistant packaging waiver, preference for receiving prescriptions by mail)

Once the patient’s profile is located or created and the existing information is verified, selecting the appropriate drug product is the next step in the order entry process. Most outpatient computer systems, like inpatient systems, allow drug product choice by typing in a mnemonic or by accessing an alphabetical listing of some sort. These are the typical prescription processing steps:

1. Enter the patient’s medical record number or name and verify them. This safety step ensures that the drug is dispensed to the correct patient.

### Assessing Order Authenticity

Screening prescriptions for potential forgeries, particularly those for controlled substances, is part of routine prescription processing. The technician should screen prescriptions for anything that looks unusual, such as a dispense quantity in excess of normal quantities or an unusual or unrecognizable signature. Any suspicious prescription should be discreetly presented to the pharmacist for further evaluation.

Prescription forgeries often take one of two forms: (1) erasure or overwriting of the strength or dispensing quantity of the drug (e.g., changing a 3 to an 8), and (2) theft of preprinted prescription pads that may result in legitimate-looking prescriptions.

One thing a technician can do to help prevent prescription forgery is determine if a DEA number on a controlled substance prescription is valid. A valid DEA number consists of two letters and seven numbers, such as “BB 1 1 9 7 9 6 7.” If the holder of the DEA number is a registrant, such as a physician or pharmacy, the first letter is an “A” or “B.” If the holder of the DEA number is a mid-level practitioner, such as a qualified nurse practitioner, the first letter is an “M.” The second letter is related to the registrant’s name. In the case of a physician, it is the first letter of his or her last name.

The seven numbers are also used to determine a legitimate DEA number. The odd group—the 1st, 3rd, and 5th numbers in the sequence, and the even group—the 2nd, 4th, and 6th numbers—are added in the following manner so that the sum relates to the 7th number:

BB 1 1 9 7 9 6 7
Odd Group 1 + 9 + 9 = 19
Even Group 1 + 7 + 6 = 14
Sum of odd (19) and 2 x even group (14 x 2) = 19 + 28 = 47

The last digit of this odd/even group sum is the same as the last digit of the DEA number.
2. Enter or verify existing third-party billing information to ensure correct billing and copayment.
3. Compare the order with the patient profile in detail to identify duplications or other concerns.
4. Enter the prescription. A variety of information must be entered into the computer at this point, and systems vary as to the order in which it is entered. The following are required elements:
   ■ Physician’s name
   ■ Directions for use, including special comments
   ■ Fill quantity
   ■ Initials of the pharmacist checking the prescription
   ■ Number of refills authorized

At the time of computer processing, an error message may interrupt transmission of the prescription to the third-party payer. The following are some common error messages and their meanings:

   ■ Refill Too Soon: This message deals with refill prescriptions and the elapsed time between filling prescriptions. Typically, third parties allow patients to receive a 30-day supply of medications. If the patient attempts to refill a prescription within a significantly shorter period (eg, 15 days after the last prescription), the prescription cannot be processed without prior approval from the third-party payer.

   ■ Missing/Invalid Patient ID: This or a similar message indicates that the patient who is entered into the pharmacy computer does not appear to be enrolled in the insurance program. On receiving this message, the technician should examine the patient information entered for mistakes. Perhaps the name was misspelled, identification number mistyped, or other required information left out. Because many insurance plans use a Pharmacy Benefit Manager (PBM) to manage their pharmacy services, the prescription may need to be processed under the name of the PBM instead of the name of the third-party payer.

   ■ Drug–Drug or Drug–Allergy Interaction: Most pharmacy software will screen the patient profile for drug and allergy information. If interactions are detected, the program will alert the user. Some software will not only identify an interaction but also indicate its potential severity. A technician who receives a drug–drug or drug–allergy interaction message should alert the pharmacist to the problem.

   ■ Nonformulary/Not Covered: Many third-party payers have formularies (lists of covered drugs). This message indicates that the drug is not covered, and payment will not be made for that drug. A technician who receives this message should alert the pharmacist.

5. Fill and label the prescription. The following components must generally appear on a prescription label, whether typed or computer-generated (may vary by state):
   ■ Patient’s name
   ■ Date the prescription is being filled (or refilled)
   ■ Prescriber’s name
   ■ Sequential prescription number
   ■ Name of the drug (including manufacturer if filled generically)
   ■ Quantity to be dispensed
   ■ Directions for use
   ■ Number of refills remaining (or associated refill period)

Labeling includes more than just the actual prescription label. The inpatient section of this chapter noted that labeling for inpatient use is often abbreviated or in a form of shorthand. For home use, however, this practice is not acceptable. Beyond the prescription label itself, auxiliary information is often included in the form of special labels affixed to the container or drug information leaflets for patients to read at home. Instructions for home use must include the following at a minimum:

   ■ Administration directions (eg, “Take,” “Insert,” “Apply”)
   ■ Number of units constituting one dose and the dosage form (eg, 2 tablets)
   ■ Route of administration (eg, “by mouth,” “vaginally”)
   ■ How frequently or at what time (eg, “twice daily,” “daily at 9 a.m.”)
   ■ Length of time to continue, if applicable (eg, “for 10 days,” “until finished”)
   ■ Indication of purpose, if applicable (eg, “for pain,” “for blood pressure”)

At the time of dispensing, the pharmacist or technician must be sure the patient fully understands how to use the medication. This is also an appropriate time to consider
receives a message that the claim has been rejected, resolving these third party issues becomes a time-consuming part of the prescription process.

Collecting Payment and Patient Counseling

Technicians are usually involved in point-of-sale (POS) transactions, which involve checking out patients and collecting payment when prescription orders are complete.

1. Verify the patient’s name and other identifying information to ensure the medication is being given to the correct patient.
2. Legal requirements regarding patient counseling must be met; offer to have the pharmacist visit with the patient if they would like counseling.
3. New patients must be given a copy of the pharmacy’s patient privacy policy in compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations.
4. The patients’ signature is required when they receive the HIPAA information and by some states if they refuse counseling and by some third party payers when they take possession of the prescription.

Transferring Prescriptions

The laws regarding the transfer of prescriptions between pharmacies vary among states and among different classes of drugs. However, the pharmacist is always ultimately responsible for the information transferred. The transfer of a prescription to another pharmacy is usually initiated by a phone call from the pharmacy needing a transferred prescription. A technician may pull the original prescription from files or pull up the data on the computer, but the actual transfer of information is usually the responsibility of the pharmacist.

The same is true for prescriptions being transferred into the pharmacy. In this case, the process begins when a patient requests to transfer the prescription from another location. At that point, the technician must obtain from the patient as much information as possible about the prescription. At a minimum, the pharmacist needs the patient’s name and the name of the pharmacy currently holding the prescription. If a patient brings in an old container, it may be useful to troubleshoot the label. For example, if the label indicates that there are no refills, the physician will have to be called to authorize the refill.

NDC Numbers

NDC numbers are identification numbers used by drug manufacturers to identify their product. Each number is specific for a specific product. NDC numbers are used for verifying the correct drug has been used to fill the prescription and for remittance to third party companies.

- First group of numbers: represent the manufacturer. All products made by a specific manufacturer will have the same first number.
- Second group of numbers: represent the specific product.
- Third group of numbers: represent the package size.

In most cases, NDC numbers must be transmitted to a third party in a 5-4-2 configuration, even though the manufacturers do not always present them to us in that configuration. If we do not bill the NDC # correctly, the third party company’s computer cannot read it correctly, and this could result in an error in payments, or no payment at all.

The NDC format is very specific, so placement of the zeros to create a 5-4-2 format is also very specific. The zero is always placed at the beginning of the incorrect group of numbers.

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language barriers, such as illiteracy or a primary language other than English.

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Handling Restricted Use Medications

There are certain medications that can only be prescribed and dispensed in a community or ambulatory care pharmacy under specific conditions due to special precautions regarding their use. The FDA requires a Risk Evaluation and Mitigation Strategy (REMS) when it determines that a strategy is necessary to ensure the benefits of using the drug outweigh the potential risks. Examples of drugs with REMS include: alosetron (Lotronex®), clozapine (Clozapil®, Fazaclo®), isotretinoin (Accutane®, Amnesteem®, Claravis®, Sotret®), thalidomide (Thalomid®), and dofetilide (Tikosyn®).

The FDA has designated other drugs that are required to be dispensed with Medication Guides. A Medication Guide is patient information approved by the FDA to help patients avoid serious adverse events, inform them about known serious side effects, and provide directions for use to promote adherence to the treatment. These are available for specific drugs or classes of drugs and must be dispensed with the prescription. Common examples dispensed in community and ambulatory care pharmacies include nonsteroidal anti-inflammatory drugs (NSAID) and antidepressants.

Investigational Drugs

Investigational Drug services may be a form of services seen in a hospital or specialty pharmacy service. Before a study is approved to be conducted, a study protocol is developed, reviewed, and approved by the Institutional Review Board of the facility. In order to carry out a successful drug study there are specific requirements and procedures that must be followed. These include:

- proper storage
- record keeping
- inventory control
- preparation
- dispensing
- labeling of all investigational drugs

Good Compounding Practices

Chemicals for compounding are approved by the Food and Drug Administration (FDA); however, the practice of compounding is controlled by the individual state boards of pharmacy. Certain aspects of compounding and the role of the FDA were not clearly defined in federal law until, in 1997, the Food and Drug Administration Modernization Act (FDAMA) was passed. This legislation clearly defined the roles of both compounding pharmacies and the FDA. In the summer of 2002, however, the legislation was declared unconstitutional because of advertising restrictions. Nonetheless, the guidelines of the 1997 FDAMA still offer a structure for compounding pharmacists to follow until future legislation addresses the issue.

The United States Pharmacopeia (USP 27) offers guidelines for compounding. The following chapters of the USP 27 review specific areas of compounding:

- Chapter 795 Pharmaceutical Compounding—Nonsterile Preparations
- Chapter 797 Pharmaceutical Compounding—Sterile Preparations
- Chapter 1075 Good Compounding Practices

The following are key areas of compounding:

1. Responsibility of the compounder
2. Compounding environment
3. Stability of compounded preparations
4. Ingredient selection
5. Compounded preparations
6. Compounding processes
7. Compounding records and documents
8. Material Safety Data Sheets (MSDS) file
9. Quality control
10. Patient counseling

Responsibility of the Compounder

The compounder is responsible for all aspects of the compounding process, including, but not limited to, appropriately trained personnel and the key areas of Chapter 795 that follow. Special training is required for all personnel who prepare sterile products.

Compounding Environment

The compounding area should have adequate space for equipment and support materials. Controlled temperature and lighting are needed for chemicals and finished
medications. The area must be kept clean for sanitary reasons and to prevent cross contamination. A sink with hot and cold running water is essential for handwashing and cleaning of equipment.

Stability of Compounded Preparations
Stability is defined in USP-NF as “the extent to which a preparation retains, within specified limits, and throughout its period of storage and use, the same properties and characteristics that are possessed at the time of compounding.”

Primary packaging of the finished medication is of utmost importance. The choice of container is guided by the physical and chemical characteristics of the finished medication. Considerations such as light sensitivity and the medication binding to the container are examples of concern in maximizing stability.

Beyond-use labeling should be included on all medications (expiration dates apply to manufactured products). Examples of considerations for determining beyond-use dates include whether the medication is aqueous or non-aqueous, expiration date of the ingredients used, storage temperature, references documenting the stability of the finished medication, and the USP.

Ingredient Selection
Sources of ingredients vary widely. USP or National Formulary (NF) chemicals are the preferred source of chemicals for compounding. Other sources may be used, but the compounder has a responsibility to be certain the chemical meets purity and safety standards. Manufactured medications are another acceptable source of ingredients. It would be inappropriate to use any chemical withdrawn from use by the FDA.

Compounded Preparations
Preparations should contain at least 90%, but not more than 110%, of the labeled active ingredient, unless more restrictive laws apply. Compounding guidelines in USP-NF specifically address the following drug forms:

- Capsules, powders, lozenges, and tablets
- Emulsions, solutions, and suspensions
- Suppositories
- Creams, topical gels, ointments, and pastes

Compounding Processes
The goal of the compounding process is to “minimize error and maximize the prescriber’s intent.” The following list is a sample of areas to consider in the compounding process:

- Evaluation of the appropriateness of the prescription
- Calculations of the amount of ingredients
- Identification of equipment needed to properly compound the prescription
- Proper hand cleaning and gowning
- Evaluation of the final medication for weight variation, proper mixing, and consistency
- Proper notations in the compounding log
- Appropriate labeling of the final medication
- Properly clean and store all equipment

Compounding Records and Documents
USP Chapter 795 requires pharmacies to maintain a formulation record (also known as the master formula) and a compounding record for each compounded preparation. The goal of record-keeping is to allow another compounder to reproduce the same formulation at a later date. Two parts of the records and documentation are the formula, or formulation record, and the batch log, or compounding record.

The formulation record is a file of compounded preparations, much like a recipe. It would include chemicals in the formula, equipment needed to prepare the formula, and mixing instructions for preparing the formula.

The compounding record is the log (or record) of an actual batch being prepared. It would include manufacturers and lot numbers of chemicals used, the date of preparation, an internal identification number (commonly called lot number), a beyond-use date, and any other pertinent information regarding the preparation.

Quality Control
Quality control is a final check on the preparation to ensure safety and quality of the preparation. The compounder should evaluate the finished preparation both physically and by reviewing the compounding procedure to be certain the preparation is accurate. Discrepancies should be noted and evaluated to determine if the preparation is acceptable.

Patient Counseling
With any prescription, the patient should be counseled on the correct use of the medication. Compounded medications are often different in method of use or the type of dispensing container used, so special care should be taken to be certain the patient understands the proper use of the medication.
Equipment Used in Nonsterile Compounding

Compounding requires specialized equipment to obtain the best quality medications. An electronic balance is commonly used for speed and accuracy of measurement (see Figure 1-1). Graduates (ie, glass or plastic cylinders and conicals) are used to measure the volume of liquid ingredients (Figure 1-2). It is recommended to use the smallest graduate that will hold the volume to be measured. In addition, it is important to measure the volume of liquid accurately by placing the graduate on a stable surface (ie, counter top of work area) and read the measurement at the bottom of the meniscus.

An ointment slab (also called a “pill tile”) is a square glass tile that is used for preparing and mixing creams and ointments. Similarly, many facilities use ointment paper (eg, pads of 12” x 12” disposable parchment paper) instead of an ointment slab because of convenience in reducing clean-up time (Figure 1-3).

Mortars and pestles are used to crush, grind, and blend various ingredients. The mortar is a deep bowl, and the pestle is a club-shaped tool that when stamped or pounded vertically into the well of the mortar causes the contents of the mortar to become pulverized (see Figure 1-4). Mixing is usually achieved by moving the pestle in a circular motion in the mortar. Mortars are available in a variety of materials and sizes. Glass, porcelain, ceramic, and Wedgwood™ are commonly used. Wedgwood™ offers a rough surface to allow grinding and reduction of particle size but is very difficult to clean and thus prevent cross contamination of preparations. Glass and porcelain offer smooth, easily cleaned surfaces.

Ointment mills are commonly found in compounding pharmacies. Most have three rollers with small, adjustable spaces between the rollers (see Figure 1-5). When preparations pass through the rollers, particle size is reduced.

Parenteral Drug Administration

Medications can be administered to patients in numerous ways. Medications not given to patients by mouth (enterally) are referred to as parenterally administered. Parenteral administrations can include intravenous (IV), intramuscular (IM), and subcutaneous (SQ), or below the skin. IV solutions are commonly administered to patients as a means of replacing body fluids and as a vehicle for
Introducing drugs into the body. Medications are not beneficial to the patient until they reach the blood and are distributed to the body. IV medications are introduced directly into the blood and therefore have the most rapid onset of action. IV medications, therefore, have many benefits over oral medications, which have to be absorbed from the gastrointestinal tract, or IM medications, which have to be absorbed through the muscle mass. IV medications can be given to patients who are unconscious, uncooperative, nauseated, vomiting, or otherwise unable to take medications orally. Direct administration of IV medications into the blood also provides a predictable rate of administration. Certainly, IV medications have disadvantages, such as the risk of infection, the pain of the injection, and the immediate effect of the administration in the body.
event of an error. Some medications are not suitable for IV administration because of their stability or absorbive properties.

Special training is required for personnel who prepare and administer sterile IV solutions. The process of preparing IV products using preset steps to ensure a sterile final product is known as aseptic technique. Basic aseptic technique should be used when handling parenteral dosage forms, as well as irrigations and ophthalmics (see Chapter 12 of the Manual for Pharmacy Technicians, Medication Dosage Forms and Routes of Administration).

Risks of IV Therapy

IV therapy offers a rapid, direct means of administering many life-saving drugs and fluids. A high percentage of IV therapy is administered without any problems, but there are some risks:

- **Infection**—Infections can result if a product contaminated with bacteria is infused into a patient. Because the IV bypasses the body’s normal barrier system, bacteria reach the bloodstream directly. Bacteria can be introduced into products during preparation, administration, production, and through improper storage. The rate of infection or sepsis due to contaminated infusions has steadily decreased since health care practitioners and product manufacturers have implemented training and quality assurance programs. Despite these efforts, human touch contamination continues to be the most common source of IV-related contamination.

- **Air embolus**—The incidence of an air embolus is low because many solutions are administered using infusion pumps equipped with an alarm, called an air-in-line alarm, that sounds when air is in the IV line. Solutions infused by gravity do not need alarms because the infusion automatically stops when there is no more fluid for gravity to push through the IV line. Even when a bag runs dry, large amounts of air are not infused. In adults, 150 or 200 ml of air given quickly through an IV can result in harm. Infants and pediatric patients are adversely affected by a much lower amount of air. Filters are available on some IV sets, and they also stop air bubbles and add another measure of safety.

- **Bleeding**—IV therapy may cause bleeding. When the IV catheter is removed, bleeding may occur around the catheter site. If the patient has a condition that results in prolonged bleeding time, extra care and caution should be used, especially when removing the catheter.

- **Allergic reaction**—When a patient has an allergic reaction to a substance given parenterally, the reaction is usually more severe than if the same substance were given by another route (eg, by mouth, topically, or rectally). One reason for this is that substances given parenterally cannot be retrieved like substances given by other routes. For example, substances administered topically can easily be washed off, those given orally can be retrieved by inducing vomiting or by pumping the stomach, and those given rectally can be flushed out using an enema. When a drug that has caused allergic reactions in a large number of patients is given intravenously, the patient should be monitored closely. If the likelihood of an allergic reaction is especially high, a test dose (a small amount of the drug) may be given to see how the patient reacts.

- **Incompatibilities**—Some drugs are incompatible with other drugs, containers, or solutions. If an incompatibility exists, the drug may precipitate, be inactivated, or adhere to the container. These undesirable outcomes may be difficult to detect with the naked eye. A visual inspection of the final product should always be performed to observe any cloudiness, coring, or signs of irregularity. Solutions with known or detectable incompatibilities should not be administered to patients.

- **Extravasation**—Extravasation occurs when the IV catheter punctures and exits the vein under the skin, causing drugs to infuse or infiltrate into the tissue. Extravasation may happen when the catheter is being inserted or after it is in place if the extremity with the IV catheter is moved or flexed too much. Using a stiff-arm board to prevent excessive movement near the catheter site may help maintain regular flow and prevent extravasation and infiltration. Extravasation and infiltration can be painful and usually requires that the IV be restarted. Some drugs, such as certain chemotherapy agents, may cause severe tissue damage if they infiltrate the tissue. While there are medications to alleviate some of the effects of extravasation and hot and cold compresses to arrest progression, in some cases this tissue damage can be so severe that it requires surgery or even loss of the limb.
**Particulate matter**—Particulate matter refers to unwanted particles present in parenteral products. Some examples of particulate matter are microscopic glass fragments, hair, lint or cotton fibers, cardboard fragments, undissolved drug particles, and fragments of rubber stoppers, known as cores. Particulate matter that is injected into the bloodstream can cause adverse effects. Improvements in the manufacturing processes have greatly reduced the presence of particulates in commercially available products. Care must be taken in the pharmacy so that particulate matter is not introduced into products. All products should be visually inspected for particulate matter before dispensing. Some institutions may use inline filters to help minimize the amount of particulate that reaches the patient.

**Pyrogens**—Pyrogens, the by-products or remnants of bacteria, can cause reactions (eg, fever and chills) if injected in large enough amounts. Because a pyrogen can be present even after a solution has been sterilized, great care must be taken to ensure that these substances are not present.

**Phlebitis**—Phlebitis, or irritation of the vein, may be caused by the IV catheter, the drug being administered (because of its chemical properties or its concentration), the location of the IV site, a fast rate of administration, or the presence of particulate matter. The patient usually feels pain or discomfort, often severe, along the path of the vein. Red streaking may also occur. If phlebitis is caused by a particular drug, further diluting the drug, then giving it more slowly, or giving it via an IV catheter placed in a vein with a higher, faster-moving volume of blood may be helpful.

### Aseptic Preparation of Parenteral Products

As the use of parenteral therapy continues to expand, the need for well-controlled admixture preparation has also grown. Recognizing this need, many pharmacy departments have devoted increased resources to programs that ensure the aseptic preparation of sterile products. The following are the main elements on which these programs focus:

- Development and maintenance of good aseptic technique in the personnel who prepare and administer sterile products
- Development and maintenance of a sterile compounding area complete with sterilized equipment and supplies
- Development and maintenance of the skills needed to properly use an LAFW

#### Aseptic Technique

Aseptic technique is a means of manipulating sterile products without contaminating them. Proper use of an LAFW and strict aseptic technique are the most important factors in preventing the contamination of sterile products. Thorough training in the proper use of the LAFW and strict aseptic technique, followed by the development of conscientious work habits, is of utmost importance to any sterile products program.

### Sterile Compounding Area, the Clean Room

Sterile parenteral solutions must be free of living microorganisms and relatively free of particles and pyrogens. Room air typically contains thousands of suspended particles per cubic foot, most of which are too small to be seen with the naked eye. These suspended particles include contaminants such as dust, pollen, smoke, and bacteria. Reducing the number of particles in the air improves the environment in which sterile products are prepared and can be done by following several practices.

A sterile compounding area’s counters, work surfaces, and floors should be cleaned daily while walls, ceilings, and storage shelving should be cleaned monthly at a minimum. Segregated compounding areas must be separate from normal pharmacy operations, nonessential equipment, and other materials that produce particles. For example, the introduction of cardboard into the clean environment should be avoided. Traffic flow into a clean area should be minimized. Floors should be disinfected periodically, and trash should be removed frequently. Trashcans should be taken outside the IV room before pulling the trash from the container. This will minimize the creation of particulate matter and the risk of spills in the clean room. More sophisticated aspects of clean room design include special filtration or treatment systems for incoming air, ultraviolet irradiation, air-lock entry portals, sticky mats to remove particulates from shoes, and positive room air pressure to reduce contaminant entry from adjacent rooms or hallways. Clean rooms are often adjoined by a room, called an anteroom, that is used for nonaseptic activities related to the clean environment.
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room operation, such as order processing, gowning, and stock storage.

Sterile products should be prepared in Class 100 environments, which means environments containing no more than 100 particles per cubic foot that are 0.5 micron or larger in size. LAFWs are frequently used to achieve a Class 100 environment.

Laminar Airflow Workbenches
The underlying principle of laminar airflow workbenches (LAFW) is that twice-filtered laminar layers of aseptic air continuously sweep the work area inside the hood to prevent the entry of contaminated room air. There are two common types of LAFW: horizontal flow and vertical flow.

Horizontal LAFW
LAFW that sweep filtered air from the back of the hood to the front are called horizontal LAFW (see Figure 1-6). Horizontal flow workbenches use an electrical blower to draw contaminated room air through a prefilter. The prefilter, which is similar to a furnace filter, removes only gross contaminants and should be cleaned or replaced regularly. The prefiltered air is then pressurized to ensure that a consistent distribution of airflow is presented to the final filtering apparatus. The final filter constitutes the entire back portion of the hood’s work area. This high efficiency particulate air, or HEPA, filter removes 99.97% of particles that are 0.3 micron or larger, thereby eliminating airborne microorganisms, which are usually 0.5 microns or larger.

Vertical LAFW
Laminar flow workbenches with a vertical flow of filtered air are also available. In vertical LAFW, HEPA-filtered air emerges from the top and passes downward through the work area (see Figure 1-6). Because exposure to some antineoplastic (anticancer) drugs may be harmful, these drugs are usually prepared in vertical LAFW to minimize the risk of exposure to airborne drug particulates. The types of vertical laminar airflow hoods (LAH) used for the preparation of antineoplastics contain airflow within the hood and are referred to as biological safety cabinets (BSC).

The critical principle of using LAFW is that nothing must interrupt the flow of air between the HEPA filter and the sterile object. The space between the HEPA filter and the sterile object is known as the critical area. The introduction of a foreign object between a sterile object and the HEPA filter increases wind turbulence in the critical area and the possibility that contaminants from the foreign object may be carried onto the sterile work surface and thereby contaminate an injection port, needle, or syringe. To maintain sterility, nothing should pass behind a sterile object in a horizontal LAH or above a sterile object in a vertical LAFW.

Materials placed within the LAFW disturb the patterned flow of air blowing from the HEPA filter. The zone of turbulence created behind an object could potentially extend outside the hood, pulling or allowing contaminated room air into the aseptic working area. When laminar airflow is moving on all sides of an object, the zone of turbulence extends approximately three times the diameter of that object. When laminar airflow is not accessible to an object on all sides (for example, when placed adjacent to a vertical wall), the zone of turbulence may extend six times the diameter of the object. Working with objects at least 6 inches from the sides and front edge of the hood, without blocking air vents is therefore advisable to maintain unobstructed airflow between the HEPA
Assisting the Pharmacist

Jewelry should not be worn on the hands or wrists when working in the LAFW because it may introduce bacteria or particles into the clean work area.

Actions such as talking and coughing should be directed away from the LAFW working area, and unnecessary motion within the hood should be avoided to minimize the turbulence of airflow.

Smoking, eating, and drinking are prohibited in the aseptic environment.

All aseptic manipulations should be performed at least 6 inches within the hood to prevent potential contamination caused by the closeness of the worker's body and backwash contamination resulting from turbulent air patterns developing where LAFW air meets room air.

LAFWs should be tested by qualified personnel every 6 months, whenever the hood is moved, or if filter damage is suspected. Specific tests are used to certify airflow velocity and HEPA filter integrity.

Although the LAFW provides an aseptic environment, safe for the manipulation of sterile products, strict aseptic technique must be used in conjunction with proper hood operation. The use of the LAFW alone, without the observance of aseptic technique, cannot ensure product sterility.

Personal Attire

The first component of good aseptic technique is proper personal attire. Compounding personnel should remove personal outer garments, all cosmetics, and all hand, wrist, and other visible jewelry or piercings before entering the ante room or segregated compounding area. Clean room attire should include dedicated shoes or shoe covers, head and facial hair covers, and face masks/eye shields applied in this order to help reduce particulate or bacterial contamination. After hand washing as described below, clean garments, which are relatively particulate free, should be worn when preparing sterile products. Clean room attire will depend on institutional policies and often are related to the type of product being prepared. Many facilities provide clean scrub suits or gowns for this purpose. Scrub suits should not be worn home to ensure that no contaminants are transported home and that the process of cleaning the clothing does not introduce lint onto the low-lint clothing. In addition, suits should be covered up when leaving the pharmacy to minimize the contamination from areas such as the cafeteria.
Handwashing
Touching sterile products while compounding is the most common source of contamination of pharmacy-prepared sterile products. Because the fingers harbor countless bacterial contaminants, proper hand washing is extremely important. Every entry into a sterile product should include scrubbing your hands, nails, wrists, and forearms to elbows thoroughly for at least 30 seconds with a brush, warm water, and appropriate bactericidal soap before performing aseptic manipulations. Dry hands completely, using either lint-free disposable towels or an electronic hand dryer.

Gloving
After appropriate hand washing is complete and attire is put on, antiseptic hand cleansing should be performed using a waterless, alcohol-based surgical hand scrub just prior to the last item worn before compounding begins, sterile gloves. Sterile gloves are only sterile until they touch something unsterile or until they are torn and allow bacteria from the hands to enter the work area. For example, if it becomes necessary to scratch or touch the face while wearing gloves, they will need to be changed. For these reasons, always wash your bare hands thoroughly as noted above, before unwrapping and putting on the gloves. Occasionally, workers develop allergies to latex as a result of repeated use of latex gloves. As a result, many institutions have now turned to using only non-latex gloves.

Equipment and Supplies
Another important factor in aseptic preparation of sterile products is the correct use of appropriate sterile equipment and supplies, including syringes and needles.

Syringes
Syringes are made of either glass or plastic. Most drugs are more stable in glass, so glass syringes are most often used when medication is to be stored in the syringe for an extended period. Some medications may react with the plastics in the syringe, which would alter the potency or stability of the final product. Disposable plastic syringes are most frequently used in preparing sterile products because they are cheaper, durable, and are in contact with substances only for a short time. This minimizes the potential for incompatibility with the plastic itself.

Syringes are composed of a barrel and plunger (see Figure 1–7). The plunger, which fits inside the barrel, has a flat disk or lip at one end and a rubber piston at the other. The top collar of the barrel prevents the syringe from slipping during manipulation; the tip is where the needle attaches. To maintain sterility of the product, the syringe tip or the plunger should not be touched. Many syringes have a locking mechanism at the tip, such as the Luer-lock, which secures the needle within a threaded ring. Some syringes, such as slip-tip syringes, do not have a locking mechanism. In this case, friction holds the needle on the syringe.

Syringes are available in numerous sizes, ranging from 0.5 to 60 milliliters (ml). Calibration marks on syringes represent different increments of capacity, depending on the size of the syringe. Usually, the larger the syringe capacity, the larger the interval between calibration lines. For example, each line on a 10 ml syringe represents 0.2 ml, but on a 30 ml syringe, each line represents 1 ml.

To maximize accuracy, the smallest syringe that can hold a desired amount of solution should be used. Syringes are accurate to one-half of the smallest increment marking on the barrel. For example, a 10 ml syringe with 0.2 ml markings is accurate to 0.1 ml and can be used to measure 3.1 ml accurately. A 30 ml syringe with 1 ml markings, however, is only accurate to 0.5 ml and should not be used to measure a volume of 3.1 ml. Ideally, the volume of solution should only take up one-half to two-thirds of the syringe capacity. This avoids inadvertent touch contamination when the syringe plunger is pulled all the way back.
When measuring with a syringe, the final edge (closest to the tip of the syringe) of the plunger piston, which comes in contact with the syringe barrel, should be lined up with the calibration mark on the barrel that corresponds to the volume desired (see Figure 1-8).

Syringes are sent from the manufacturer assembled and individually packaged in paper overwraps or plastic covers. The sterility of the contents is guaranteed as long as the outer package remains intact. Therefore, packages should be inspected, and any that are damaged should be discarded. The syringe package should be opened within the LAH to maintain sterility. The wrapper should be peeled apart, not ripped or torn. To minimize particulate contamination, discarded packaging or unopened syringes should not be placed on the LAFW work surface.

Syringes may come from the manufacturer with a needle attached or with a protective cover over the syringe tip. The syringe tip protector should be left in place until it is time to attach the needle. For attaching needles to Luer-lock-type syringes, a quarter turn is usually sufficient to secure the needle to the syringe.

**Needles**

Like syringes, needles are commercially available in many sizes. Sizes are described by two numbers: gauge and length. The gauge of the needle corresponds to the diameter of its bore, which is the diameter of the inside of the shaft. The larger the gauge, the smaller the needle bore. For example, the smallest needles have a gauge of 27, whereas the largest needles have a gauge of 13. The length of a needle shaft is measured in inches and usually ranges from 3/8 to 3 1/2 inches.

The components of a simple needle are the shaft and the hub (see Figure 1-9). The hub attaches the needle to the syringe and is often color-coded to correspond to a specific gauge. The tip of the needle shaft is slanted to form a point. The slant is called the bevel, and the point is called the bevel tip. The opposite end of the slant is called the bevel heel.

Needles are sent from the manufacturer individually packaged in paper or plastic overwraps with a protective cover over the needle shaft. This guarantees the sterility as long as the package remains intact. Damaged packages should be discarded.

No part of the needle itself should be touched. Needles should be manipulated by their overwrap and protective covers only. The protective cover should be left in place until the needle or syringe is ready to be used. A needle shaft is usually metal and is lubricated with a sterile silicone coating so latex vial tops can be penetrated smoothly and easily. For this reason, needles should never be swabbed with alcohol.

Some needles are designed for special purposes and therefore have unique characteristics. For example, needles designed for batch filling have built-in vents (vented needles) to avoid the need to release pressure that might form in the vial. Another example is needles with built-in filters, meant to be used with products requiring filtering, such as drugs removed from a glass ampule.

**Drug Additive Containers**

Injectable medication additives may be supplied in an ampule, vial, or prefilled syringe. Each requires a different technique to withdraw medication and place it in the final dosage form.
Vials
Medication vials are glass or plastic containers with a rubber stopper secured to the top, usually by an aluminum cover. Vials differ from ampules in that they are used to hold both powders and liquids. The rubber stopper is usually protected by a flip-top plastic cap or aluminum cover.

Protective covers do not guarantee sterility of the rubber stopper. Therefore, before the stopper is penetrated, it must be swabbed with 70% isopropyl alcohol and allowed to dry. The correct swabbing technique is to make several firm strokes in the same direction over the rubber closure, always using a clean swab.

Vials are closed-system containers, because air or fluid cannot pass freely in or out of them. In most cases, air pressure inside the vial is similar to that of room air. In order to prevent the formation of a vacuum inside the vial (less pressure inside the vial than room air), the pressure should be normalized by first injecting a volume of air equal to the volume of fluid that is going to be withdrawn, into the vial. This step should not be done with drugs that produce gas when they are reconstituted, such as ceftazidime, or with cytotoxic medications.

Ampules
Ampules are composed entirely of glass and, once broken (ie, opened), become open-system containers (Figure 1–10). Because air or fluid may now pass freely in and out of the container (no vacuum effect), it is not necessary to replace the volume of fluid to be withdrawn with air.

To open an ampule, the head must be broken from the body of the ampule. To make the break properly, the ampule neck is cleansed with an alcohol swab and the swab should be left in place. This swab can prevent accidental cuts to the fingers as well as shattering of glass particles and aerosolized drug.

Automated Compounding Sterile Product Filling Equipment
Although hospitals and regulatory agencies have strict guidelines that must be followed, including rigorous training and competencies, the technical complexity of sterile product preparation lends itself to inconsistency among employees. Additionally, compounded sterile products create potentially challenging situations for pharmacists to verify product preparation accuracy. Automation can eliminate sources of preparation errors inherent to human factors; this technology ensures proper handling, and accurate and sterile preparation of the IV product.

Labeling
Once an IV admixture or other sterile product is compounded, it should be properly labeled with the following information:

1. Patient name, identification number, and room number (if applicable)
2. Bottle or bag sequence number, when appropriate
3. Name and amount of drug(s) added
4. Name and volume of admixture solution
5. Approximate final total volume of the admixture, when applicable
6. Prescribed flow rate (in milliliters per hour)
7. Date and time of scheduled administration
8. Date and time of preparation
9. Expiration date
10. Initials of person who prepared and person who checked the IV admixture
11. Auxiliary labeling—supplemental instructions and precautions
Many labels also now contain a bar code that contains information regarding the medication, the patient, and the anticipated administration. These are generated by the pharmacy computer to reduce the frequency of medication administration errors. Each product should also include an expiration date, beyond which it should not be used.

Preparation and Handling of Cytotoxic and Hazardous Drugs

Some medications can be hazardous to those who touch or inhale them. Because hazardous drugs initially involved drugs used to treat cancer, the terms antineoplastic and chemotherapeutic were used to describe them.

Preparation of these agents requires special procedures for labeling, storage, and transport. Use of protective clothing, BSCs, and special handling of spills and waste are also important. Special techniques related to the actual administration of these products to patients are not covered here. Additional information is available from ASHP in the form of a Technical Assistance Bulletin on Handling of Cytotoxic and Hazardous Drugs.

Protective Apparel

There is no substitute for good technique, but protective apparel is another fundamental element in protecting personnel who handle or prepare hazardous drugs.

Most procedures require the use of disposable coveralls or a solid front gown. These garments should be made of low-permeability, lint-free fabric. They must have long sleeves and tight-fitting elastic or knit cuffs. They should not be worn outside the work area and should be changed immediately if contaminated. Shoe and hair covers may also be required, depending on the institution’s policies.

Wearing gloves is essential when working with hazardous drugs. Wash hands thoroughly before putting on the gloves and after removing them. Use good quality, disposable, powder-free latex gloves, such as surgical latex. These gloves are preferred because of their fit, elasticity, and tactile sensation. If only powdered gloves are available, wash powder off before beginning to work. Non-latex gloves are also available for those with an allergy to latex. If two pairs are needed, tuck one pair under the cuffs of the gown and place the second pair over the cuff. If an outer glove becomes contaminated, change it immediately. Change both the inner and the outer gloves immediately if the outer glove becomes torn, punctured, or heavily contaminated. If only one pair is worn, tuck the glove under or over the gown cuff so that the skin is not exposed.

Biological Safety Cabinets

One of the most important pieces of equipment for handling hazardous drugs safely is the Biological Safety Cabinet (BSC). A BSC is a type of vertical LAFW that is designed to protect workers from exposure as well as to help maintain product sterility during preparation. BSCs must meet standards set by the National Sanitation Foundation (NSF Standard 49). Do not use horizontal LAFWs to prepare hazardous drugs. BSCs must be operated continuously, 24 hours per day, and they should be inspected and certified by qualified personnel every 6 months.

Preparing Hazardous Drugs

Before technicians handle a cytotoxic or other hazardous drug, they must demonstrate proper manipulative technique and use of protective equipment and materials.

Drug Information

Pharmacy technicians are challenged with drug information questions frequently throughout the workday and are called upon to become knowledgeable about the handling, availability, and uses of medications. A basic knowledge of the resources available will make the technician more resourceful and better able to assist the pharmacist with certain drug information requests. Pharmacy reference books and electronic media (including the Internet) that are available in all practice settings often hold answers to typical day-to-day practice-related questions. Before responding to a drug information question, technicians must clearly differentiate questions that fall within their scope of practice from those that must be answered only by a pharmacist.

Technicians should identify themselves as pharmacy technicians so the person asking the question will know the type of information that may appropriately be conveyed. If there is any doubt about the nature of the question, the technician should defer the question to the pharmacist. It is important for the technician to learn who the person initiating the request is and to obtain the necessary contact information (phone, fax, pager, etc.) in case the person needs to be called back. The search for and response to drug information requests will be different depending on who is requesting the information. Knowing information
about the requestor, their training, and their knowledge of the subject will have an impact on what the final response will be and how it will be given. Obtaining background information will help to determine what the needs of the requestor are and will make the search for information more efficient. Background information is especially important to determine if the question pertains to a specific patient or if it is a question that requires interpretation, and therefore the expertise of a pharmacist. The urgency of the request and the extent of the information needed should also be determined so an appropriate amount of time is allotted to answer the request. Classifying the type of request helps to narrow the search and makes the search process more efficient. Table 1-1 lists common types of questions that technicians may get, with examples of each. Technicians should not interpret a patient-specific question or provide information that may require professional judgment. A simply stated question can actually be a complex patient-specific situation. The pharmacist has to find out more about the patient’s specific problems and apply clinical judgment to answer the question appropriately. Many times, the person requesting the information may indirectly be asking for a pharmacist’s point of view or interpretation of a situation, and may thus require an in-depth analysis and recommendation from the pharmacist. Attempting to interpret or answer such a question could result in miscommunication and delivery of inaccurate information. Both scenarios could be potentially harmful to the patient. Examples of questions that require a pharmacist’s interpretation and that should not be answered by a technician are provided in Table 1-2.

### Conducting the Search: Choosing the Right References

The key to answering questions quickly and accurately is knowing where the necessary information is likely to be found. The first step is to consult tertiary references, then secondary references, and finally primary references.

Tertiary references are general references that present documented information in a condensed and compact format. They include textbooks; compendia (eg, *American Hospital Formulary Service, Drug Information (AHFS DI), Drug Facts and Comparisons*); computerized systems such as Micromedex® Clinical Information System; review articles; and much of the information found on the Internet. Tertiary references are easy to use, convenient, readily accessible, concise, and compact. Disadvantages of tertiary references are that information may not be timely, the information could contain errors, and tertiary references may not offer enough information on a specific topic because of space restrictions.
Assisting the Pharmacist

Table 1–2. Drug Information Questions Appropriate for Pharmacists

<table>
<thead>
<tr>
<th>Question Classification</th>
<th>Examples</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification and Availability</td>
<td>What is paracetamol and what is its U.S. equivalent?</td>
<td>Although it is appropriate for a technician to obtain technical information about availability (eg, anticipated length/reasons for a shortage), questions that require clinical knowledge, such as therapeutic alternatives, must be answered by a pharmacist.</td>
</tr>
<tr>
<td>Allergies</td>
<td>Which narcotic is safe to use in a patient with a codeine allergy?</td>
<td>For allergy questions, the pharmacist must obtain more patient-specific information, such as a description of the allergy and the condition being treated. Clinical judgment is required.</td>
</tr>
<tr>
<td>Dosing and Administration</td>
<td>What is the usual dose of propranolol? How long should ciprofloxacin be given for a urinary tract infection? What is the best way to give gentamicin IV?</td>
<td>Answers to dosing and administration questions depend on many factors, especially the indication for use and patient-specific information (eg, age, weight, and kidney and liver function).</td>
</tr>
<tr>
<td>Compatibility</td>
<td>Is Primaxin compatible with dopamine?</td>
<td>More information is needed (eg, doses, concentrations, fluids, and type of IV lines), and a pharmacist must interpret information found in a reference and apply it to the situation.</td>
</tr>
<tr>
<td>Drug Interactions</td>
<td>Is it OK to take aspirin with warfarin?</td>
<td>Drug interaction questions are complex and require patient-specific information and interpretation by a pharmacist in order to apply the significance of a potential interaction to a specific patient.</td>
</tr>
<tr>
<td>Side Effects</td>
<td>What are the side effects of Lexapro? Can Celebrex cause renal failure?</td>
<td>Package inserts and textbooks provide lists of side effects that are often difficult to interpret and convey. Also, a pharmacist must interpret whether the request is being made because an adverse event is suspected with one or more medications.</td>
</tr>
<tr>
<td>Pregnancy and Lactation</td>
<td>Is albuterol safe to use in pregnancy? Can I get a flu shot if I am breastfeeding?</td>
<td>Pregnancy and lactation questions are complicated because more information is needed about the patient, the stage of pregnancy, and/or age of the infant. A pharmacist must interpret the findings and apply them to the specific situation.</td>
</tr>
<tr>
<td>Therapeutic Use</td>
<td>Has clonidine been used to treat opiate withdrawal?</td>
<td>The use of drugs for non-FDA approved uses often requires evaluation and interpretation of the literature and clinical judgment.</td>
</tr>
</tbody>
</table>

Secondary references include indexing systems such as Medline that provide a list of journal articles on the topic that is being researched. Secondary systems are used when new or very up-to-date information is required or when no information can be found in tertiary references.

Primary references are original research articles published in scientific journals, such as the American Journal of Health-System Pharmacy (AJHP) or the Journal of the American Pharmacists Association (JAPhA).

Other resources include pharmaceutical manufacturers and specialized drug and poison information centers.

If the information cannot be found in a tertiary reference, then the technician should consult a pharmacist, who may advise an alternative search strategy or consult a secondary reference. If time permits, the technician should consult as many resources as possible and compare information among resources.

Common References

Technicians should familiarize themselves with the references in their practice settings to determine which sources best fit their needs. Using a systematic approach when faced with a drug information question will aid in understanding the nature of the request, obtaining pertinent background information, and answering the question. Numerous resources are available to assist with answering drug information requests. Becoming familiar with common resources will make the search process more efficient. It is critical for pharmacy technicians to be able to differentiate between basic drug information questions that they can answer and questions that require clinical knowledge.
The references described in the next few sections are summarized in Table 1-3 with examples of the types of information one might find in each.

### General Drug Information

**Drug Facts and Comparisons** (a part of Wolters Kluwer Health) is easy to use and available in regularly updated print and electronic versions. It is a comprehensive general drug information reference that provides complete drug monographs. It is organized by therapeutic class (eg, antihistamines, topicals) and includes tables that allow quick comparisons of drugs within the same class.

**United States Pharmacopeia Drug Information** (USPDI, published by Thomson) is a three-volume set that provides medication information for health care professionals (Volume I) and patients (Volume II). The third volume (*Approved Drug Products and Legal Requirements*) provides information on laws affecting pharmacy practice.

*The Physicians’ Desk Reference* (PDR, published by Thomson Medical Economics) contains manufacturers’ package inserts. A package insert is a manufacturer’s product information sheet that provides general drug information, such as how the drug works, indications, adverse effects, drug interactions, dosage forms, stability, and dosing information. The PDR is not comprehensive and contains information only on select brand name drugs. The information is written by the manufacturer and approved by the FDA. It contains only information about FDA-approved uses of the drug and does not provide information comparing that drug with similar medications. Therefore, using the PDR to compare products is not as straightforward as using other reference books.

### Table 1–3.  Common Drug Information Requests and Reference Sources

<table>
<thead>
<tr>
<th>Type of Information Needed</th>
<th>References Likely to Have the Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Availability</td>
<td>Facts &amp; Comparisons Drug Information Handbook Internet PDR</td>
</tr>
<tr>
<td>Product Identification</td>
<td>Micromedex Clinical Pharmacology RedBook (not indication)</td>
</tr>
<tr>
<td>Drug Uses</td>
<td>USPDI Pharmaceutical Manufacturer</td>
</tr>
<tr>
<td>Drug Monographs</td>
<td>Facts &amp; Comparisons PDR Clinical Pharmacology USPDI Micromedex</td>
</tr>
<tr>
<td>Injectable Drug Compatibility/Stability Information</td>
<td>AHFS Clinical Pharmacology Facts &amp; Comparisons Drug Information</td>
</tr>
<tr>
<td></td>
<td>Handbook PDR (FDA-approved indications only) Micromedex USPDI</td>
</tr>
<tr>
<td>Preparation</td>
<td>AHFS Clinical Pharmacology Facts &amp; Comparisons Drug Information</td>
</tr>
<tr>
<td>Calculations</td>
<td>Handbook Micromedex PDR</td>
</tr>
<tr>
<td>Hazardous Chemicals and Drugs</td>
<td>Micromedex Package inserts PDR OUSPDI</td>
</tr>
<tr>
<td>Pharmacy Law</td>
<td>AHFS King’s Guide Trissel’s Handbook on Injectable Drugs Package</td>
</tr>
<tr>
<td>Patient Information</td>
<td>Usdg Micromedex PDR</td>
</tr>
</tbody>
</table>

judgment, and therefore should be answered by a pharmacist. The references described in the next few sections are summarized in Table 1-3 with examples of the types of information one might find in each.
American Hospital Formulary Service Drug Information (AHFS DI, published by the American Society of Health-System Pharmacists, ASHP) is a detailed, comprehensive, general drug information reference. This textbook provides complete drug monographs that are organized by therapeutic class (e.g., anti-infectives, cardiovascular). It provides detailed information about the use of a drug, its side effects, dosing considerations, and so on, and its coverage is not limited to FDA-approved uses of medications. It is especially useful for preparation and administration instructions for injectable products.

Lexi-Comp’s Drug Information Handbook and Drug Information Handbook for the Allied Health Professional (published by Lexi-Comp) are handbooks containing general drug information monographs. They are widely used because they are quick, convenient, and easy to use. The Drug Information Handbook is alphabetically organized in dictionary format according to generic name. The Drug Information Handbook for the Allied Health Professional is not as comprehensive as the Drug Information Handbook, but it may be appealing to technicians because it allows quick access to basic data on the most frequently used medications. Both publications contain extensive appendixes with helpful charts, abbreviations, measurements, and conversions.

Mosby’s Drug Consult (published by Elsevier Science) is a comprehensive general drug information reference. It provides complete drug monographs that are organized alphabetically by generic drug names. This textbook is more comprehensive than the PDR. A key feature is its indexing system, which allows identification of all drugs within a therapeutic class, schedules of controlled substances, pregnancy categories, and so on.

American Drug Index (published by Facts and Comparisons) is an alphabetical listing of drugs with brief information on each agent, including drug name (generic, brand, chemical name), manufacturer, dosage form, strength and packaging information, and general uses (e.g., general anesthetic, narcotic, antitussive). It also contains pharmaceutical manufacturers’ phone numbers and addresses, weight and measuring conversions, and a list of drugs that should not be crushed. Its extensive cross-indexing is useful to quickly identify a brand or generic product or determine product availability information.

Micromedex® Healthcare Series is a comprehensive reference system that is accessed electronically via CD-ROM, Internet, or personal digital assistant (PDA). Depending on the subscription, it contains comprehensive drug information, poison information, foreign drug information, tablet and capsule identification, disease and trauma information, herbal information, stability information, compatibility information, pregnancy information, patient information, and more.

Specialty References

Availability/Cost

Red Book (published by Medical Economics) contains up-to-date product information and prices for prescription drugs, over-the-counter products, and medical supplies. It contains NDC numbers for all products, available packaging, and therapeutic equivalence ratings (according to the FDA’s Orange Book). It has a comprehensive listing of manufacturers, wholesalers, and third-party administrator directories. There are sections with other useful practical information, such as lists of sugar-, lactose-, galactose-, and alcohol-free products; sulfite-containing products; medications that should not be crushed; and color photographs of many prescription and over-the-counter products.

Compatibility and Stability

Trissel’s Handbook on Injectable Drugs (published by American Society of Health-System Pharmacists, ASHP) is a textbook often used in hospital and home health care pharmacies. It focuses solely on injectable medications. Information includes data on the solubility, compatibility, and stability of many different medications. Specifically, this handbook is useful to determine when two medications may be safely mixed together in an IV bag, a syringe, or at a Y-site on an administration set. This reference also addresses special handling requirements of certain agents (glass vs. plastic containers, light restrictions, filters, refrigeration requirements, expiration, etc.).

King Guide to Parenteral Admixtures (published by King Guide Publications, Inc.) is another reference that is useful for compatibility and stability of injectable medications.

Extended Stability of Parenteral Drugs

Extended Stability of Parenteral Drugs (published by American Society of Health-System Pharmacists, ASHP) contains stability data of injectable drugs that extends beyond 24 hours. The reference is intended for use by alternate site infusion practices, such as home infusion.
Miscellaneous References

Material Safety Data Sheets (MSDS) are information sheets provided by manufacturers for chemicals or drugs that may be hazardous in the workplace. The primary purpose of the MSDS is to provide information about the specific hazards of the chemicals or drugs (i.e., to describe acute and chronic health effects), guidelines for their safe use, and recommendations to treat an exposure or clean up a spill.

Drug Information and Poison Control Centers

Formal Drug Information Centers are another source of drug information. The centers throughout the country vary in the types of services they provide, but most centers provide drug information for health-care professionals, assist with formulary management, and train pharmacy students, residents, and pharmacists. Some centers provide drug information for consumers as well.

The Internet

The technician must take care to ensure that the information is current and up-to-date, and that it is accurate and from a reputable source. Generally, Web sites that are sponsored by the government, pharmacy and medical organizations, and medical centers are the most reputable. Table 1-4 lists useful Web sites for drug information and a brief description of what each site contains.

Compounding

USP Pharmacist’s Pharmacopeia (published by U.S. Pharmacopeia) is a reference that includes the official standards and procedures to ensure the strength, quality and purity of sterile and non-sterile compounded preparations. The individual drug monographs contain information on compounding, packaging, labeling, and storage of pharmaceuticals. The reference also includes information on veterinary compounding and food ingredients, colorings, preservatives, and flavorings. It is a useful resource for pharmacy compounding because it provides information on legal requirements and laws that apply to compounding practices, as well as articles on the basics of compounding.

Trissel’s Stability of Compounded Formulations (published by the American Pharmacists Association, APhA) summarizes formulation and stability studies that are published for compounded formulations. Its drug monographs provide guidance for preparing the products as well as expiration dating, proper storage, and repackaging.

Herbal Medications and Dietary Supplements

Natural Medicines Comprehensive Database (published by Therapeutic Research Faculty) is a commonly used reference for natural medicines, including herbs and dietary supplements. Individual monographs list the name of the product, its common and scientific names, uses, safety, effectiveness, dosage and interactions with drugs, foods, labs, or diseases/conditions. It is available in both print and electronic forms.
<p>| Table 1–4. Useful Web Sites for Obtaining Drug Information |
|------------------|------------------|---------------------------------|
| <strong>Web site</strong>                     | <strong>Address</strong>                                 | <strong>Description</strong>                                                   |
| Food and Drug Administration     | <a href="http://www.fda.gov">www.fda.gov</a>  | Home page for the FDA; contains numerous useful links for both consumers and health-care professionals. |
| FDA Center for Drug Evaluation and Research (CDER) | <a href="http://www.fda.gov/cder">www.fda.gov/cder</a> | Contains links for consumers and health-care professionals regarding drug information, such as new drug approvals, drug shortages, safety information, and generic drug bioequivalence (Orange Book). |
| Drugs@FDA                        | <a href="http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm">www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm</a> | Contains information about FDA-approved drugs. Users can find package labeling information, generic drug products for brand name products, patient information (including Medication Guides), and review the approval history of drugs. |
| Centers for Disease Control and Prevention (CDC) | <a href="http://www.cdc.gov">www.cdc.gov</a>  | Home page for the CDC; contains information about diseases, health topics, vaccines, traveler's health, bioterrorism, etc. |
| CDC Vaccine Information Statements | <a href="http://www.cdc.gov/vaccines/pubs/vis/default.htm">www.cdc.gov/vaccines/pubs/vis/default.htm</a> | Link to Vaccine Information Statements that explain the benefits and risks of vaccines. |
| National Institutes for Health (NIH) | <a href="http://www.nih.gov">www.nih.gov</a>  | Home page for the NIH; contains information about health topics, clinical trials, and the various divisions of the NIH. |
| American Society of Health-System Pharmacists (ASHP) | <a href="http://www.ashp.org">www.ashp.org</a>  | Home page for ASHP; contains news related to health-system pharmacy and many helpful links for pharmacy professionals. |
| ASHP Drug Shortages Resource Center | <a href="http://www.ashp.org/shortage">www.ashp.org/shortage</a>  | Up-to-date information on current drug shortages, including which products are affected and why, the anticipated time to resolution, and alternatives. |
| American Pharmacists Association (APhA) | <a href="http://www.pharmacist.com">www.pharmacist.com</a>  | Home page for APhA; contains news related to pharmacy and many helpful links for pharmacy professionals. |
| Institute for Safe Medication Practices (ISMP) | <a href="http://www.ismp.org">www.ismp.org</a>  | Homepage for the ISMP; contains medication error alerts, a section for reporting, products available for purchase, and medication error prevention strategies. |
| Virtual Library Pharmacy         | <a href="http://www.pharmacy.org">www.pharmacy.org</a>  | Contains links to pharmacy associations, pharmaceutical manufacturers, governmental sites, hospitals, journals and books, and more. |</p>
<table>
<thead>
<tr>
<th>Self-Assessment Questions</th>
</tr>
</thead>
</table>
| **1.** Abbreviations are generally considered to be unsafe and should therefore never be used in prescriptions.  
   a. True  
   b. False |
| **2.** The first step in receiving either a prescription or a medication order is to verify that all necessary information is present, although this information may vary depending on the pharmacy site (outpatient versus inpatient).  
   a. True  
   b. False |
| **3.** The abbreviation for “before meals” is  
   a. a.a.  
   b. hs  
   c. pc  
   d. ac |
| **4.** Which piece of information is critical in an ambulatory pharmacy environment when filling a prescription, but is often not known by the pharmacy in a hospital?  
   a. patient’s allergies  
   b. name of the ordered drug  
   c. dose of the ordered drug  
   d. patient’s insurance information  
   e. name of the doctor |
| **5.** Every state’s laws regarding prescription transfer are the same.  
   a. True  
   b. False |
| **6.** The first set of numbers in an NDC number signify  
   a. the package size  
   b. the specific product  
   c. the manufacturer  
   d. the schedule of the controlled substance |
| **7.** At the Point of Sale the patient’s signature is required  
   a. when they receive the HIPAA information  
   b. when they receive a Patient Information Sheet  
   c. by some third Party Companies when the patient receives the prescription |
| **8.** Examples of drugs with REMS include clozapine, thalidomide, and  
   a. isotretinoin and doxetilide  
   b. isotretinoin and sildenafil  
   c. alosetron and methadone  
   d. sildenafil and tadalafil |
| **9.** Parenteral administration refers to drugs  
   a. given by mouth  
   b. administered only intravenously  
   c. administered intravenously and intramuscularly  
   d. given only subcutaneously |
| **10.** Which of the following is a possible risk associated with IV therapy?  
   a. infection  
   b. bleeding  
   c. air embolus  
   d. incompatibilities  
   e. all of the above |
| **11.** Which of the following is false regarding the use of a Laminar Airflow Workbench (LAFW)?  
   a. Hoods should be allowed to run for 15–30 minutes before use if they are not left on continuously.  
   b. All compounding should be done at least 3 inches from the front edge of the hood.  
   c. Only essential objects should be taken into the hood.  
   d. Jewelry should not be worn on the hands or wrists when working in the hood.  
   e. Actions such as talking or coughing should be directed from the LAFW work area. |
| **12.** Clean room attire should include  
   a. shoe covers  
   b. head covers  
   c. facial hair covers  
   d. face mask  
   e. sterile gloves  
   f. all the above |
Self-Assessment Questions

13. Vials differ from ampoules in that they are used to hold both liquids and powders.
   a. True
   b. False

14. A ____ is the most important piece of equipment for handling and preparing hazardous drugs safely.
   a. LAFW
   b. BSC
   c. latex gloves
   d. automated compounder

15. Which reference is important in describing good compounding practices for technicians?
   a. Lexi-Comp’s Drug Information Handbook for the Allied Health Professional
   b. Micromedex
   c. Package inserts
   d. PDR
   e. USP 27

16. Which question can a pharmacy technician answer?
   a. When will the shortage of methylprednisolone be over?
   b. How much acetaminophen should I give my 2 month old infant?
   c. Can propranolol make me dizzy?
   d. Does simvastatin interact with grapefruit juice?
   e. What should I substitute for morphine if my patient is allergic?

17. Which reference has the best information about IV compatibility?
   a. American Drug Index
   b. PDR
   c. Drug Facts and Comparisons
   d. Package inserts
   e. Handbook on Injectable Drugs

18. Drug Facts and Comparisons is considered a(n)
   a. tertiary general drug reference
   b. primary general drug reference
   c. specialty drug reference that includes only FDA approved drugs

19. The valid DEA number for Dr. Terry L Jones would be
   a. AT 4326915
   b. AJ 2178944
   c. AT 2178946
   d. AJ 432910

20. The NDC number for a product on the package label is 0536-3922-01. Which NDC number listed below would be in the proper form for this drug for remittance to a third party payer?
   a. 0536-3922-01
   b. 05363992201
   c. 00536-3922-01
   d. 05360-3922-01
Self-Assessment Answers

1. b  
2. a  
3. c  
4. d  
5. b  
6. c  
7. f  
8. a  
9. c  
10. e  
11. b  
12. f  
13. a  
14. b  
15. e  
16. a  
17. e  
18. a  
19. b  
20. c